8 November 2012
[26-12]

Review Report – Proposal P293

Nutrition, Health & Related Claims

On 6 June 2008, the then Australia and New Zealand Food Regulation Ministerial Council[1] asked Food Standards Australia New Zealand (FSANZ) to review its decision in relation to Proposal P293 – Nutrition, Health & Related Claims[2].

Following several extensions to the due date for the completion of this review, FSANZ was required to review the decision by 31 October 2012.

FSANZ has reviewed its decision and has re-affirmed the approval of Standard 1.2.7 and other standards, subject to a number of amendments.

[1] Now known as the COAG Legislative and Governance Forum on Food Regulation
[2] The review request required a review *in relation to P293*. FSANZ understood this to mean a request to review Standard 1.2.7 – Nutrition, Health and Related Claims and the variations to other standards of *the Australia New Zealand Food Standards Code* that were approved as a result of P293 and has proceeded on that basis. A reference to the review or approval of Standard 1.2.7 in this report should also be taken to be a reference to a review or approval of the variations to those other standards.

Table of Contents

1 EXECUTIVE SUMMARY 3

1.1 Review request 3
1.2 Additional requests from the Forum 3
1.3 Matters addressed in the review 4
1.4 Implementation of Standard 1.2.7 7

2 INTRODUCTION 8

2.1 Review request 8
2.2 Background 8

3 GROUNDS FOR REVIEW 10

3.1 Additional requests from the Forum 10

4 FSANZ'S APPROACH TO THE REVIEW 11

4.1 Stakeholder consultation 11
4.2 Additional consumer research and review of literature 12
4.3 Revision of the regulation impact statement (ID No: 6203) 12

5 FSANZ RESPONSE TO REVIEW ISSUES 13

5.1 Regulation of general level health claims 13
5.2 Enforcement 26
5.3 Definition of supplier 28
5.4 Endorsements and endorsing organisations 29
5.5 Infant formula products 30
5.6 'V' points for fruit juice in the nutrient profiling scoring criterion 31
5.7 Application of nutrient profiling scoring criterion to foods with nutrition content claims (including 'claimable foods') 33
5.8 Food for infants 38
5.9 Cost-benefit analysis 40
5.10 Nutrition information panel data 45

6 REGULATORY APPROACH FOR 'FAT-FREE' AND '% FAT-FREE' CLAIMS 46

7 OPTIONS 48

7.1 Protection of public health and safety 48
7.2 The provision of adequate information relating to food to enable consumers to make informed choices 48
7.3 The prevention of misleading or deceptive conduct 49
7.4 Subsection 18(2) consideration 49
7.5 Section 59 considerations 50

8 DECISION 50

8.1 Reasons for decision 50
8.2 Transitional arrangements 51
8.3 Implementation and review 52

9 REFERENCES 53

Attachment A – Approved variations to the *Australia New Zealand Food Standards Code* 54
Attachment B – Explanatory Statements 113

Supporting documents

The following documents used to prepare this Report are available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm.

SD1	Summary of submitter comments on options 1 & 2 for the regulation of general level health claims (March 2009 Consultation Paper)
SD2	Consumers and Nutrition Content Claims. A study of responses to vitamin, mineral and other claims. Roy Morgan Research 2009.
SD3	FSANZ Reanalysis: Consumers and nutrition content claims. A study of responses to vitamin, mineral and other claims. FSANZ 2011
SD4	Literature review on nutrition content claims research published since 2007
SD5	Consideration of additional regulation of 'fat-free' and & fat-free' claims *Attachment 5.1*: Literature review on the effects on consumer behaviour of fat-free nutrition content claims on high sugar foods
SD6	Revised Regulation Impact Statement for P293 *Attachment 6.1*: Updated cost-benefit analysis for P293 *Attachment 6.2*: Addendum to the updated cost-benefit analysis for P293 *Attachment 6.3*: Impact of 'fat-free' claims on cost-benefit analysis
SD7	Health Claims Management Plan – An approach for the regulation of general level health claims (superseded)
SD8	Substantiation process for food-health relationships
SD9	Consideration of EU approved health claims
SD10	International comparison of regulatory requirements for nutrition content and health claims
SD11	Summary of amendments to Standard 1.2.7 and other standards since the Final Assessment Report

1 Executive summary

1.1 Review request

On 6 June 2008, the then Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a review of Food Standards Australia New Zealand's (FSANZ's) decision to approve a standard to regulate nutrition, health and related claims.

The grounds for the review were that draft Standard 1.2.7 – Nutrition, Health and Related Claims:

- was not consistent with existing policy guidelines set by the Ministerial Council
- was not consistent with the objectives of the legislation which establishes FSANZ
- did not protect public health and safety
- was difficult to enforce or comply with in both practical or resource terms
- placed an unreasonable cost burden on industry and/or consumers.

Jurisdictions subsequently identified 14 specific issues or concerns on which the above grounds were based. As part of consideration of these issues, additional work has been undertaken particularly in relation to the regulatory approach for general level health claims, the clarity of the Standard and the application of the nutrient profiling scoring criterion to foods with nutrition content claims. Due to the high level of interest in the review of the Standard, there has been extensive consultation on key issues.

The timeline for completion of the review was extended a number of times due to the overlap with the government response to *Labelling Logic: A Review of Food Labelling Law and Policy (2011)* (Blewett et al. 2011). In addition, due to Ministers requesting additional work, the completion date was twice further extended to give a final due date of 31 October 2012.

1.2 Additional requests from the Forum

At the Legislative and Governance Forum on Food Regulation (the Forum) meeting in December 2011, FSANZ provided an interim report in response to the review request. At that meeting, FSANZ was asked to undertake two further tasks:

- to consult broadly on the draft Standard before presenting a final standard to Ministers
- to further consider 'fat-free' claims due to concerns that such claims may mislead consumers.

FSANZ undertook additional public consultation on these two issues in February 2012. The outcomes of the consultation on the draft Standard are discussed in section 5.2. In response to submitter comments, FSANZ made further changes to the draft Standard to improve clarity of intent.

Consideration of the issue of 'fat-free' claims including the outcomes of the consultation is provided in section 6. After evaluating all available information and submissions received, FSANZ concluded that there be no additional regulatory provisions for 'fat-free' and '% fat-free' claims at this time.

In response to concerns of some stakeholders with the FSANZ pre-approval approach for general level health claims as proposed in the February 2012 consultation paper, the Forum agreed to give further consideration to the treatment of general level health claims in Standard 1.2.7.

At its meeting in July 2012, the Forum considered options for regulating general level health claims. FSANZ was asked to consider an approach where the regulatory system for general level health claims included pre-approved food-health relationships, as well as the option of self-substantiation of new food-health relationships that comply with detailed criteria set out in the Standard. Following this request and further analysis and consultation, FSANZ has included both FSANZ pre-approved food-health relationships and the option of industry self-substantiation of food-health relationships underpinning general level health claims in Standard 1.2.7 (see section 5.1).

1.3 Matters addressed in the review

FSANZ has reviewed its decision and has re-affirmed the approval of Standard 1.2.7 (as at Attachment A), subject to a number of amendments in response to the review request.

The following table summarises the 14 issues raised in the review request and FSANZ's response. Issues are grouped according to whether the response is to amend Standard 1.2.7, clarify intent only, or not change Standard 1.2.7. Note that the responses for four issues related to the regulatory approach for general level health claims are presented together.

Issue	Summary of FSANZ's Response
1. Review Issues – amending Standard 1.2.7	
Regulation of general level health claims and associated issues (co-regulation, biologically active substances, weight loss/maintenance claims, wording conditions)	
Industry self-substantiation for general level health claims was considered to be resource intensive for enforcement authorities and difficult to enforce. Health claims about biologically active substances should be pre-approved by FSANZ since industry self-substantiation could result in industry recommending different amounts of a biologically active substance to achieve the health effect. Claims about weight loss/maintenance should be	Food businesses will have the option of deriving general level health claims from either FSANZ pre-approved or industry self-substantiated food-health relationships. At gazettal, Standard 1.2.7 will include a list of 212 FSANZ pre-approved food-health relationships. This list includes food-health relationships adapted from United States of America (USA), Canada and European Union (EU) approved claims. FSANZ will periodically (via proposals) add food-health relationships that are the basis for health claims published by the EU, Canada and USA, where considered appropriate for use in Australia and New Zealand If food businesses choose to self-substantiate they will be required to: • notify FSANZ of the established food-health relationship before using the associated claim • certify that the notified food-health relationship has been established by a process of systematic review as described in Standard 1.2.7 • provide records to a relevant authority, if requested, that demonstrate the systematic review was conducted in accordance with the process described in Standard 1.2.7. To support industry innovation and first-to-market market advantage, applications for new food-health relationships will be able to be assessed without public notification using the 'high level health claims variation' procedure provided in the *Food Standards Australia New Zealand Act 1991*. The degree of certainty required to establish food-health relationships underpinning all general level health claims, whether pre-approved or self-substantiated, will be the same. The same degree of certainty will also be required to establish food-health relationships underpinning high level health claims as was proposed at final assessment. FSANZ has pre-approved one food-health relationship for weight loss/maintenance. Should food businesses want to make general level health claims about biologically active substances or weight

Issue	Summary of FSANZ's Response
prohibited because substantiation would be difficult, resource intensive for enforcement agencies and create uncertainty for industry.	loss/maintenance, they will need to meet the requirements in the Standard for self-substantiation as noted above. The notification process will assist enforcement authorities in identifying possible compliance issues involved with food-businesses self-substantiating these particular food-health relationships.
Prescribed wording for general level health claims would increase enforceability and improve the clarity of the Standard. The level of prescription for the wording of high level health claims was considered appropriate.	Note that Standard 1.2.7 does not prescribe the exact wording of claims. For all pre-approved food-health relationships underpinning both general and high level health claims the Schedules list pre-approved food-health relationships and any specific conditions that may apply including reference to any specific population group. There are also general requirements for dietary context statements to accompany a health claim. In relation to those food-health relationships that are self-substantiated, food businesses will need to meet the general requirements for health claims.
FSANZ should consider a co-regulatory scheme for regulating nutrition content claims and general level health claims	Issues associated with a possible co-regulatory model have been considered. FSANZ has reaffirmed the regulatory approach for nutrition content claims and health claims in Standard 1.2.7. The Forum expressed support for this approach at its meeting in June 2012. Following the request from the Forum in July 2012 and further analysis and consultation, FSANZ has incorporated pre-approval and industry self-substantiation of food-health relationships underpinning general level health claims, in Standard 1.2.7.
Enforcement	
Concerns with enforcement fell into two main categories; enforcement generally due to the complexity of the Standard, and more specifically enforcement of the industry self-substantiation approach for general level health claims.	Some minor changes to Standard 1.2.7 have been made in order to improve the workability and enforceability of the Standard, including some minor changes in intent. Other amendments were made to improve readability and clarity and to improve formatting. The Implementation Sub-Committee Health Claims Working Group is developing compliance and guidance materials to assist with the implementation of Standard 1.2.7. FSANZ is developing guidance on the food-health relationship substantiation process. It is anticipated that the guidance will be finalised around the time of gazettal of Standard 1.2.7.
Definition of supplier	
The term 'supplier' in Standard 1.2.7 was of concern because of a resulting lack of clarity about who in the supply chain must hold records for substantiating nutrition content claims and general level health claims. Imported foods were the key issue. There was a desire to minimise the cost burden on industry and enforcement.	References to 'supplier' in Standard 1.2.7 have been removed, except in relation to endorsements, where, who the supplier is intended to be has been clarified. In relation to nutrition content claims, FSANZ considers that there is no need under the Standard to specifically require a food business to hold applicable evidence, to substantiate such claims. In relation to general level health claims, the previous reference to 'the supplier' has been removed. The Standard now refers to 'the person who is responsible for making the health claim'.
2. **Review issues – amending Standard 1.2.7 to clarify intent only**	
Endorsements and endorsing organisations	
The proposed approach whereby an endorsement made by an endorsing body would be exempt from the requirements of Standard 1.2.7 if specific conditions were met, would be difficult to enforce or comply with in both practical or resource terms.	FSANZ has reaffirmed its position at final assessment, that the requirements of Standard 1.2.7 will not apply to an endorsement (that is a nutrition content claim or health claim) made by an endorsing organisation (now referred to as 'endorsing body'), if specific conditions are met. The definitions of 'endorsing body' and 'endorsement' have been clarified to address enforcement concerns.

Issue	Summary of FSANZ's Response
Infant formula products	
The clarity of the Standard in prohibiting claims on infant formula products was of concern. It was considered that the wording of the current prohibition in Standard 2.9.1 would not necessarily prohibit nutrition content and health claims on infant formula products, therefore specific exclusions for claims on infant formula products should also be included in Standard 1.2.7.	Standard 1.2.7 has been amended to clarify that infant formula products are prohibited from carrying nutrition content and health claims. This does not represent a change in intent in relation to claims on infant formula products which has remained consistent throughout development of Standard 1.2.7.
'V' points for fruit juice in the nutrient profiling scoring criterion	
There was opposition to the permission for fruit juice (not vegetable juice) to count towards 'V' points in the nutrient profiling scoring criterion as it was considered that excessive consumption of fruit juice is associated with adverse health effects.	FSANZ has reaffirmed its position at final assessment, namely that fruit juice will be eligible to score V points in the nutrient profiling scoring criterion. This is based on the inclusion of fruit juice as an alternative to fruit, in the Australian and New Zealand dietary guidelines. FSANZ has made it clear in the drafting that juice as standardised in Standard 2.6.1 can score V points.
3. Review issues – no changes to Standard 1.2.7	
Application of nutrient profiling scoring criterion to foods with nutrition content claims	
The application of the nutrient profiling scoring criterion to foods carrying health claims, but not to foods carrying nutrition content claims was not supported because it was considered that: • it was inconsistent with the Ministerial Council Policy Guideline • FSANZ research was limited by only exploring the effects of nutrition content claims for well-known nutrients, and not examining effects of nutrition content claims about vitamins and minerals and biologically active substances. Also only a narrow range of product types were tested • there were inconsistencies between previous research on consumer understanding and current research on consumer behaviour.	FSANZ has reaffirmed its position at final assessment, namely that the nutrient profiling scoring criterion will not be generically applied to foods carrying nutrition content claims. The requirement to meet the nutrient profiling scoring criterion for health claims remains. The Forum expressed support for this approach at its meetings in June and July 2012. FSANZ commissioned an additional consumer research study as part of the review. The additional consumer research generally indicates that the presence of nutrition content claims about vitamins, minerals and biologically active substances on foods that do not meet the nutrient profiling scoring criterion does not enhance nutrition or health evaluations of products, or purchase intention. The study had input from the FSANZ Social Science Expert Advisory Group, and the reports were peer reviewed by overseas and local experts. FSANZ has also completed a literature review on the effects of nutrition content claims on consumer choice and nutrition or health evaluations of foods. This review was peer reviewed by two experts in consumer behaviour. Few studies included foods of lower nutritional quality. The review suggests that nutrition content claims do not mislead consumers about the nutritional value or health benefits of foods. However, the review findings are equivocal about the effects of nutrition content claims on consumers' stated intention to purchase foods, as research findings tend to depend on the methodology used. The findings from the literature review therefore do not alter FSANZ's position to not apply the nutrient profiling scoring criterion to foods with nutrition content claims. The external consultant, the Centre for International Economics (CIE), advised that if the nutrient profiling scoring criterion was applied to all foods carrying nutrition content claims, the total costs of the Standard are likely to outweigh total benefits.
Food for Infants	
There was concern that FSANZ had	FSANZ has reaffirmed its position at final assessment, namely that:

Issue	Summary of FSANZ's Response
interpreted 'infant foods' or 'baby foods' in the Policy Guideline to mean 'infant formula' (as defined in Standard 2.9.1). It was suggested that infant foods should be prohibited from carrying any claims to avoid exploiting the specific needs of infants.	• specific nutrition content claim permissions and conditions within Standard 2.9.2 – Foods for Infants remain in operation • other nutrition content claims and health claims be permitted in accordance with Standard 1.2.7. FSANZ considers that nutrition content and health claims could provide useful information about the nutritional needs of infants.
Cost benefit analysis	
There were two main concerns about the cost-benefit analysis: • the inadequacy of the cost estimates for the enforcement of Standard 1.2.7 • aspects of the methodology.	FSANZ sought updated costs for FSANZ pre-approval of general level health claims from the jurisdictions in June 2008. The methodologies used for the cost-benefit analysis have been validated during the review by the external consultant, CIE. The regulation impact statement (RIS) and the cost-benefit analysis prepared at final assessment have been revised to take into consideration today's prices and costs and also to compare various regulatory options for general level health claims. The overall net benefit of Standard 1.2.7 has declined from an estimated A$95 million in 2008 to A$84 million in 2012 at net present value. FSANZ considers that the change from industry self-substantiation of all general level health claims proposed at final assessment to industry self-substantiation combined with FSANZ pre-approved food-health relationships at review, is likely to result in a more favourable net benefit for Standard 1.2.7 than that estimated for the Standard when food-health relationships could only be self-substantiated. The Office of Best Practice Regulation (OBPR) considers the RIS satisfies the Council of Australian Governments' (COAG's) best practice regulation requirements for a decision RIS. (ID No: 6203)
Nutrition information panel data	
Nutrition information panel values were not sufficiently accurate to be used for the nutrient profiling scoring criterion or for substantiation of nutrition content claims.	FSANZ considers that the issue of nutrition information panel accuracy cannot be addressed in the review of Standard 1.2.7. Accuracy, compliance and monitoring of the nutrition information panel values could be considered by the enforcing authorities.

1.4 Implementation of Standard 1.2.7

There will be a three-year transition period for Standard 1.2.7 commencing on gazettal, with no additional stock-in-trade period.

FSANZ plans to undertake further work during the transition period including establishing the High level Health Claims Committee, considering the use of authoritative sources for self-substantiation of food-health relationships, completing the consideration of food-health relationships from EU approved claims for possible inclusion in Standard 1.2.7, developing and implementing a process to maintain the scientific currency of pre-approved food-health relationships, considering the nutrient profiling scoring criterion in the light of developments that may arise from the proposed use of the scoring criterion for front-of-pack labelling, as well as possible exemptions for certain foods, and preparing a proposal to further consider the qualifying criteria for nutrition content claims about dietary fibre.

FSANZ anticipates releasing the revised *Application Handbook* (which includes substantiation requirements for applicants wishing to seek approval of food-health relationships underpinning both general and high level health claims) for public consultation in November 2012.

FSANZ is developing guidance on the food-health relationship substantiation process and plans to undertake targeted consultation in November 2012 to seek stakeholder views on this document.

An Implementation Sub-Committee working group is developing a compliance strategy to aid consistent implementation of the new Standard by jurisdictions. Guidance materials for industry are also being prepared.

It is anticipated that all documents will be completed around the time Standard 1.2.7 is likely to be gazetted.

2 Introduction

2.1 Review request

On 6 June 2008, the then Ministerial Council requested a review of the FSANZ's decision in May 2008 to approve a standard to regulate nutrition, health and related claims. Draft Standard 1.2.7 was prepared under Proposal P293 – Nutrition, Health & Related Claims and provides a regulatory management and substantiation framework for nutrition content, health claims and related claims such as endorsements.

In 2009, an independent review of food labelling law and policy commenced (Blewett et al. 2011). Due to the labelling review, the timeline for completion of the review of Standard 1.2.7 was extended a number of times. In addition, due to Ministers requesting additional work, the completion date was twice further extended to give a final due date of 31 October 2012.

2.2 Background

After receiving the *Policy Guideline on Nutrition, Health and Related Claims*[3] (Policy Guideline) from the then Ministerial Council in December 2003, FSANZ prepared Proposal P293 – Nutrition Health and Related Claims to:

- support industry innovation, giving consumers a wider range of healthy food choices

[3] The Policy Guideline is at http://www.foodstandards.gov.au/foodstandards/legislativeandgovernanceforumonfoodregulation/policyguidelines.cfm

- ensure that food labels bearing nutrition, health or related claims provide adequate information to enable consumers to make informed choices
- prevent misleading or deceptive nutrition, health or related claims on food labels or in food advertising
- have regard to Ministerial Council policy guidance.

P293 seeks to address the ambiguities and limitations under the current regulatory arrangements that restrict industry innovation and lead to difficulties with enforcement.

At final assessment[4], the FSANZ Board approved Standard 1.2.7 to regulate nutrition content, general level and high level health claims.

Nutrition content claims describe or indicate the presence or absence of energy, a nutrient or biologically active substance in food. For example: *this food is high in calcium.*

General level health claims refer to the presence of a nutrient or substance in a food and its effect on a health function. General level health claims may not refer to a serious disease or to a biomarker of a serious disease. For example: *calcium is good for healthy bones and teeth.*

High level health claims refer to the presence of a nutrient or substance in a food and its relationship to a serious disease or to a biomarker of a serious disease. For example: *Diets high in calcium may reduce the risk of osteoporosis.*

It was proposed that there would be a 'step-up' approach in regulation from nutrition content claims to general level health claims to high level health claims and that:

- all claims would be substantiated
- wording conditions[5] and qualifying criteria for nutrition content, general level and high level health claims would be specified in the Standard
- foods carrying general level and high level health claims would be required to meet the nutrient profiling scoring criterion (i.e. to restrict use of health claims on products considered to be of 'lower nutritional quality')
- food-disease relationships underpinning high level health claims would be pre-approved by FSANZ
- food businesses could choose one of four methods to substantiate general level health claims and provide records of substantiation to enforcement authorities on request.

The FSANZ Board approved Standard 1.2.7 in May 2008. The Board's reasons for this decision included that:

- the Standard provided an expanded regulatory approach for nutrition, health and related claims
- the Standard offered industry an opportunity to innovate and take advantage of incorporating health claims in their marketing strategies
- consumers would have information on nutrition content and health claims on food at point of sale or in advertising, and would have the ability to make more informed purchasing decisions

[4] All previous reports relating to P293 are at http://www.foodstandards.gov.au/foodstandards/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm

[5] 'wording conditions' does not mean that the exact wording of a nutrition content or health claim is prescribed in the draft Standard.

- the potential to mislead consumers under the current regulatory arrangements, either through non-regulated nutrition content claims or implied health claims, would be mitigated as these issues were clearly addressed in the Standard
- the Standard would resolve ambiguities and limitations under the current regulatory arrangements and facilitate effective enforcement actions by enforcement agencies
- the Standard would be broadly consistent with comparable arrangements overseas
- the regulation impact statement indicated that the Standard would deliver an incremental improvement in the economic welfare of Australia and New Zealand
- the Policy Guideline and national nutrition policies had been taken into account during the development of the Standard.

3 Grounds for review

The then Ministerial Council requested that FSANZ review its decision to approve Standard 1.2.7 on the grounds that the Standard:

- was not consistent with existing policy guidelines set by the Forum
- was not consistent with the objectives of the legislation which establishes FSANZ
- did not protect public health and safety
- was difficult to enforce or comply with in both practical or resource terms
- placed an unreasonable cost burden on industry and/or consumers.

In consultation with the jurisdictions, FSANZ identified the following 14 specific issues in the review request:

1. Regulation of general level health claims
2. Health claims about biologically active substances
3. Weight loss claims
4. Wording conditions for general level health claims and split claims
5. Enforcement
6. Definition of supplier
7. Endorsements and endorsing organisations
8. Infant formula products
9. 'V' points for fruit juice in the nutrient profiling scoring criterion
10. Application of nutrient profiling scoring criterion to foods with nutrition content claims (including 'claimable foods')
11. Food for infants
12. Cost-benefit analysis
13. Nutrition information panel data
14. Co-regulation.

3.1 Additional requests from the Forum

The Forum asked FSANZ to undertake additional work on two occasions during the review of Standard 1.2.7 (December 2011 and July 2012).

In December 2011, FSANZ provided the Forum with an interim report in response to the review request. At that meeting, FSANZ was asked to undertake two further tasks:

- to consult broadly on the draft Standard itself before presenting a final standard to Ministers
- to further consider 'fat-free' claims due to concerns that such claims may mislead consumers.

FSANZ undertook additional public consultation on these two issues in February 2012 (see section 4.1). The outcomes of the consultation on the draft Standard are discussed in section 5.2. Consideration of the issue of 'fat-free' claims including the outcomes of the consultation is provided in section 6.

In response to the concerns of some stakeholders about the FSANZ pre-approval approach for general level health claims as proposed in the February 2012 consultation paper, the Forum agreed to give further consideration to the treatment of general level health claims in Standard 1.2.7.

In July 2012, Ministers considered options for the regulation of general level health claims. Ministers subsequently asked FSANZ to consider an approach where the regulatory system for general level health claims included pre-approved food-health relationships as well as an alternative pathway for self-substantiation of food-health relationships underpinning general level health claims.

Refer to sections 4.1 and 5.1 for details of the consultation FSANZ undertook on the regulation of general level health claims.

4 FSANZ's approach to the review

FSANZ has considered all 14 issues and undertaken additional work particularly in response to three of the 14 issues: the regulatory approach for general level health claims, clarity of the draft Standard and the application of the nutrient profiling scoring criterion to foods with nutrition content claims.

Given that in July 2012, the Forum asked FSANZ to consider inclusion of an alternate pathway of industry self-substantiation of general level health claims in the Standard, the review issues relating to the regulatory approach for general level health claims (issues 1-4) and co-regulation (issue 14) are presented together in this report (see section 5.1).

4.1 Stakeholder consultation

The *Food Standards Australia New Zealand Act 1991* (FSANZ Act) does not require consultation to be undertaken as part of a review process. However, due to the high level of interest in Standard 1.2.7 FSANZ has undertaken both broad and targeted consultation (see Table 1).

Table 1: Stakeholder consultation undertaken by FSANZ during the review of Standard 1.2.7

Date	Topic	Format	Response/participants
March 2009	• Options for regulation of general level health claims • Revision of text and structure of the draft Standard	Public consultation	71 submissions (refer to SD1 for overview of submitter comments)
March – April 2010	• Health claims management plan	Targeted consultation	Key industry, consumer, public health stakeholder groups and jurisdictions
November 2010	• Health claims management plan	Targeted consultation	All interested parties and submitters to P293 invited 119 stakeholders attended

Date	Topic	Format	Response/participants
Last quarter of 2011	• Pre-approval of general level health claims	Targeted consultation	Key industry, consumer, public health stakeholder groups and jurisdictions
February 2012	• Clarity and intent of draft Standard • Additional regulation of 'fat-free' claims	Public consultation	83 submissions (refer to section 5.1.3.4 for overview of submitter comments)
August 2012	• Self-substantiation of general level health claims	Targeted consultation	Key industry, consumer, public health stakeholder groups
September 2012	• Self-substantiation of general level health claims	Targeted consultation	Jurisdictions
October 2012	• Self-substantiation in draft Standard • EU approved claims	Targeted consultation	Key industry, consumer, public health stakeholder groups
October 2012	• Self-substantiation in draft Standard • EU approved claims	Targeted consultation	Jurisdictions

Comments from the consultations were taken into account in the review of Standard 1.2.7. Most of the consultation activities were focussed on the regulatory approach for general level health claims. Stakeholder views relating to the development of the regulatory approach for general level health claims are included in section 5.1.

4.2 Additional consumer research and review of literature

Consumer research was commissioned to address concerns that FSANZ had not investigated the effect of nutrition content claims about vitamins, minerals and biologically active substances on consumer purchase intention and product evaluations. The outcomes of this research are discussed in section 5.7. The final commissioned report and a report on a re-analysis of the data prepared by FSANZ are included as SD2 and SD3 respectively.

Two additional literature reviews were also completed. FSANZ prepared a review on the effects of nutrition content claims on consumers (SD4) and commissioned a review on the consumer use and understanding of fat-free claims on foods of lower nutritional quality (SD 5). Both literature reviews have been peer reviewed by experts in consumer behaviour.

4.3 Revision of the regulation impact statement (ID No: 6203)

Following consultation with the Office of Best Practice Regulation (OBPR) about the effect of changes to Standard 1.2.7 on the regulation impact statement (RIS), FSANZ revised the RIS that was prepared for the Final Assessment Report. The revised RIS (SD6) includes:

- the rationale for P293 and the problem it sought to address
- an update of the cost-benefit analysis that was prepared by the Centre for International Economics (CIE) for the Final Assessment Report (Attachment 6.1 to SD6 for the updated cost-benefit analysis)
- additional sensitivity analysis for the updated cost-benefit analysis (Attachment 6.2 to SD6)
- analysis of the options for the regulation of general level health claims

- an evaluation of the effect of additional regulation of fat-free and % fat-free claims on the cost-benefit analysis that was prepared in 2008 at final assessment (Attachment 6.3 to SD6).

The OBPR has advised FSANZ that the revised RIS meets the Council of Australian Government's best practice regulation requirements for a decision RIS.

Section 5.9 presents the response to concerns with the cost-benefit analysis expressed in the review request and a discussion of the revised RIS.

5 FSANZ response to review issues

The following sections discuss the 14 issues identified in the review request. Note a number of these 14 issues relate to more than one of the grounds for the review. Each section details FSANZ's position at final assessment, the concerns in the review request and FSANZ's response. The issues are presented in the following order:

Review issues that have resulted in changes to Standard 1.2.7:

- regulation of general level health claims (including co-regulation, biologically active substances, weight loss claims, wording conditions)
- enforcement
- definition of supplier.

Review issues that have resulted in changes to Standard 1.2.7 to clarify intent only:

- endorsements and endorsing organisations
- infant formula products
- 'V' points for fruit juice in the nutrient profiling scoring criterion.

Remaining review issues (no changes to Standard 1.2.7):

- application of nutrient profiling scoring criterion to foods with nutrition content claims
- food for infants
- cost-benefit analysis
- nutrition information panel data.

5.1 Regulation of general level health claims

5.1.1 Approach at final assessment

In the 2008 Final Assessment Report, FSANZ stated that general level health claims[6] would be substantiated according to a Scientific Substantiation Framework (see Schedule 2 of Standard 1.2.7 in the Final Assessment Report).

[6] A general level health claim refers to the presence of a nutrient or substance in a food and to its effect on a health function (e.g. calcium and bone health). A general level health claim cannot refer to a serious disease or condition or to an indicator of a serious disease (e.g. blood cholesterol).

Under this framework, food businesses would be required to self-substantiate general level health claims using one of the following four methods:

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

The supplier of the food carrying the general level health claim was to have records that substantiated the claim and make these available to the enforcement authority upon request.

Specific conditions were provided in the Standard for general level health claims about biologically active substances as follows:

- the level of the biologically active substance in the food had to be stated in the claim
- the supplier had to have records substantiating the amount of biologically active substance that was required to be consumed per day to achieve the claimed health effect
- the amount consumed per day to achieve the claimed health effect had to be declared as part of the claim
- a serve of the food had to contain at least 10% of the amount required to be consumed per day to achieve the claimed health effect.

Specific conditions were also provided in the Standard for general level health claims about weight loss as follows:

- the food had to a) meet the conditions for *low energy* claims; or b) contain at least 40% less energy compared to the same quantity of the reference food; and if b) applied, the claim had to state the identity of the reference food and the difference between the energy value of the food and the reference food
- the importance of exercise was required to be stated in the wording of the claim.

In 2008, the wording that expressed the property of the food, the claimed health effect, the population group (if necessary), and the dietary context, were required to be included for all general level health claims[7]. However, as the specific wording elements of the claim were not listed in the Standard (as they were for high level health claims) it was left to the food business to identify the appropriate claim statements to be used in the claim.

At final assessment, Standard 1.2.7 included a provision that a shortened version of a health claim (referred to as a 'split' claim) could be made on a label if the health claim in its entirety was stated elsewhere on the same label/advertisement, and a directive statement was provided in conjunction with the shortened health claim, to direct consumers to the health claim in its entirety.

Example:
on front of pack: *Calcium is good for strong bones* (see back for details)

on back of pack: *Calcium is good for strong bones, when consumed as part of a healthy diet high in calcium.*

[7] 'wording conditions' does not mean that the exact wording of a nutrition content or health claim is prescribed in Standard 1.2.7.

5.1.2 Issues raised in review request

The key concerns with self-substantiation of general level health claims were as follows:

- It would be difficult to enforce and resource prohibitive due to the need for enforcement authorities to assess evidence and the wording of claims (compared with pre-approved food-health relationships which have the associated population group (if appropriate), dietary context statement and conditions specified in the Standard).

- The amount of biologically active substance required to achieve the health effect would be identified by the food business with potentially different levels being used by different businesses thereby resulting in confusion for consumers.

- Weight loss claims should be prohibited because:

  - of the difficulties associated with assessing substantiating evidence
  - 'diet' nutrition content claims already imply a lower energy food and therefore weight loss claims are not required
  - consumers may be misled because no one food has intrinsic weight reducing properties.

- The lack of prescribed wording for general level health claims would reduce the enforceability and clarity of the Standard. The level of prescription for the wording of high level health claims was considered appropriate.

- 'Split' claims could be misinterpreted by consumers, particularly as the wording and 'size' for general level health claims was not prescribed (as they were for high level health claims). With regard to 'size', it is unclear whether the concern was about font size or the length of the claim.

In the review request, the Ministerial Council requested consideration of a co-regulatory scheme as an alternative for regulating general level health claims and nutrition content claims. The rationale for this request was based on the view that the Standard was complex and compliance and enforcement problems would be significant for industry and regulators, and that in principle, a co-regulatory scheme would be more practical and effective for these claims.

5.1.3 Consideration of the regulatory approach for general level health claims

In response to the review request and subsequent stakeholder views, between June 2008 and February 2012 FSANZ considered three approaches for regulating general level health claims – co-regulation, FSANZ pre-approval, and an outcomes-based approach incorporating a health claims management plan. Following the Forum's consideration of the regulatory approach for general level health claims in July 2012, FSANZ considered including industry self-substantiation in Standard 1.2.7 in addition to pre-approval.

A brief outline of the approaches considered and additional requests from the Forum are provided in this section.

5.1.3.1 Co-regulation

FSANZ has considered a co-regulatory approach for general level health claims in response to comments in the review request and submitter views expressed in response to the March 2009 consultation paper. Some submitters proposed a co-regulatory approach with a non-regulatory component for general level health claims, either with or without some requirement for third party assessment of suitable claims.

Co-regulation was seen by some submitters as the balance between protecting public health, preventing misleading conduct and facilitating trade. It was argued that a co-regulatory system could facilitate responses in a timely manner when change is required and that such a system favours minimum effective regulation for low risk claims and full regulation for high risk claims.

FSANZ's development of the preferred regulatory approach for nutrition content and health claims has been based on legislative requirements and constraints under the FSANZ Act, the guidance provided by the Ministerial Policy Guideline, the regulatory impact statement developed for P293 and government regulatory policy principles such as COAG *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies 2004*.

At draft assessment, FSANZ undertook an analysis of three options for regulating nutrition, health and related claims: Option 1 (status quo), Option 2 (new standard and guideline[8]); Option 3 (new standard only). FSANZ recommended that a new standard (only) be prepared for regulating nutrition content and health claims and this has remained the preferred approach. The rationale for this decision was based on stakeholder support, the cost-benefit analysis and the difficulty for stakeholders in having to refer to both a standard and a guideline.

In response to submitter comments, FSANZ has considered a co-regulatory model whereby FSANZ would develop a standard with some provisions for claims and industry would seek third party certification before making claims in the market place. This third party certification could then be used by enforcement agencies in order to assess whether health claims met the substantiation requirements of the standard. FSANZ considers that such a third party certification or verification model has no legislative backing under the current state, federal and New Zealand legislative and regulatory environment. A voluntary system would not provide the certainty desired by enforcement agencies or industry and a mandatory third party certification system would require legislative reform since a standard has to set objective criteria in advance in accordance with section 16 of the FSANZ Act.

Overall, setting up a well-grounded and supported co-regulatory system would first require broad in-principle stakeholder support. It also raises a significant number of new issues, such as enforceability, that would take considerable commitment to resolve, including the possibility of legislative change. Since the request by the Forum in July 2012 to consider an additional approach for general level health claims, (see section 5.1.3.4) did not include a co-regulatory approach, FSANZ has not considered such an approach any further.

5.1.3.2 Industry self-substantiation versus FSANZ pre-approval (March 2009 consultation)

FSANZ released a consultation paper in March 2009 seeking stakeholder views on two options for regulating general level health claims.

Option 1 was based on industry self-substantiation as recommended in the Final Assessment Report, but with minor amendments. The amendments included more explicit guidance for industry on the data requirements for scientifically establishing food-health relationships.

[8] At that time, the term 'guideline' referred to a co-regulatory system. It was proposed a committee consisting of representation from food industry, jurisdictions, consumer groups, public health groups and FSANZ would monitor the use of nutrition content and general level health claims and evaluate the performance of a guideline developed by FSANZ.

Option 2 (presented as the preferred option) proposed pre-approval of food-health relationships which could be used as the basis for general level health claims and provided a list of 105 such relationships in the revised draft Standard. A food business would need to make an application to FSANZ for inclusion of a new food-health relationship in the new Standard before using a health claim based on that relationship.

An overview of submitter comments on Options 1 and 2 is presented in SD1.

There was a lack of consensus across stakeholder groups for either Option 1 or Option 2 for the regulation of general level health claims. However, most jurisdictions and public health stakeholders supported Option 2 because they considered that Option 2 would ensure that food-health relationships would:

- be approved only where there is sufficient evidence
- result in a reduced resource burden for enforcement agencies and a reduced risk of inconsistent enforcement
- be possible to be implemented immediately within the existing legislative framework and not be likely to result in increased costs for industry in assembling evidence for an application compared with that for self-substantiation.

In contrast, food industry submitters were generally more supportive of Option 1, as it was seen to allow more flexibility, competition and innovation. In particular, industry would have the ability to keep new claims confidential until a product was launched on the market. Product labelling would not require significant changes and thus Option 1 was considered less disruptive to industry. The comment was also made that industry self-substantiation has already been operating successfully and is subject to consumer and other fair trading laws.

5.1.3.3 Outcomes-based approach – health claims management plan

Due to the lack of stakeholder consensus for either Option 1 or 2 (as presented in the March 2009 consultation paper), FSANZ developed a further option of an outcomes-based approach for regulating general level health claims. Under this approach, a food business could not make a general level health claim unless they had a health claims management plan. Before marketing a product with a specific claim, the food business would action the plan by putting together a dossier of information/evidence, including substantiating the specific food/property-health relationship in the manner detailed in the plan. Refer to SD7 for further details of this approach.

Following extensive discussions with the ISC Health Claims Working Group on implementing the health claims management plan approach, it was concluded that the approach would be difficult to enforce, and was therefore not developed further.

5.1.3.4 Additional requests from the Forum on the regulatory approach for general level health claims

Further stakeholder consultation (February 2012)

At the Forum meeting in December 2011, Ministers considered an interim report from FSANZ and asked FSANZ to undertake two additional tasks:

- to consult broadly on the draft Standard before presenting a final standard to Ministers
- to further consider ‘fat-free’ claims due to concerns that such claims may mislead consumers.

In response to this request from Ministers, in February 2012, FSANZ undertook additional public consultation on the clarity, enforceability and user-friendliness of draft Standard 1.2.7 and whether the draft Standard reflected regulatory intent. Refer to section 6 for discussion on fat-free claims.

In general, submitters considered that the clarity and enforceability of the draft Standard was improved and that the Standard did achieve the regulatory intent. However, in addition there were a number of submitters who commented on the proposed pre-approval approach for general level health claims.

Under the approach proposed in the February 2012 consultation paper, food-health relationships underpinning all health claims (general and high level health claims) would be pre-approved by FSANZ. To provide for industry innovation and first to market advantage, it was proposed that applications for new food-health relationships could be assessed without public notification using the 'high level health claims variation' procedure provided in the FSANZ Act.

It was proposed that there would be approximately 115 pre-approved food-health relationships in the draft Standard at gazettal which manufacturers would be able to use as the basis of a health claim.

The majority of industry submitters had strong objections to the pre-approval approach, while consumer/public health groups supported pre-approval along with some jurisdictions due to ease of enforcement and confidence in the validity of claims.

Consideration of industry self-substantiation (July 2012)

In response to concerns from industry and some jurisdictions about the pre-approval approach for general level health claims, at its meeting on 1 June 2012, the Forum agreed to give further consideration to the treatment of these claims in the draft Standard following consultation with key consumer/ public health and industry groups. The Food Regulation Standing Committee (FRSC) undertook consultation with industry, public health and consumer stakeholders and subsequently reported to Ministers.

In July 2012, Ministers agreed to ask FSANZ to consider an approach where the regulatory system for general level health claims included the following features:

- pre-approved food-health relationships as well as the option of self-substantiation of new food-health relationships that comply with detailed criteria set out in the Standard
- the level of evidence for self-substantiated food-health relationships to be the same as that for pre-approved food-health relationships underpinning general level health claims
- food businesses self-substantiating a food-health relationship be required to hold and make available to enforcement authorities on request, a document which meets the requirements for self-substantiation set out in the Standard
- an authorised person to notify FSANZ and be required to declare that the food business had met the requirements for self-substantiation set out in the Standard.

5.1.4 FSANZ response - regulatory approach for general level health claims

5.1.4.1 General requirements for general level health claims

Food businesses wishing to make general level health claims will be able to base their claims on either:

- food-health relationships pre-approved by FSANZ and listed in Schedule 3 of Standard 1.2.7; or
- self-substantiated food-health relationships established in accordance with Standard 1.2.7.

All general level health claims will need to comply with the following requirements that have not changed since 2008:

- Foods carrying health claims must meet the nutrient profiling scoring criterion, except special purpose foods standardised in Part 2.9 of the Code.

- The health claim must include the food or property of food and the specific health effect claimed for that food or property of food.

- The population group to which the health effect relates, must be stated together with the health claim, if applicable.

- A dietary context statement must also be included with the claim. The dietary context statement must state that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods and be appropriate to the type of food carrying the claim, the property of food that is the subject of the claim and the health effect claimed, as applicable.

- A statement of the form of the food to which the claim relates must be included with the claim, unless the form of the food to which the claim relates is the food in the form in which it is sold.

- The food and property of food and the health effect can be presented as a separate statement (a 'split claim'), however, those elements must appear on the same label or in the same advertisement as the complete statement required by the Standard. An indication of where the complete statement is located must be provided with the separate elements.

In the review request there was concern about the lack of prescribed wording for general level health claims with the suggestion that the level of prescription for the wording of high level health claims could be used. This approach has now been applied to pre-approved food-health relationships underpinning general level health claims. Schedule 3 lists pre-approved food-health relationships and any specific conditions that may apply including reference to any specific population group. There are also requirements for dietary context statements to accompany a health claim. Note that Standard 1.2.7 does not prescribe the exact wording of health claims. In relation to those food-health relationships that are self-substantiated, food businesses will need to meet the general requirements for health claims as listed above.

At final assessment, the provision for split claims was included in the Standard to allow flexibility for the wording and positioning of claims on labels for industry. This provision will be maintained thereby striking a balance between ensuring the full context of the claim is provided and permitting shorter statements for flexibility. This approach is supported by the Policy Guideline which makes reference to split claims, indicating that where claims are separated into sections, 'the first part of the claims must direct the reader to further information provided elsewhere in the same communication medium'.

5.1.4.2 FSANZ pre-approval of food-health relationships underpinning general level health claims

On gazettal of the new Standard, a list of 212 pre-approved food-health relationships will be available for a food business to use to derive general level health claims (Schedule 3 of Standard 1.2.7). This list has been developed from the following sources:

- UK Joint Health Claims Initiative (includes well established nutrient function statements)
- USA Food and Drug Administration (USFDA)
- Health Canada
- some of FSANZ's pre-approved high level health claims
- approved claims in the EU.

FSANZ has considered the extensive comments received on the list of pre-approved food-health relationships provided in the March 2009 and February 2012 consultation papers and has made some changes to the list in response to these comments. Some submitters requested that claims currently in the market but not supported by pre-approved food-health relationships, be assessed for inclusion in the list, however such requests have not been considered as part of the review, except where relationships have been adopted from the EU. Given the addition of the self-substantiation pathway, food businesses will be able to use this option to meet the requirements of the Standard.

Consideration of approved claims from the EU, USA and Canada

FSANZ considers the procedures used by the European Food Safety Authority (EFSA), the USFDA and Health Canada to evaluate food-health relationships to be broadly equivalent to the procedure to be used in Australia and New Zealand (see SD8).

In May 2012, the EU approved 222 health claims in addition to its earlier list of 19 approved health claims. FSANZ has reviewed all of these claims (241 in total) for possible inclusion in Standard 1.2.7. In undertaking this task, FSANZ has applied the overarching principle that the EFSA has assessed each approved health claim and required a similar degree of certainty and high quality evidence to that proposed by FSANZ for substantiating a food-health relationship (see SD8).

In addition, FSANZ has evaluated any conditions for making the claim (i.e. the relevant population, the dietary context and specific conditions for the composition of the food carrying the claim) for each food-health relationship to ensure that claims based on the pre-approved food-health relationships are relevant to the Australian and New Zealand population.

In summary, FSANZ has included 97 food-health relationships from 103 EU approved claims making a total of 212 pre-approved relationships that industry can use to derive general level health claims (Table 1 at SD9 for the 97 food-health relationships). Eighty-six EU claims were already in the list of 115 pre-approved food-health relationships in February 2012 (Table 2). Food-health relationships derived from 20 EU claims will not be added to the Standard. The reasons for exclusion are provided in Table 3 at SD9.

FSANZ has yet to make a decision on 32 food-health relationships (Table 4 at SD9). FSANZ anticipates finalising consideration of these food-health relationships in batches during the transition period, beginning with those of greatest priority to industry. Food health relationships derived from EU approved claims will be assessed for inclusion in Standard 1.2.7 using the 'high level health claims variation' proposal procedure set out in the FSANZ Act.

FSANZ has already incorporated food-health relationships from approved health claims in the USA and Canada in Standard 1.2.7. FSANZ will continue to monitor the approval of health claims in the USA, Canada and the EU and consider adopting relevant food-health relationships in the Standard. Public comment would be sought when changes to the Code are proposed.

Some industry stakeholders have requested consideration of probiotic health claims approved overseas, in particular in Canada. Health Canada has four pre-approved non-strain specific probiotic claims. They are general claims that refer to the nature of probiotics and not their health effects or benefits and so they do not meet the definition of a general level health claim in Standard 1.2.7. Health Canada recently advised (July 2012) that it was reviewing these claims as part of a review of its regulation of foods that are marketed as natural health products. These products, or NHPs as they are referred to in Canada, are similar to complementary medicines or dietary supplements in Australia and New Zealand. Given the uncertainty with the outcome of the review in Canada and that the EU has not approved any health claims about probiotics, FSANZ has not considered any health claims about probiotics to date. Ongoing monitoring of approved health claims overseas may change this situation. Standard 1.2.7 does permit nutrition content claims about the presence of probiotic micro-organisms but it does not include any pre-approved health claims for probiotics.

Applications for pre-approved food-health relationships

Food businesses will be able to have applications for the approval of new food-health relationships assessed without public notification, by virtue of the 'high level health claims variation' procedure in the FSANZ Act (subdivision G).

The 'high level health claims variation' procedure enables applicants to have an application seeking approval of a new food-health relationship to underpin both general and high level health claims assessed without the normal public notification process. This addresses, in part, concerns expressed in submitter comments arising from the 2009 consultation and provides both the opportunity for first to market advantage and the certainty afforded by the pre-approval process. On acceptance of an application, FSANZ will be required to advise the Food Regulation Standing Committee and the High Level Health Claims Committee[9] of the nature of the application and the process to be used to assess the application. FSANZ is required to take into account any recommendations from these committees in assessing an application. Food businesses will also have the options of paying application fees to expedite commencement of FSANZ's assessment according to current FSANZ procedures and allowing FSANZ to call for public submissions. Once FSANZ has completed the assessment and approved a new food-health relationship, Ministers will be notified in the normal manner.

Applicants seeking pre-approval of a new food-health relationship will be required to submit evidence according to the FSANZ *Application Handbook*. FSANZ is preparing amendments to the *Handbook* to cover the substantiation requirements for applicants wishing to seek approval of food-health relationships (similar to that required for self-substantiation of food-health relationships), and any additional requirements for applicants seeking other changes to Standard 1.2.7. It is anticipated that the amendments to the *Handbook* will be released for public consultation in November 2012, to ensure that the *Handbook* is updated around the time the Standard is likely to be gazetted.

[9] According to the 'high level health claims variation' procedure in the FSANZ Act, a committee (known as the High Level Health Claims Committee) must be established.

Currency of pre-approved food-health relationships

FSANZ is developing a process to maintain the scientific currency of food-health relationships in the Standard and expects to begin this work during the transition period. As part of this work FSANZ is proposing to:

- consider the food-health relationships supporting high level health claims that are in Schedule 2 of Standard 1.2.7 as these were originally evaluated by the former Health Claims Scientific Advisory group before March 2006
- re-evaluate the food-health relationships that were examined in 2005–6 but were not included in Standard 1.2.7 as they did not to meet the required degree of certainty for establishing the food-health relationship. The aim will be to determine whether or not there is additional evidence that would change the assessment of the relationship.

A proposal would be prepared and public comment sought if changes to the Code were thought to be needed.

5.1.4.3 Self-substantiation of food-health relationships underpinning general level health claims

Food businesses will have the option of self-substantiating food-health relationships underpinning general level health claims providing they comply with requirements set out in Standard 1.2.7.

Standard 1.2.7 requires the person making a claim derived from a self-substantiated food-health relationship to notify the FSANZ Chief Executive Officer of the relationship that has been established between a food or property of food and a health effect) (paragraph 17(4)(b) of Standard 1.2.7). The notified relationship must have been established using a systematic review as outlined in Schedule 6. The person giving this notification must provide their name and the Australian or New Zealand address of that person, and certify that the relationship that has been notified has been established by a process of systematic review as described in Schedule 6 (paragraph 18(1)(a-c) of Standard 1.2.7). If the certificate is provided for a body corporate, the certificate must be signed by a senior officer of that body corporate. Further, if requested by a relevant authority, records must be provided that demonstrate the systematic review was conducted in accordance with the requirements for a systematic review outlined in Schedule 6 (paragraph 18(1)(d) of Standard 1.2.7). Those records must also demonstrate that the notified relationship is a reasonable conclusion of the systematic review.

FSANZ is yet to finalise the administrative arrangements for the notification process. It is proposed that a template form will be provided for food businesses to use. After receiving the information (name of 'person' giving the notice, address of that 'person', established food-health relationship) (refer to clause 18 in Standard 1.2.7), the details would be added to the notification listing. This listing will be available on the FSANZ website. FSANZ's role is limited to administering the notification process. FSANZ will not be considering the merits of food-health relationships notified in this manner.

5.1.4.4 Substantiation of food-health relationships

Substantiation is the process of evaluating the evidence for a food-health relationship. The key objective of the substantiation process is to determine whether the evidence for the relationship between a food or property of food and a health effect is robust and therefore 'established'.

The substantiation process is based on a systematic review of the relevant scientific evidence. This process must be used to determine whether a causal relationship between a food or property of food and the health effect can be established. An outline of this process is provided in SD8. Schedule 6 in Standard 1.2.7 sets out the requirements for establishing a food-health relationship underpinning a general level health claim.

This systematic review process also applies for food businesses making applications for pre-approval of food-health relationships supporting either general or high level health claims.

The key elements of a systematic review for establishing a food-health relationship include:

- describing the food-health relationship (food or property of food and the health effect)
- undertaking a documented search of relevant scientific evidence using identified inclusion and exclusion criteria
- assessing the evidence including consideration of the relevance of the relationship to the Australian and New Zealand populations and an evaluation of the quality of each study
- assessing whether a causal relationship is established between the food or property of food and the health effect based on the totality and weight of evidence giving most weight to high quality studies
- a concluding statement as to whether the relationship between the food or property of food and the health effect is established.

To determine whether a causal relationship between the food or property of food and the health effect is established, consideration needs to be given to the totality and weight of evidence and thus whether the evidence is robust and therefore unlikely to be overturned by another well conducted study.

The degree of certainty required for substantiating food-health relationships underpinning general level health claims will be the same as that proposed at final assessment in 2008. FSANZ also proposed at that time that the degree of certainty required to support general level health claims would be similar to that for high level health claims. This approach is maintained at review. In summary, this means that the degree of certainty required to establish food-health relationships underpinning all health claims will be the same, whether pre-approved or self-substantiated.

The degree of certainty used to establish food-health relationships that support pre-approved health claims in four international jurisdictions (Australia and New Zealand, USA, Canada and EU) is similar and reflects the key elements described above. Further detail is provided in SD8.

Schedule 6 provides the elements that must be included in a systematic review for a self-substantiated food-health relationship underpinning a general level health claim. Food businesses are able to use an existing systematic review provided elements 1 to 6 are applied to any additional relevant scientific data not included in the existing systematic review, and the conclusions from the new scientific data are incorporated with the conclusions from the existing systematic review. FSANZ has considered industry requests to be able to use authoritative sources (e.g. EFSA opinions, Institute of Medicine statements) to establish a food-health relationship and will further consider this issue during the transition period in consultation with all stakeholders.

Guidance for food businesses on the process for a systematic review will be available (refer to section 8.3 for further details on the guidance document).

5.1.4.5 General level health claims about biologically active substances and weight loss/maintenance

In the review request, jurisdictions expressed concern about the possible self-substantiation of general level health claims about biologically active substances and weight loss. In addition, submitters responding to the March 2009 consultation paper expressed concern about including a pre-approved food-health relationship about weight loss in Standard 1.2.7, noting that it would be difficult to substantiate, and could be misleading as no one food can influence weight loss or management. One submitter considered that some formulated meal replacements could be energy dense (high in energy) and therefore blanket approval for these foods to carry weight loss or weight maintenance claims is not appropriate.

FSANZ has pre-approved one weight loss related food-health relationship: energy (property of food) and 'contributes to weight loss or weight maintenance' (specific health effect). This food-health relationship is restricted to use on food products which meet the conditions for making a 'diet' nutrition content claim or for formulated meal replacements, which are intended to be consumed in place of one or two meals per day and could contribute to lower energy intakes, and thus assist in achieving weight loss or weight maintenance. FSANZ considers that the evidence supports consumption of certain foods which can contribute to weight loss or management in the context of a healthy, energy controlled diet and regular exercise.

In response to concerns about formulated meal replacements, FSANZ has set a maximum energy level of 1200 kJ/serving for products carrying a health claim about weight loss or weight maintenance. This is consistent with levels in EU Regulation *96/8/EC Foods intended for use in energy-restricted diets for weight reduction*, and *Codex Standard 181-1991 - Codex standard for formula foods for use in weight control diets*.

Food businesses may choose to self-substantiate food-health relationships underpinning general level health claims about biologically active substances or weight loss/maintenance. If they do so, they will be required to provide on request by an enforcement authority, documentation demonstrating they have undertaken the substantiation process as described in Standard 1.2.7, as for any other self-substantiated food-health relationship. As part of this process, the food business will need to determine whether a causal relationship has been established between the food or property of food and the health effect based on the totality and weight of evidence. The notification process will assist enforcement authorities in identifying possible compliance issues involved with food-businesses self-substantiating these particular food-health relationships.

5.1.4.6 International regulations for health claims

The regulatory approach for health claims in Standard 1.2.7 distinguishes between general level and high level health claims to provide industry with the option of self-substantiating food-health relationships underpinning general level health claims. Other jurisdictions such as the EU, Canada and the USA also distinguish between different types of claims (see SD10). These jurisdictions require pre-approval of claims with the exception of structure/function claims in the USA and non-nutrient function claims in Canada.

5.1.4.7 Stakeholder consultation on self-substantiation and EU approved claims

FSANZ has undertaken targeted consultation on several occasions with key industry, consumer and public health stakeholders and the jurisdictions to seek views on incorporating the requirements for self-substantiation of food-health relationships in Standard 1.2.7 (see Table 1 in section 4.1).

Overall, stakeholders supported the revised drafting and the approach for the consideration of EU approved claims. Most jurisdictions supported the level of detail in the Standard for self-substantiation of a food-health relationship. Public health and consumer stakeholders still favour a pre-approval approach rather than industry self-substantiation, however they accept the provision of self-substantiation in the Standard provided the Standard:

- includes details of a systematic review for self-substantiating a food-health relationship
- is enforceable and enforcing authorities actively monitor claims in the market for compliance with the Standard.

Industry stakeholders generally support the general provisions in the Standard relating to self-substantiation, however, some industry stakeholders consider that requirements for self-substantiation should be less prescriptive and more outcome focussed in the Standard, with the details provided in guidance. In addition, some industry stakeholders asked for authoritative sources to be permitted for self-substantiation of food-health relationships and that FSANZ finalise the incorporation of EU approved health claims in Standard 1.2.7 with some urgency. FSANZ has taken these comments into account in finalising Standard 1.2.7.

5.1.5 Conclusion

In response to the review request and additional requests from the Forum, and after consideration of the requirements of the Act, FSANZ has amended Standard 1.2.7 to permit two pathways for substantiating food-health relationships underpinning general level health claims: either FSANZ pre-approval or industry self-substantiation.

FSANZ considers that providing two pathways for substantiating food-health relationships underpinning general level health claims strikes a balance for the needs of all stakeholders by:

- requiring all claims to be substantiated thereby providing both a level playing field for industry and confidence for consumers
- requiring food businesses to follow the process for a systematic review set out in the Standard when self-substantiating a food-health relationship underpinning a general level health claim, thereby reducing the potential for consumers to be misled
- requiring food businesses to notify FSANZ if they have established a food-health relationship using the self-substantiation process, thereby enhancing consumer confidence in the regulatory system
- providing food businesses with an extensive list of 212 pre-approved food-health relationships for immediate use on gazettal of the new Standard
- supporting industry innovation, confidentiality and flexibility with the launching of new general level health claims on the market using the self-substantiation process, or the use of the ‘high level health claims variation’ procedure provided in the FSANZ Act for applications seeking FSANZ pre-approval of food-health relationships
- FSANZ periodically translating appropriate food-health relationships into the new Standard that are the basis for health claims approved by the EU, USA and Canada, thereby reducing the need for industry to either self-substantiate or prepare applications for new food-health relationships
- not prescribing the wording of health claims
- not placing an unreasonable cost burden on jurisdictions, food businesses or consumers
- having an enforceable Standard.

5.2 Enforcement

5.2.1 Issues raised in review request

There was concern expressed about the enforceability of the Standard. FSANZ sees this issue as falling into two main categories: enforcement generally, and more specifically enforcement of Method 4 (systematic review) of the Scientific Substantiation Framework for general level health claims as proposed at final assessment. Enforcement relating to general level health claims is covered in section 5.1 above.

Comments about enforcement of the Standard generally, included:

- Jurisdictions do not have the tools to check if an individual or company is complying with the Standard as the Standard does not relate to food safety.

- The only available enforcement tool for a breach of the Standard is a prosecution, which is time consuming, expensive, and uncertain.

- The Standard will create incentives for industry non-compliance (which is not the case for food safety standards).

- The Standard is difficult to enforce because it is too complex.

- The Standard poses unique enforcement challenges in terms of evidence because health claims can be made in connection with food, for example, on websites or in brochures.

- Due to the 'home jurisdiction rule', some jurisdictions will incur the majority of enforcement responsibility and cost.

- The Standard will not foster consumer confidence or create a level playing field for industry due to enforcement issues.

5.2.2 Consultation on revised drafting

FSANZ re-drafted Standard 1.2.7 to better achieve intent and to improve clarity and ease of comprehension. The re-drafting focussed on three main areas:

- separation of concepts (so that clauses only dealt with one concept, and similar concepts were grouped together)
- standardisation of provisions (similar provisions repeated throughout the Standard were expressed in similar language)
- simplification and clarification.

The re-drafted Standard was included in the March 2009 consultation paper and comment from submitters on the clarity and ease of enforcement and compliance was sought. These comments were taken into consideration and further amendments to the draft Standard and other standards were made and provided for consultation in February 2012.

In addition, as part of the consultation carried out in February 2012, FSANZ removed provisions relating to dietary information, cause-related marketing and claims about a property of food naturally present or absent in other similar foods. These claims will be regulated as nutrition content claims or health claims as applicable, and/or, potentially by Australian and New Zealand consumer law if they are considered to be misleading.

Most submitters who commented agreed that the revised drafting improved clarity and

reduced ambiguity. Some submitters noted a range of editorial concerns which have been addressed.

Some submitters considered that there would still be enforcement issues because:

- enforcement would still be too resource intensive
- interpretation is likely to differ amongst agencies
- content is essentially not changed so the Standard is still complex
- there is no certainty that claims will be monitored or the Standard enforced (industry).

5.2.3 FSANZ response

While the final version of the Standard is shorter and easier to follow, FSANZ acknowledges that due to the subject matter of the Standard, a level of complexity remains. However, FSANZ has had full regard to the intent of the Policy Guideline and has developed a revised Standard which is enforceable and proportionate.

During the re-drafting process, FSANZ made some minor changes to the Standard in order to improve the workability and enforceability of the Standard, including some minor changes in intent. Refer to SD11 for an outline of these changes. Other more minor editorial and formatting amendments have also been made.

The issues around possible differing interpretation of the Standard across jurisdictions and uncertainty with monitoring and enforcement are not unique to implementation of this Standard. The ISC Health Claims Working Group has considered issues associated with the implementation of the Standard and is developing guidance documents that are expected to be available around the time of gazettal of Standard 1.2.7.

5.2.4 Conclusion

FSANZ has redrafted the Standard to better achieve intent and to improve clarity and ease of comprehension. FSANZ considers the re-drafted Standard, along with implementation guidance from the ISC Health Claims Working Group, will reduce the potential for enforcement issues arising from the new Standard.

5.3 Definition of supplier

5.3.1 Approach at final assessment

FSANZ proposed that the 'supplier' would be required to hold evidence substantiating nutrition content claims and health claims. There were also record keeping requirements that applied to the 'supplier of the food' under the conditions for endorsements. 'Supplier' is defined in Standard 1.1.1 as 'the packer, manufacturer, vendor or importer of the food in question'.

5.3.2 Issues raised in review request

The review request indicated there was a lack of clarity regarding who in the supply chain must hold records for substantiating nutrition content claims and health claims. That is, it was unclear whether the 'supplier of the food' was referring to each person who supplies the food or if it was the supplier who makes the claim. It was thought that if it was the former, this would impose a significant cost burden to industry, and would not provide a means for effective and efficient enforcement. Who should hold records for imported foods was considered to be a key issue.

5.3.3 FSANZ response

The requirement for the supplier to hold the evidence substantiating a nutrition content claim has been removed, as it is considered that there is no applicable evidence that should specifically be required to be held under the new Standard, to substantiate these claims.

In relation to general level health claims, the reference to 'the supplier' has been removed. The Standard now refers to 'the person who is responsible for making the health claim'.

Provisions relating to requirements for suppliers using endorsements have been redrafted. The Standard now specifies that the supplier of food may make or include an endorsement for the food if they comply with the record keeping requirements (and providing the endorsement is not therapeutic in nature and the endorsing body meets certain requirements). Hence it is clear that the recording keeping provisions apply to the supplier making the claim. For imported foods, the Standard specifies that the importer of the food must keep the required records.

5.3.4 Conclusion

References to ‘supplier’ in the Standard have been removed, except in relation to endorsements, where ‘who the supplier is intended to be’, has been clarified. For general level health claims, the Standard now refers to ‘the person who is responsible for making the health claim’.

5.4 Endorsements and endorsing organisations

5.4.1 Approach at final assessment

Standard 1.2.7 stated that requirements relating to a nutrition content claim or health claim would not apply to an endorsement made by an endorsing organisation, if specific conditions were met. The supplier of the food was required to have records demonstrating that the organisation that certified the endorsement is an endorsing organisation as defined in Standard 1.2.7 and these records had to be made available upon request to the relevant authority.

5.4.2 Issues raised in review request

Concerns in the review request in relation to endorsements and endorsing organisations were as follows:

- The exemption from the Standard for an endorsement by any endorsing organisation was inconsistent with the Policy Guideline and would be difficult to enforce or comply with in both practical or resource terms.

- It would be ‘impossible’ to check the credentials of endorsing organisations that are based outside of Australia.

- The definition of endorsing organisation was unclear and inadequate. In particular, the use of the term ‘independence’ in the definition required clarification.

A pre-approval model for endorsements was suggested, whereby there would be an exclusive list of endorsing organisations in the Standard.

5.4.3 Approach proposed in the March 2009 consultation paper

The original intent of the approach at final assessment was retained but the drafting provided in the March 2009 consultation paper was clarified with regards to:

- who must hold the relevant records
- the definitions of ‘endorsement’ and ‘endorsing organisation’ (referred to as ‘endorsing body’ in the 2009 drafting)
- the term ‘independent organisation’ (this was omitted from the definition of endorsing organisation and replaced with the requirement that the endorsing body is not related to the supplier using the endorsement)
- the situation of when an endorsement is placed on a label before importation. The 2009 draft Standard provided 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.

Submitter comments were not sought specifically in relation to the regulation of endorsements.

5.4.4 FSANZ response

The approach at final assessment will be retained. In response to comments in the review request, FSANZ has revised the drafting to clarify the definition of endorsing organisation (now termed 'endorsing body') and also who has to hold the relevant records and for how long. FSANZ considers these changes will support enforcement activities.

The Policy Guideline includes guidance on endorsements as follows*: Endorsement Programs that state or imply a nutrition, health, or related claim must comply with these principles and the requirements of the relevant category of claim. They will require a statement to explain why the endorsement has been granted (e.g. meets nutrient criteria required by the endorsement program).* In drafting the conditions around endorsements, there has been some deviation from the Policy Guideline based on FSANZ consumer research and submitters' comments in response to assessment reports. To force endorsements to comply with all elements of the Standard for the relevant claim would mean some endorsement programs in their current forms would be unable to operate. FSANZ is unaware of any problems with current endorsements and therefore has no justification for imposing such an approach.

5.4.5 Conclusion

In summary, FSANZ has substantially re-drafted the provisions for endorsements, retaining the same intent but providing further clarity. Hence the requirements of the new Standard that relate to a nutrition content claim or health claim will not apply to an endorsement (that is a nutrition content claim or health claim) made by an endorsing body, if specific conditions are met.

5.5 Infant formula products

5.5.1 Approach at final assessment

The intent was that nutrition content claims and health claims on infant formula products (designed for infants under 12 months) would not be subject to Standard 1.2.7 but would be regulated under Standard 2.9.1 – Infant Formula Products. The intent of the drafting of Standard 2.9.1 was that such claims would be prohibited.

5.5.2 Issues raised in review request

There was concern with the clarity of the proposed regulations in prohibiting claims on infant formula products, particularly that the wording of the prohibition in clause 20 of Standard 2.9.1 would not necessarily prohibit nutrition and health claims on infant formula (for example, under clause 20(g), claims could relate to particular health or physiological outcomes rather than targeting a particular condition, disease or disorder). It was considered that the existing labelling provisions in Standard 2.9.1 and in Standard 1.1A.2 – Transitional Standard – Health Claims would still be open to interpretation. It was suggested that consideration be given to a specific exclusion for claims on infant formula in Standard 1.2.7.

5.5.3 FSANZ response

In the Preliminary Final Assessment Report, FSANZ proposed that infant formula products be an ineligible food in draft Standard 1.2.7, and unless permitted by Standard 2.9.1, would be prohibited from making a nutrition content claim or health claim. The drafting was amended in the Final Assessment Report to clarify that the status quo for claims on infant formula products (under Standard 2.9.1) was clearly retained, by excluding infant formula products from regulation under Standard 1.2.7.

FSANZ now understands that the approach taken at final assessment did not clearly prohibit

claims on infant formula products.

As a consequence, Standard 1.2.7 has been amended to prohibit infant formula products from carrying nutrition content and health claims (the approach taken in the Preliminary Final Assessment Report). Therefore, any claims that are not permitted by Standard 2.9.1 will be clearly prohibited.

Since the Final Assessment Report, FSANZ has addressed a drafting issue arising from the labelling provisions in Standard 2.9.1 through Proposal P306 – Addition of Inulin/FOS and GOS to Food. In that Proposal, FSANZ amended clause 20 of Standard 2.9.1 to clarify that the label on a package of infant formula must not contain a reference to the presence of any nutrient or nutritive substance except in the 'nutrition information statement' or statement of ingredients. The 'nutrition information statement' is a single statement which must contain all the nutrition information requirements specified in clause 16 of Standard 2.9.1. This means that other than in the statement of ingredients or nutrition information statement, a reference to a nutrient or nutritive substance elsewhere on the package, such as a nutrition content claim about a particular nutrient, is prohibited.

In 2011, FSANZ received the Policy Guideline for the Regulation of Infant Formula Products. FSANZ intends to review Standard 2.9.1, having regard to this guideline. FSANZ released the Consultation Paper - Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code on 26 September, and submissions closed on 7 November 2012. Information received through this process will inform a proposal to review and revise relevant standards in the Code. Any further issues relating to claims on infant formula products will be considered as a part of that process.

5.5.4 Conclusion

FSANZ has reaffirmed that infant formula products be prohibited from carrying nutrition content and health claims. This does not represent a change in FSANZ's intent in relation to claims on infant formula products which has remained consistent throughout the development of Standard 1.2.7.

5.6 'V' points for fruit juice in the nutrient profiling scoring criterion

5.6.1 Approach at final assessment

Fruit juices, including concentrated juices and purées, which met the definition of 'fruit juice' in Standard 2.6.1 – Fruit Juice and Vegetable Juice, were permitted to score points for their fruit component ('V' points) in the nutrient profiling scoring criterion. This enabled many fruit juices, and some foods containing fruit juice, to meet the nutrient profiling scoring criterion and hence carry health claims.

5.6.2 Issues raised in review request

The review request included a view that because fruit juice could score 'V' points in the nutrient profiling scoring criterion, this would allow a health claim on fruit juice and would promote irresponsible food consumption patterns. It was therefore suggested that fruit juice should be ineligible to carry a health claim.

It was considered that the recommended approach was inconsistent with the Policy Guideline, in particular Policy Principle 4 which states that *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*.

It was noted that the Dietary Guidelines for Australian Children and Adolescents identify the tendency of children to consume high amounts of fruit juices which are of lower nutritional value than whole fruit. Excessive consumption of fruit juice by children is associated with adverse health effects such as failure to thrive, loss of appetite and dental disease.

5.6.3 FSANZ response

In the Final Assessment Report, the decision to allow fruit juice to score V points (and hence pass the nutrient profiling scoring criterion and carry health claims) was based on:

- Australia and New Zealand national dietary advice, which consider fruit juice as fruit, although there are qualifiers. The New Zealand guidelines specify that only one serve of juice can be counted as fruit and the *Australian Guide to Healthy Eating* says 'choose fruit more often than juice'
- the original UK model, which permitted fruit juice to score V points.

The National Health and Medical Research Council (NHMRC) is currently revising the *Australian Guide to Healthy Eating* and the *Australian Dietary Guidelines*. In the draft *Australian Guide to Healthy Eating* released for consultation in December 2011, it was proposed that fruit juice be listed as a fruit alternative, however, it was noted that 125 ml fruit juice should only be used occasionally as a substitute for other fruits. It is anticipated that the revised *Australian Guide to Healthy Eating* and *Australian Dietary Guidelines* will be released in early 2013.

It should be noted that in the Final Assessment Report, there was a further risk mitigating factor that has been maintained in the final Standard. This is that fruit juice (which is eligible to score V points) is defined in Standard 2.6.1 and there are provisions for its composition in this Standard, including the addition of no more than 40 grams of sugar per kilogram of juice. Fruit drinks however, as defined in Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks, may have higher quantities of sugar added, but less fruit juice, and will therefore not score the same number of V points as fruit juice. Fruit drinks are therefore less likely than juices to pass the nutrient profiling scoring criterion.

In the Final Assessment Report, Standard 1.2.7 specified that V points were not permitted to be scored for constituents or extracts of the food, or where the food is no longer present in its typical whole proportion. Although not specifically stated in Standard 1.2.7, it was intended that juice as standardised in Standard 2.6.1 was an exception to this rule. FSANZ has since clarified the wording in the Standard to better reflect the intent.

5.6.4 Conclusion

The approach at final assessment has been reaffirmed, namely that fruit juice meeting the definition of 'fruit juice' in Standard 2.6.1 will be eligible to score V points in the nutrient profiling scoring criterion. This recommendation is based on the inclusion of fruit juice as an alternative to fruit, in Australian and New Zealand dietary guidelines.

5.7 Application of nutrient profiling scoring criterion to foods with nutrition content claims (including 'claimable foods')

5.7.1 Approach at final assessment

Food vehicle eligibility criteria (such as the nutrient profiling scoring criterion) were not applied generically to foods carrying nutrition content claims, although specific eligibility criteria were applied to some, where considered appropriate e.g. the nutrient profiling scoring criterion was applied to foods carrying nutrition content claims about glycaemic index and to claims about energy content using the descriptor 'diet'.

In addition, at final assessment, Standard 1.3.2 was changed to remove the current restrictions around food vehicles permitted to carry vitamin and mineral nutrition content claims ('claimable food' criteria). The effect of this was to allow a broader range of foods to carry vitamin and mineral content claims when the claimed nutrient was present and other criteria were met. This approach was intended to simplify regulation and align this aspect of the regulation of nutrition content claims about vitamins and minerals with other types of nutrition content claims, such as those about fat or dietary fibre.

5.7.2 Issues raised in review request

FSANZ's decision to not apply the nutrient profiling scoring criterion to foods carrying nutrition content claims was not supported because it was considered:

- it was inconsistent with the Policy Guideline (Policy Principles 3 and 4 and the Claims Pre-requisite that discusses the need for social responsibility)
- it encouraged the consumption of energy dense, nutrient poor foods and beverages, which is inconsistent with dietary guidelines and efforts to promote or moderate consumption of certain foods
- FSANZ research was limited by only exploring effects of nutrition content claims for well-known nutrients and not examining effects of nutrition content claims about vitamins and minerals and biologically active substances
- there were inconsistencies between previous research on consumer understanding and current research on consumer behaviour.

Concerns were also expressed about the proposed removal of the 'claimable food' criteria based on the view that there would be nothing to restrict nutrition content claims about vitamins and minerals appearing on a variety of mixed foods such as confectionery and snack foods.

5.7.3 FSANZ response

5.7.3.1 Consumer research on the application of generic eligibility criteria to foods with nutrition content claims

FSANZ research studies

Three consumer research studies were commissioned to specifically investigate the effect of nutrition content claims on consumer purchase intention and nutrition evaluations using Australian and New Zealand consumers (Colmar Brunton Social Research 2008; Roy Morgan Research 2008; Roy Morgan Research 2009). The first two studies were discussed in the Final Assessment Report.

Ministers expressed concern that the 2008 study was limited by exploring the effects of nutrition content claims on consumers' health and nutrition evaluations for only well-known macro-nutrients (fat, sugar and fibre), and for not examining effects of nutrition content claims about vitamins, minerals, and biologically active substances ('micronutrients'). In response, FSANZ designed and commissioned a further major consumer study to answer the key research question: *are consumers' nutrition evaluations and intentions to purchase influenced by micronutrient content claims on foods of 'lower nutritional quality'*?[10] (Roy Morgan Research 2009) (refer to SD2). Before undertaking the study, the design was discussed with the FSANZ Social Sciences Expert Advisory Group.

The study was implemented using an online presentation of mock ice cream, frozen lasagne, fruit drink, and potato chips packages. Each of the four products was presented with either no micronutrient content claim, or one of two micronutrient claims. The results from this study were consistent with the findings from the earlier study on macronutrients. The study found that the nutrition content claims did not enhance nutrition evaluations or affect purchase intentions. The report was peer reviewed by two international social scientists with experience in food choice research.

FSANZ also undertook additional analysis of the micronutrient content claims data set (FSANZ 2011) (see SD3 for the reanalysis report), as was performed for the study into macronutrient content claims (Jolley 2007). The reanalysis leveraged off the peer review of the first content claims study, was assisted by feedback from members of the FSANZ Social Sciences Advisory Group, and was externally peer reviewed. The reanalysis also found that nutrition content claims did not enhance nutrition evaluations or affect purchase intentions.

International literature

FSANZ undertook a review of relevant literature on the effects of nutrition content claims on consumer purchase intention and perception of nutritional value and health benefit published since 2007, the end date for published literature reviewed for the 2008 Final Assessment Report. The review identified national and international studies using various methodologies and is provided at SD4. The review was peer reviewed by two experts in consumer behaviour.

The key finding relevant in this context is that the weight of evidence indicates that nutrition content claims do not appear to significantly enhance purchase intentions on foods which also carry additional nutrition information (such as a nutrition information panel).

The review found that:

- Studies published since 2007 used diverse methodologies which had a strong influence on the research findings. Within methodologies, particular design elements (e.g. stimuli realism, product/claim combinations, presence of other nutrition information and mode of delivery) also influenced whether nutrition content claims were found to have statistically significant effects.

- Importantly, consumers' *perceptions of the overall nutritional value and health benefits* of foods were generally not influenced by the presence of nutrition content claims where nutrition information was available too (e.g. as a nutrition information panel or similar). This included several studies which specifically looked at foods of lower nutritional quality, or included nutrition profile (healthier and less healthy) as a variable.

[10] 'lower nutritional quality' refers to products that do not pass the nutrient profiling scoring criterion

However, studies where nutrition information was not available to participants found that some product/claim combinations enhanced consumers' *perceptions of nutritional value* and *health benefits.*

- Studies examining consumers' *preferences* for foods with and without nutrition content claims found that (with the exception of one product/claim combination) *preferences* for foods increased when they carried a nutrition content claim.

- Only two experiments examined whether nutrition content claims could lead to consumers preferring less healthy foods to healthier foods within a food category. Both of these studies found that even in the presence of a nutrition content claim on a less healthy product, the majority of consumers would still select a healthier product without a nutrition content claim. However, the presence of a nutrition content claim did reduce the size of the majority of participants selecting the healthier product by increasing the proportion of participants selecting the less healthy product.

- Eight studies, in which participants evaluated one product at a time, examined the effect of nutrition content claims on participants' self-reported purchase intentions. These studies found no effect from nutrition content claims when participants were able to access nutrition information about the foods they were evaluating. Those that did not include nutrition information had mixed findings, with some nutrition content claims increasing purchase intention, some reducing purchase intention and one claim having no effect.

- Only one study was able to examine the effects of nutrition content claims on actual *purchases*, although the study had a number of limitations in terms of making generalisations. The study used standardised shelf tags carrying nutrition content claims which were displayed on all microwave popcorn products which met nutrient criteria. The information provided by the standardised labels would have been more salient to shoppers than manufacturer nutrition content claims as the information was displayed next to price information. Shoppers are also likely to have perceived the information as more credible, as it was standardised and not provided by manufacturers. The experiment found that sales of microwave popcorn with particular nutrition content claims increased, while one nutrition content claim (low fat) led to decreases in the sales of popcorn carrying the claim.

  No studies examined whether consumers' *preferences* or *purchases* across food categories would be influenced by the presence of nutrition content claims. In other words, some studies found that nutrition content claims may encourage consumers to purchase a different brand within a food category (such as breakfast cereal), but did not examine whether a nutrition content claim could encourage a consumer to purchase or select from a food category they would otherwise not have.

- Each of the experiments included in the literature review only tested the effects of a small number of attributes on consumers' perceptions of nutritional value and health benefits, preferences, purchase intention or actual purchases. When attributes such as brand, and nutrition profile (healthier or less healthy) were included these tended to have a larger effect on consumers' evaluations or preferences. Additionally, most of the experiments did not include attributes such as brand, price and taste. This is likely to result in larger effect sizes for nutrition content claims than would be the case in a real life shopping environment, where these attributes are present.

Overall, the literature suggests that nutrition content claims do not mislead consumers about the nutritional value or health benefits of foods.

The research is equivocal about the effects of nutrition content claims on consumers' intention to purchase foods, as research findings tend to depend on the methodology used. Studies requiring participants to choose between foods within a food category generally found that the proportion of participants selecting a particular food increases when it carries a nutrition content claim. In contrast, experiments in which participants were randomly assigned to evaluate either a product with a nutrition content claim or to evaluate the same product without a nutrition content claim found that exposure to a claim did not increase participants' purchase intentions. However, some increases in purchase intentions were found where participants were not able to access nutrition information about the product, as they would be able to do in a real life shopping environment in Australia or New Zealand.

The mechanism via which nutrition content claims may influence consumers' purchases or preferences is not clear. Generally, the research studies examined in the literature review did not test hypotheses regarding how nutrition content claims influence purchases or preferences. However, it does not appear that nutrition content claims influence purchases or preferences by enhancing consumers' perceptions of the nutritional value or health benefits of foods. Previous research (Roe et al. 1999) has suggested that nutrition content claims encourage consumers to stop searching for nutrition information earlier than they would in the absence of a claim. However, two studies examined in the literature review tested for this effect and found no difference in information use between participants exposed to a nutrition content claim and those who were not.

5.7.3.2 International regulations

The approach in Standard 1.2.7 is consistent with the approach in Canada, where nutrient profiling is not applied to foods carrying nutrition content claims. However nutrient profiling is proposed in the EU for nutrition content claims (although profiling is not yet in effect and the specifics are yet to be developed), and in the USA, a disclosure statement is required if a food carrying a nutrition content claim contains one or more of specified nutrients at levels that exceed set quantities.

5.7.3.3 Claimable food criteria

As part of the overall approach for regulating nutrition content claims, the 'claimable food' criteria that currently place some restrictions around food vehicles permitted to carry vitamin and mineral nutrition content claims have been removed. This approach allows a broader range of foods to provide information about vitamins and minerals and provides consistency with the regulation of nutrition content claims about other properties whereby such claims are permitted and generic food vehicle eligibility criteria do not apply. Other current restrictions around vitamin and mineral nutrition content claims will, however, continue as follows: foods must contain at least 10% of the relevant reference value of the claimed vitamin or mineral, either from naturally occurring vitamins or minerals, fortification (as per permissions in the Code), or from a fortified food as an ingredient.

5.7.4 Conclusion

After completing additional commissioned research and analysing the relevant studies and information available to date, FSANZ reaffirms that the nutrient profiling scoring criterion will not be generically applied to foods carrying nutrition content claims.

As stated at final assessment, the nutrient profiling scoring criterion will be applied specifically to foods carrying claims about energy content using the 'diet' descriptor and to glycaemic index claims.

FSANZ considered that since 'diet' claims may imply an effect on the body (i.e. weight loss) it was appropriate to require foods carrying such claims to pass the nutrient profiling scoring criterion. In relation to glycaemic index claims, these claims are considered to refer to the effect of a food on blood glucose levels. They are therefore not about the presence or absence of a food property like other nutrition content claims. This requirement also applies to glycaemic load (GL) claims, although this was not made explicit at final assessment. This has been clarified in Standard 1.2.7.

In addition, as stated in the Final Assessment Report, specific disqualifying criteria will be applied to foods carrying certain nutrition content claims (e.g. foods carrying cholesterol claims must meet conditions relating to saturated fat).

FSANZ notes that the Policy Guideline does not specify whether or not food vehicle eligibility criteria should apply to foods carrying nutrition content claims. In June and July 2012, the Forum expressed its support for the application of a nutrient profiling scoring criterion to foods carrying health claims to ensure health claims only appear on healthy foods.

The rationale for not applying the nutrient profiling scoring criterion to foods carrying nutrition content claims is as follows:

- The results of recent consumer studies commissioned by FSANZ (Roy Morgan Research 2008; Roy Morgan Research 2009) found no positive effects of nutrition content claims on the evaluations of foods of 'lower nutritional quality'[11]. These studies also found no positive effect on consumer intention to purchase foods. The FSANZ studies had robust designs and were peer reviewed by domestic and international experts.

- A review of international literature[12] on the effect of nutrition content claims on consumer purchase intention and evaluations of foods revealed few studies exploring foods of lower nutritional quality. Therefore, there is an insufficient evidence base from which to draw definitive conclusions about the possible effect of nutrition content claims on foods of lower nutritional quality on consumer evaluations or purchase intention. However, the weight of evidence indicates that nutrition content claims on foods carrying other nutrition information have limited, if any, influence on behaviour.

- On consideration of all the relevant studies in the literature review (that included both healthy and less healthy foods), to a large extent, the findings were influenced by the methodology and particular design elements used (e.g. stimuli realism, product/claim combinations, presence of other nutrition information, mode of survey delivery) resulting in divergent conclusions. Where a single product was evaluated, the studies suggested that nutrition content claims do not enhance product evaluations or intention to purchase foods when nutrition information is available. In contrast, where study design required a choice between foods in the same category, it was found that nutrition content claims may lead to a positive influence on the expression of preference, however the same studies also showed no effect on evaluations of nutrition or health properties of the food.

[11] 'lower nutritional quality' refers to foods that do not pass the nutrient profiling scoring criterion
[12] The review included studies published since the preparation of the Final Assessment Report in 2008

- The balance of evidence from consumer research studies to date suggests that when nutrition information is available, the presence of nutrition content claims on foods of 'lower nutritional quality' is unlikely to lead to purchases of such products as nutrition and health evaluations are generally unaffected. Therefore, FSANZ's approach is not inconsistent with Policy Principles 3 and 4 in the Policy Guideline.

- The Centre for International Economics (CIE) estimated that 4.7% of foods would be affected if the nutrient profiling scoring criterion was applied to foods carrying fat-free and % fat-free claims, and that this would impose a cost of A$126 million on industry (Attachment 6.3 to SD6). If the nutrient profiling scoring criterion was applied to all foods carrying nutrition content claims, the cost to industry is likely to be considerably higher. CIE notes in its report that under this scenario, the total costs of the Standard are likely to outweigh total benefits.

- Some specific nutrition content claims (e.g. claims about fatty acids, lactose, gluten) are currently regulated by provisions in Standard 1.2.8 – Nutrition Information Requirements and generic food eligibility criteria are not applied. The approach in Standard 1.2.7 is therefore consistent with the current regulatory approach.

- A front-of-pack labelling scheme is currently being developed as an outcome of the independent review of food labelling law and policy (Blewett et al. 2011). Such a scheme may, in the future, have an impact on industry use and consumer understanding of claims.

5.8 Food for infants

5.8.1 Approach at final assessment

In the Final Assessment Report, FSANZ stated that specific nutrition content claim permissions within Standard 2.9.2 – Foods for Infants, would continue to be permitted. Other nutrition content claims and general level health claims would be permitted in accordance with Standard 1.2.7. Because food for infants must already meet certain prescribed compositional requirements in Standard 2.9.2, they would be exempt from the nutrient profiling scoring criterion for making general level health claims.

5.8.2 Issues raised in review request

There was concern that FSANZ had interpreted 'infant foods' or 'baby foods' in the Policy Guideline to mean 'infant formula' (as defined in Standard 2.9.1). It was suggested that infant foods should be prohibited from carrying any claims to avoid exploiting the specific needs of infants.

Under point 1 of Claim Pre-requisites, the Policy Guideline states that *claims can be made providing the eligibility criteria ... (and any excluded categories of foods, such as alcohol and infant foods) are complied with*. Reference to infant foods is also made under 'Additional Guidance', in the context of considering whether exclusions for certain categories of food from making nutrient content claims e.g. infant food should be specifically stated in the standard. Under the Claims Classification Criteria, the guideline also notes: *The standard may also set out ... categories of foods which may be excluded from making claims (e.g. alcohol and baby foods)*.

5.8.3 FSANZ response

The Policy Guideline refers to the terms 'infant foods' and 'baby foods' but does not define either of these terms.

Currently under the Code, nutrition claims are permitted in relation to food for infants. Certain other claims, such as a reference to a disease or physiological condition, are prohibited under Transitional Standard 1.1A.2. Nutrient function claims are not currently expressly prohibited or permitted (a nutrient function claim describes the biological role of a substance in normal growth, development, maintenance and other like functions of the body, for example, 'Iron contributes to normal growth and development'). This Transitional Standard applies to foods for infants in the same way as it applies to other foods, and nutrient function claims are currently not explicitly precluded in relation to foods for infants. FSANZ is not aware of a problem in relation to current use of nutrition content claims on infant foods and considers that nutrition content and health claims could provide useful information about the nutritional needs of infants.

At the international level, Codex allows scope for individual countries/groups to determine their own position in relation to permitting claims on infant foods. The *Guidelines for Use of Nutrition and Health Claims*[13] indicate that nutrition and health claims should not be permitted on foods for infants or young children except as specifically provided for – either in other relevant Codex Standards or under national legislation. The Codex Standard for Processed Cereal Based Foods for Infants and Young Children (Codex Stan 074-1981, Rev 1 – 2006) indicates that nutrition claims may be permitted under national legislation on cereal based foods.

In the USA and Canada, nutrition content claims and general level health claims/structure-function claims are allowed on foods for children under two years old, including infant formula products. The Canadian regulatory system permits a limited number of nutrition content claims on foods for this age group, and does not prohibit general level (structure-function) health claims. In the USA, there is no specific prohibition on nutrition content claims for infant foods. Structure-function claims are not prohibited or required to be notified to the USA Food and Drug Administration, and neither are they provided for via a 'positive list' – hence there is scope to use this type of claim on infant foods in the USA.

Under regulations for the EU there is no specific prohibition in relation to foods for young children. Claims referring to children's development and health are treated in a manner similar to 'reduction of disease risk' claims – and to date have required a positive opinion from EFSA before consideration by the EU. The EU is developing a dedicated list of permitted claims referring to children's development and health (however, the term 'children' has not been defined). FSANZ notes that EFSA has issued opinions in relation to infants. This approach would provide a mechanism for controlling and/or limiting both the number and content of permitted claims. FSANZ's approach to permit food for infants to carry health claims, subject to specific conditions, is therefore consistent with permissions given by those overseas regulatory authorities described above. FSANZ has taken this position throughout the assessment of P293.

5.8.4 Conclusion

FSANZ has reaffirmed the recommendations made in relation to claim permissions for infant foods in the Final Assessment Report, namely that:

- specific nutrition content claim permissions and conditions within Standard 2.9.2 remain in operation
- other nutrition content claims and health claims are permitted in accordance with Standard 1.2.7.

[13] CAC/GL 23-1997, Rev. 2-2008.

FSANZ considers that nutrition content and health claims could provide useful information about the nutritional needs of infants.

5.9 Cost-benefit analysis

In addition to considering the concerns about the cost-benefit analysis in the review request, FSANZ has also investigated the likely effects of the changes to Standard 1.2.7 made during the review, on the cost-benefit analysis. The latter issue is discussed in section 5.9.3.3.

5.9.1 Approach at final assessment

At final assessment, FSANZ commissioned the Centre for International Economics (CIE) to undertake a cost-benefit analysis on the effects of draft Standard 1.2.7, as presented in the Preliminary Final Assessment Report. CIE assessed the effects on consumers and the food industry. FSANZ independently collected data on the effects on government enforcement agencies, which were incorporated into CIE's overall results for Australia and New Zealand. In summary, CIE estimated the combined Australian and New Zealand benefit of the Standard at a net present value of A$95 million. The findings of the cost-benefit analysis formed part of the regulation impact statement (RIS) prepared by FSANZ.

The OBPR accepted FSANZ's RIS at final assessment as adequately meeting the criteria set down by the Council of Australian Governments (COAG) Guidelines.

See Attachments 11.1, 11.2 and 11.3 of the Final Assessment Report for the cost-benefit analysis for Standard 1.2.7[14].

5.9.2 Issues raised in review request

There were two main concerns with the cost-benefit analysis in the review request as follows:

- the inadequacy of the cost estimates for the enforcement of Standard 1.2.7, as the estimates were not based on the Standard at final assessment
- various aspects of the methodology including:
  - omission of the rationale behind government intervention, protection of public health or health inequities
  - the analysis only examining consumers being misinformed about the health attributes of a product leading to reduced consumer satisfaction and not including the protection of public health and safety
  - not taking into account the FSANZ consumer research that nutrition content claims do not influence consumer purchasing behaviour
  - confusion about the fact that nutrition content and health claims are not mandatory
  - confusion about the current prohibition of health claims (other than the claim about folate and the risk of neural tube defects)
  - over-estimation of industry costs.

[14] Refer to the FSANZ website for the cost-benefit analysis: http://www.foodstandards.gov.au/foodstandards/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm

5.9.3 FSANZ response

5.9.3.1 Enforcement costs

In response to concerns that the enforcement costs were not accurate, and because of concerns that the implications of the draft Standard were unclear from the Preliminary Final Assessment Report, FSANZ re-estimated the enforcement costs through consultations with the jurisdictions. In April 2009, FSANZ provided an opportunity for jurisdictions to provide enforcement costs based on the Standard in the Final Assessment Report and Option 2 proposed in the March 2009 consultation paper (pre-market approval of general level health claims). The outcome of this data collection exercise was that the enforcement costs for jurisdictions remained largely unchanged from those provided in the Final Assessment Report.

The enforcement costs are minor in the context of the overall cost-benefit analysis. All available data indicate that even if enforcement costs change significantly, outcomes will only be marginally affected.

5.9.3.2 Issues associated with the methodology used for the cost-benefit analysis

Rationale behind government intervention

Chapter 1 of the cost-benefit analysis (Attachment 11.1 of Final Assessment Report) includes a section on the issue of information asymmetry and the consequent rationale for government action. The main rationale for government intervention for health and nutrition labelling is due to 'asymmetric information flows'. This argument maintains that left to itself, the market will provide more information about positive nutrition and health benefits than negative attributes. Therefore government intervention can help achieve more balanced flows of information enabling consumers to make more informed purchasing decisions.

Cost-benefit analysis restricted to examining consumers being misinformed

FSANZ notes that the original cost-benefit analysis addressed the quantifiable benefits to consumers and evaluated these as a willingness to pay.

To supplement the economic cost-benefit analysis, FSANZ commissioned a health benefit analysis from the Centre for Health Economics Research and Evaluation (CHERE) to illustrate the potential health impacts of product reformulations. The CHERE analysis is illustrative rather than predictive, as it is not possible to accurately estimate the amount of reformulation that might occur when the Standard is gazetted.

CHERE undertook a scenario modelling exercise and focussed on reductions in the intake of two nutrients, sodium from processed foods, and saturated fats. This analysis concluded that if industry was to reformulate products to significantly reduce, for example, sodium levels in the food supply, substantial reductions in the burden of disease could occur for stroke and myocardial infarction. Therefore, the Standard has the potential to facilitate reductions in the burden of disease in Australia and New Zealand (refer to Section 25 of the Final Assessment Report and Attachment 11.2 – CHERE Report of the Final Assessment Report for further details).

Consumer research about nutrition content claims

The cost-benefit analysis included in the Final Assessment Report (refer Attachment 11.1 to the Final Assessment Report) is based on the finding that it is difficult to measure the effect of nutrition content and health claims on consumer purchasing decisions.

The cost-benefit analysis refers to Wonder White bread in relation to the influence of nutrition content claims on consumer purchasing behaviour, which was included in their modelling. This information showed that consumers tend not to make their purchasing decisions purely based on nutrition content claims.

The evidence suggests that consumer purchase decisions are multifaceted and complex. It is difficult to separate out the effect of nutrition content claims on labels in this decision making process. FSANZ's consumer research studies generally suggest that nutrition content claims do not influence intentions to purchase and this is supported by comparable studies in the international literature. The international literature suggests that some claims may influence some purchases, however the nature of the research methodology means that label effects are likely to be overestimated compared with those that would occur in non-experimental conditions (e.g. shopping centres). This is a consequence of other salient factors such as brand, taste, cost and convenience influencing decisions in real-life shopping environments.

Chapter 5 of the cost-benefit analysis contains the sensitivity analysis on the results of the cost-benefit analysis (refer Attachment 11.1 to the Final Assessment Report). The relevant variables that were most sensitive were the number of new products, and the number of products removed. These two variables are also difficult to measure, but despite these uncertainties, the sensitivity analysis indicated that the estimated benefits and costs were fairly robust over a broad range of assumptions.

Nutrition content and health claims are not mandatory

The cost-benefit analysis identified a range of seven market outcomes resulting from implementation of the new Standard, ranging from the introduction of a new product into the market to the removal of an existing product from the market. These outcomes were derived from consultations with representatives from industry that overall accounted for 55 per cent of food sales in Australia. It is expected that outcomes bringing new products into the market will create value and add to the benefits of the community. Outcomes that lead to products being discontinued or taken off the market will increase the costs from implementation of the Standard.

While it appears that all seven market outcomes are not mandatory (as nutrition, health and related claims are not mandatory) in fact not all outcomes would be voluntary. For example, the first two outcomes, i.e. introducing a new product or a new marketing initiative would be undertaken voluntarily by industry to capitalise on the opportunities from the Standard. Outcomes like labelling changes or reformulating existing products, may lead to additional costs for the industry to ensure compliance with the new requirements.

The cost-benefit analysis recognises that some producers will have no choice other than discontinuing their products or incurring costs to avoid non-compliance.

Current prohibition of health claims

The cost-benefit analysis is largely based on industry data and industry perceptions of affected products (input from trans-Tasman producers accounting for about 5 per cent of the total food sales in Australia). The fact that the consultation process identified market outcomes including bringing new products to the market and new marketing initiatives for existing products, suggests that the respondents recognised the opportunity afforded by the new Standard and understood that some health claims are prohibited. However, it is important to note that the current transitional health claims standard does not define 'health claim' so there is currently a lack of clarity around this. There is extensive use of general level type health claims currently in the market.

As the estimates from market outcomes of bringing new products to the market are incorporated into the cost-benefit analysis, the analysis recognises, and is not confused on the issue, that currently all health claims (except neural tube defects and folate) are prohibited. The cost-benefit analysis was also subject to sensitivity analysis in relation to the number of new products and innovation resulting from removing prohibitions on health claims.

Over-estimation of industry costs

The market predictions in the cost-benefit analysis are based on forecasts provided when the consultant surveyed industry on their likely response to Standard 1.2.7 in 2008. The costs of rectifying current non-compliant claims are included as a cost because industry indicated that this would be a response to the introduction of Standard 1.2.7. If the Standard was not introduced there would be no incentive for industry to rectify the issue of non-compliant products. Therefore, it is argued that such costs are in fact, a cost to industry arising out of the introduction of Standard 1.2.7.

5.9.3.3 Regulation impact statement

The only change made to Standard 1.2.7 in response to the review request that is of relevance to the RIS relates to the regulation of general level health claims. As discussed in section 5.1, at final assessment it was proposed that food businesses making general level health claims would self-substantiate the claims by developing and holding the evidence and making that information available on request to enforcement authorities. In response to concerns expressed about the resource and cost burden imposed on jurisdictions in assessing the evidence supporting general level health claims, FSANZ has amended Standard 1.2.7 to also include FSANZ pre-approved food-health relationships. Therefore food businesses will have the option of deriving general level health claims from pre-approved or self-substantiated food-health relationships. Refer to section 5.1.4.3 for details of the self-substantiation pathway.

Updated cost-benefit analysis (2012)

FSANZ has consulted with the OBPR about the change in the regulatory approach for general level health claims. In response to the OBPR's advice, FSANZ has prepared a Review RIS which includes an updated cost-benefit analysis (SD6).

In preparing the Review RIS, FSANZ asked CIE to update the cost-benefit analysis prepared at final assessment in 2008. Its 2012 revision (Attachment 6.1 to SD6), based on Australian Bureau of Statistics (ABS) data, indicated that food consumption had increased by 27 per cent in aggregate value on account of inflation, population and income changes. In dollar terms this amounts to an increase from A$68 billion in 2008 to A$86 billion in 2010–11. However, once inflation on account of costs and prices are discounted, food consumption, in volume terms, was estimated to have increased by only 8.5 per cent.

CIE also found that costs, prices and profit margins for the food industry have changed during the period under review. These changes were accounted for by using the Labour Price Index and Material Input Price Index. According to the ABS, labour rates have increased by 21 per cent and other material costs by 16 per cent. As a result, profit margins for the food industry have declined from 8.2–7.3 per cent.

CIE applied the new data to its original seven possible market outcomes arising from the Standard 1.2.7. The outcome is that benefits to both producers and consumers have declined since the 2008 cost-benefit analysis.

Overall benefits from new products and new marketing initiatives were estimated to have risen from A$280.7 million to A$326.1 million, while costs applying to label changes, reformulations and removals, have increased from A$192.8 million to A$246.3 million.

CIE's findings are that with costs increasing at a greater rate than benefits, net benefits have declined in their model from A$87.9 million in 2008 to A$79.8 million in 2012. Including benefits arising in New Zealand and deducting enforcement costs, the overall net benefit has declined from A$94.7 million in 2008 to A$83.8 million for 2012 at net present value.

In response to industry comments on the FSANZ pre-approval approach for general level health claims that was proposed in February 2012, FSANZ commissioned CIE to undertake sensitivity analyses around the costs of expedited applications and possible applications arising from health claims currently in the market not being underpinned by food-health relationships in Standard 1.2.7. In addition, the benefits arising from extending the transition period were estimated. Outcomes from various scenarios are at Attachment 6.2 to SD6. Overall, CIE determined from the sensitivity analysis that only a very skewed or extreme set of factors, that are not currently anticipated, could result in a net cost arising out of the introduction of Standard 1.2.7. CIE also estimated that the extension of the transition period from two to three years could result in the updated net present value benefit of A$83.8 million increasing to A$117 million.

Regulation impact statement (2012)

The RIS takes into consideration the changes made at review with regard to the regulatory approach for general level health claims (SD6).

The RIS includes consideration of three regulatory options for general level health claims:

- **Option 1**: Self-substantiation of food-health relationships as recommended at final assessment

- **Option 2**: FSANZ pre-approval of food-health relationships

- **Option 3**: FSANZ pre-approval of food-health relationships plus industry self-substantiation.

The status quo was not considered as an option as a clear benefit is likely to be achieved under all the regulatory options. This has been demonstrated in the original RIS undertaken for P293.

Overall, FSANZ considers that the change from industry self-substantiation of general level health claims proposed at final assessment to FSANZ pre-approval of food-health relationships plus industry self-substantiation at review, is likely to increase the aggregate benefit accruing to industry, jurisdictions, and consumers because:

- Those food businesses that have the capacity to undertake the systematic review process needed to self-substantiate will have the flexibility to use this option. Other food businesses, particularly small to medium enterprises (SMEs) will benefit substantially from being able to derive general level health claims from pre-approved food-health relationships.

- Industry will also benefit from the revised application process for approval of new food-health relationships which enables assessment without public notification (unless the applicants request public consultation), allowing first to market advantage.

- Where food businesses seek to have a new food-health relationship approved by FSANZ through a paid application, because this option remains voluntary, they may incur commensurate costs. Substantiation requirements will be set out in the FSANZ *Application Handbook* and will be comparable to those proposed at final assessment.

- Jurisdictions will not be burdened with the costs of assessing science supporting the food-health relationships which are pre-approved by FSANZ. Hence the cost burden for jurisdictions will be reduced compared with what prevailed at final assessment.

- Consumers may have increased confidence arising from the certainty that some health claims are underpinned by pre-approved food-health relationships. Consumers may also gain some benefit from the increased incentive industry may have to innovate in pursuing the self-substantiation approach. Concerns with the possibility that claims may be based on self-substantiated food-health relationships not supported by adequate science have been ameliorated via requirements in the Standard for food businesses to notify FSANZ before any marketing activity. In addition, FSANZ will be providing guidance on substantiation requirements.

5.9.4 Conclusion

Because of the time between the completion of the Final Assessment Report in 2008 and the finalisation of the review in 2012, a re-examination of the cost-benefit outcomes, as well as the data and assumptions on which they were based has been deemed necessary. Industry consultation has occurred throughout the review, and submissions have been taken into consideration by both CIE and FSANZ. Industry concerns have largely centred around the cost of the application process, the effect of the requirements in the Standard on existing claims in the market and a perception that in option 2, moving from self-substantiation to pre-approval would result in the substantiation bar being raised. These concerns have been addressed by retaining self-substantiation and introducing pre-approval at review.

In summary, with the addition of FSANZ pre-approved food-health relationships to Standard 1.2.7, thereby enabling industry to be able to derive general level health claims from either self-substantiated or pre-approved food-health relationships, and the extension of the transition period to three years, the overall net benefit of Standard 1.2.7 is likely to be more favourable than that estimated for the Standard when food-health relationships could only be self-substantiated. While combining self-substantiation with FSANZ pre-approved food-health relationships may not maximise the benefits to all individual stakeholders, it endeavours to maximise the net benefit to the community without seriously disadvantaging any one stakeholder group.

5.10 Nutrition information panel data

5.10.1 Approach at final assessment

At final assessment, Standard 1.2.8 required that the nutrition information panel must include the name and average quantity of any nutrient or biologically active substance in respect of which a nutrition content claim or health claim is made. In addition, if a property such as dietary fibre or calcium is relied on for the food to meet the nutrient profiling scoring criterion, Standard 1.2.7 required the average quantity of that property to be declared in the nutrition information panel.

5.10.2 Issues raised in review request

The review request indicated concern that values in the nutrition information panel may not be sufficiently accurate. It was noted that if inaccurate values were used for the nutrient profiling scoring criterion and/or the qualifying criteria for nutrition content claims and health claims, then there would be the potential for inaccurate outcomes for claims. Enforcement of nutrition content and health claims would therefore be difficult.

In addition, it was considered that there may be scope for food businesses to manipulate values in the nutrition information panel to facilitate the passing of these products through the nutrient profiling scoring criterion. It was suggested that the accuracy of nutrition information panels should be considered when the Standard is reviewed.

5.10.3 FSANZ response

FSANZ has determined that the comments on the accuracy of nutrition information panel values cannot be addressed as part of the review. Nutrition information panel accuracy, compliance and monitoring could be considered by the enforcing authorities.

5.10.4 Conclusion

It is suggested that the issue of nutrition information panel accuracy, compliance and monitoring is considered by the enforcing authorities.

6 Regulatory approach for ‘fat-free’ and ‘% fat-free’ claims

At its meeting in December 2011, the Forum asked FSANZ to further consider the regulation of fat-free and % fat-free claims due to a concern about the potential for consumers to be misled by these types of claims.

In response to this request, FSANZ released a consultation paper in February 2012 seeking comments on three options:

- status quo (regulation of % fat-free claims as proposed in the Final Assessment Report)
- voluntary action through a code of practice
- additional regulation (approaches presented were prohibition of fat-free and % fat-free claims via the application of the nutrition profiling scoring criterion, a sugar concentration threshold or definition of specific food categories, or the use of a disclosure statement on foods above a sugar concentration threshold).

Many submitters supported status quo (industry and some jurisdictions), a similar number supported additional regulation (public health stakeholders, consumers and some jurisdictions) and some submitters supported voluntary action through a code of practice (industry).

Key reasons given by submitters for supporting the status quo included the lack of evidence of a problem, possible inconsistency with considering fat-free and % fat-free claims and not other fat-related claims such as ‘low-fat’, a voluntary action by confectionery manufacturers to remove fat-free claims from over 80% of the current confectionery market, and that front-of-pack labelling currently under development may affect industry use and consumer understanding of the claims.

In contrast, key reasons provided by submitters for supporting additional regulation included reference to evidence that suggests 'fat-free' claims on 'less healthy' foods are misleading and a general desire for additional regulation of all foods carrying nutrition content claims.

FSANZ commissioned a literature review on consumer use and understanding of fat-free claims on foods of 'lower nutritional quality' (Attachment 5.1 to SD5). This review of the peer-reviewed literature revealed very few studies directly relevant to any of the research questions.

While the literature review indicated that % fat-free claims are capable of influencing consumer perception of the healthiness or energy content of foods, there was very little evidence of consumers being misled from fat-free claims on foods of 'lower nutritional quality'. There are no reported studies investigating the effect of fat-free claims on consumer purchase behaviour in relation to high sugar foods or on whether fat-free claims cause substitution behaviour whereby consumers may purchase foods of lower nutritional quality in place of foods of higher nutritional quality.

FSANZ also commissioned a report on the effect of additional regulation of fat-free claims on the cost-benefit analysis prepared in 2008 at final assessment (Attachment 6.3 to SD6). It was found that the effect depends on the approach taken. If a 30% sugar concentration threshold was applied to require a disclosure statement, it was estimated that the net benefit of Standard 1.2.7 would decline by A$5 million. If claims on foods beyond the 30% sugar concentration were prohibited, costs could rise to around A$52 million should industry make changes other than label changes, such as reformulation or product deletion. If foods not meeting the nutrient profiling scoring criterion were prohibited from carrying fat-free claims, it was estimated that costs to industry would be around A$126 million, resulting in an overall net cost to the community on implementation of the Standard.

After evaluating all available information and submissions received, FSANZ concluded that there be no additional regulatory provisions for 'fat-free' and '% fat-free' claims at this time because:

- There is a lack of evidence consumers are misled as few studies about the effect of fat-free claims on consumer purchase decisions have been reported. This is further supported by the findings from the literature review on nutrition content claims (section 5.7) which found that the weight of evidence indicates consumers are unlikely to be misled by nutrition content claims.

- Consideration of additional regulation for only selected fat-related claims could result in an inconsistent approach to the regulation of nutrition content claims. All proposed regulatory approaches present technical implementation difficulties and unintended consequences for certain products.

- CIE's evaluation of the effect of additional regulation using 2012 industry data, on the cost-benefit analysis prepared in 2008 indicates that the regulatory approach most favoured by those who supported additional regulation, the application of the nutrient profiling scoring criterion, would result in significant costs for industry that would lead to an overall net loss on implementation of Standard 1.2.7.

- A front-of-pack labelling scheme is currently being developed as part of the government's response to the independent review of food labelling law and policy (Blewett et al. 2011). If a decision is made to proceed with such a scheme it may have an effect on industry use and consumer understanding of claims, and address the concern that has been raised.

- As of October 2012, the Australian Industry Group (AIG) for the confectionery sector advised FSANZ that the industry's major players have agreed to voluntarily remove fat-free and % fat free claims from high sugar, high energy confectionery products that do not normally contain significant levels of fat, in early 2014. AIG noted that labelling changes have already commenced and will gradually filter into the marketplace. A delay in considering further regulation will allow industry time to implement this voluntary initiative and for government to then evaluate whether further regulatory action is warranted.

In summary, FSANZ has considered the issue of 'fat-free' and '% fat-free' claims and concluded there is not sufficient cause, at this time, to further regulate these claims. Given the forthcoming industry voluntary action, front-of-pack labelling and implementation of Standard 1.2.7 as a whole, FSANZ proposes that the regulation of fat-free and % fat-free claims should be included in the post-implementation review of the nutrition, health and related claims system that is foreshadowed in the Policy Guideline.

Refer to SD5 for further discussion of this issue.

7 Options

The following three options were available for the FSANZ Board to consider in response to the review request:

1. To re-affirm the approval of the draft Standard.
2. To re-affirm the approval of the draft Standard, subject to such amendments as FSANZ considers necessary.
3. To withdraw the approval of the draft Standard.

In responding to the review request and the issues raised during consultation, FSANZ has had regard to the three objectives in subsection 18(1) of the FSANZ Act during this review.

7.1 Protection of public health and safety

Standard 1.2.7 will provide an expanded regulatory framework for industry to voluntarily use nutrition content and health claims on food labels and in advertisements. The regulatory framework is intended to be consistent with broad public health messages. Consideration was given to dietary guidelines together with all available evidence and information throughout the development of Standard 1.2.7. The application of the nutrient profiling scoring criterion to foods with health claims will restrict the use of health claims to those foods considered to be 'healthier'. Compared with the current lack of clarity around permissions for general level health type claims under the Transitional Standard 1.1A.2, Standard 1.2.7 will provide certainty for health claim permissions that is likely to lead to a greater range of foods with health claims, thereby potentially broadening consumer choice of healthier foods.

7.2 The provision of adequate information relating to food to enable consumers to make informed choices

Standard 1.2.7 will enable consumers to have information on nutrition content and health claims on food at point of sale or in advertising, thereby having the ability to make informed purchasing decisions. Consideration has been given to specific regulatory requirements that assist consumers to make more informed choices and several provisions are included in the Standard. For example, a comparative claim (e.g. 'increased', 'lite') must identify the reference food, and for health claims a statement about the dietary context must be included.

7.3 The prevention of misleading or deceptive conduct

A number of requirements in Standard 1.2.7 will mitigate the possibility of consumers being misled by nutrition content and health claims. These requirements include conditions for making nutrition content and health claims, the need for all health claims to be substantiated, requirements for dietary context statements in association with health claims, and the application of the nutrient profiling scoring criterion to foods with health claims.

7.4 Subsection 18(2) consideration

As summarised below and detailed elsewhere in this Review Report, FSANZ has also had regard to the matters set out in subsection 18(2) of the FSANZ Act:

- *the need for standards to be based on risk analysis using the best available scientific evidence*

  P293 was assessed using the best scientific evidence available internationally. To support the analysis, FSANZ commissioned a number of further studies during the review including:

  - literature review on the effect of nutrition content claims on consumer choice and nutritional or health evaluations of foods (SD4)
  - literature review on the effects on consumer behaviour of fat-free nutrition content claims on high sugar foods (Attachment 5.1)
  - consumer research study on the effect of nutrition content claims about vitamins, minerals and biologically active substances on consumer behaviour (Roy Morgan 2009) (SD2).

  Other studies, commissioned to support the preparation of the draft Standard at final assessment, were included in the Final Assessment Report.

- *the promotion of consistency between domestic and international food standards*

  International food standards have been taken into account during development of Standard 1.2.7. The regulatory requirements for nutrition content and health claims in Standard 1.2.7 are not inconsistent with those in the EU, USA and Canada. There are many similarities with regulations in the EU, USA and Canada particularly for nutrition content claims and health claims referring to disease risk reduction.

- *the desirability of an efficient and internationally competitive food industry*

  Standard 1.2.7 is not expected to have a negative impact on the efficiency or international competitiveness of the food industry. There is a possibility that Standard 1.2.7 will enable some Australian and New Zealand food businesses to more easily export foods carrying health claims to international markets.

- *the promotion of fair trading in food*

  Standard 1.2.7 is not expected to have any negative impact on fair trading in food.

- *any written policy guidelines formulated by the Ministerial Council*

  In making the amendments to Standard 1.2.7, FSANZ has had regard to the Ministerial *Policy Guideline on Nutrition, Health and Related Claims.*

7.5 Section 59 considerations

In responding to the review request and issues raised during subsequent consultation, the Board also had regard to subsection 59(1) of the FSANZ Act. That subsection prescribes certain matters that FSANZ must have regard to when assessing a proposal. The subsection does not apply to assessments undertaken for the purposes of a review under section 87 of the FSANZ Act. However, it is open to the Board to have regard to these matters as relevant when undertaking such a review.

(a) Paragraph 59(2)(a) requires FSANZ to have regard to whether costs that would arise from a food regulatory measure developed or varied as a result of the Standard outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

This matter is considered in section 5.9 above.

(b) Paragraph 59(2)(b) of the FSANZ Act requires FSANZ to have regard to whether other measures (available to FSANZ or not) would be more cost-effective.

This matter was considered at final assessment (refer to sections 6 to 9 in the Final Assessment Report). Nothing raised during the review warrants a change in FSANZ's position on this issue.

(c) Paragraph 59(2)(c) requires FSANZ to consider any relevant New Zealand standards.

There is no relevant New Zealand standard.

(d) Paragraph 59(2)(d) requires FSANZ to consider any other relevant matter.

Other relevant matters have been considered.

8 Decision

The FSANZ Board re-affirmed the approval of Standard 1.2.7 and variations to Standards 1.1.1, 1.2.8, 1.3.2, 2.6.2, 2.6.4, 2.9.2, 2.9.3 and 2.10.2, subject to amendments to these Standards.

The FSANZ Board re-affirmed the approval of variations to Standard 2.9.4.

The Board also approved consequential amendments to Standards 1.1A.2, 1.2.1, 2.9.1, and 2.9.5.

The approved Standard 1.2.7 and variations to Standards 1.1A.2, 1.1.1, 1.2.1, 1.2.8, 1.3.2, 2.6.2, 2.6.4, 2.9.1, 2.9.2, 2.9.3, 2.9.4, 2.9.5, 2.10.2 are at Attachment A and the Explanatory Statements are at Attachment B.

8.1 Reasons for decision

The reasons for the FSANZ Board's decision are detailed in this Review Report and include the following:

- The Standard provides regulatory certainty for industry, enforcement agencies and consumers.

- Consumers can have confidence that health claims are well supported by scientific evidence.

- Consumers have information on nutrition content and health claims on food at point of sale or in advertising, thereby having the ability to make informed purchasing decisions.

- The potential to mislead consumers under the current regulatory arrangements, either through non-regulated nutrition content claims or lack of clarity around permissions for health claims is mitigated, as these issues are addressed in the Standard.

- The Standard supports industry innovation and marketing strategies by providing pre-approved food-health relationships and also allowing industry to self-substantiate food-health relationships underpinning general level health claims.

- The Standard resolves ambiguities and limitations under current regulatory arrangements and facilitates effective action by enforcement agencies.

- The regulation impact statement indicates that the Standard will deliver an incremental improvement in the economic welfare of Australia and New Zealand.

- The Standard is broadly consistent with comparable arrangements internationally.

- The Ministerial Policy Guideline and national dietary guidelines have been taken into account during the development of the Standard.

8.2 Transitional arrangements

There will be a three-year transition period for Standard 1.2.7, with no additional stock-in-trade period.

This means that on gazettal of Standard 1.2.7, for a period of three years, food businesses will be able to choose to comply with either the new Standard and other standards that have been amended as a consequence of the implementation of Standard 1.2.7 (for example Standard 1.2.8 – Nutrition Information Requirements and Standard 1.3.2 – Vitamins and Minerals) or comply with the Standard 1.1A.1 – Transitional Standard – Health Claims, together with other standards (such as Standard 1.2.8 and 1.3.2) as they were before the gazettal of Standard 1.2.7.

As noted previously in this report, FSANZ anticipates undertaking further work in a number of areas during the transition period including:

- establishing the High Level Health Claims Committee
- developing and implementing a process to maintain the scientific currency of pre-approved food-health relationships, including consideration of those food-health relationships evaluated by FSANZ in 2005-06
- considering of the use of authoritative sources for self-substantiation of food-health relationships underpinning general level health claims
- completing the consideration of food-health relationships from EU approved claims (as of October 2012) for possible inclusion in Standard 1.2.7 (both general and high level claims)
- on-going monitoring for new health claims approved in Canada, USA and the EU.

During the latter part of the review, some industry stakeholders asked FSANZ to further consider three additional issues:

- the nutrient profiling scoring criterion in light of developments that might arise from the proposed use of the scoring criterion for front-of-pack labelling
- possible exemption of certain foods carrying health claims from meeting the nutrient profiling scoring criterion
- qualifying criteria for nutrition content claims about dietary fibre, as the qualifying criteria in Standard 1.2.7 are higher than those in the Code of Practice on Nutrient Claims.

FSANZ intends to consider these issues during the transition period.

8.3 Implementation and review

The Standard takes effect on gazettal.

ISC is developing guidance documents to support the implementation of the new Standard and expects to have these documents available upon, or soon after, gazettal of Standard 1.2.7.

FSANZ is developing guidance on the substantiation process for food businesses either self-substantiating food-health relationships underpinning general level health claims, or making applications to FSANZ seeking approval of new food-health relationships. The FSANZ guidance document will be based on similar documents from national and international scientific bodies and regulatory agencies, and will include information on conducting best practice systematic reviews.

As of October 2012, FSANZ envisages the following topics could be included in a guidance document:

- background on purpose and guiding principles for substantiation
- documentation format
- desirability of a suitably qualified person(s) to conduct the substantiation process
- 'how-to' information for each of the elements in the substantiation process, including assessment of the quality of studies and the weight of evidence
- desirability of seeking an independent review of the documentation
- a worked example of updating an existing systematic review based on the requirements in Schedule 6
- consideration of whether proposed claims may be contrary to public health initiatives
- suggested approach for the consideration of applicable population group and dietary context
- suggested approach for determining amount of the food or property of the food, that is the subject of the claim, that should be present in foods carrying the claim.

FSANZ anticipates undertaking targeted consultation on a draft guidance document in November 2012 and finalising the document around the time the Standard is likely to be gazetted.

As noted at final assessment, the Ministerial Policy Guideline foreshadows a review of the nutrition, health and related claims system two years following the implementation of the Standard.

9 References

Blewett N, Goddard N, Pettigrew S, Reynolds C, Yeatman H (2011) Labelling logic. A review of food labelling law and policy (2011). Canberra: Commonwealth of Australia.

Colmar Brunton Social Research (2008) Consumer use of nutrition content claims in shopping environments. Report prepared for Food Standards Australia New Zealand. Canberra: Colmar Brunton Social Research. Accessed on 18 November 2011.
http://www.foodstandards.gov.au/_srcfiles/Instore%20Use%20of%20Nutrit.pdf

FSANZ (2011) FSANZ reanalysis: Consumers and nutrition content claims. A study of responses to vitamin, mineral and other claims. Canberra: FSANZ.

Jolley, D (2007) Re-analysis of quantitative data on consumer responses to nutrition content claims: Final report. Report prepared for Food Standards Australia New Zealand. Clayton: Monash Institute of Health Services Research. Accessed on 18 November 2011.
http://www.foodstandards.gov.au/_srcfiles/Reanalysis%20of%20Nutriti.pdf

Roe B, Levy AS, Derby BM (1999) The impact of health claims on consumer search and product evaluation outcomes: Results from FDA experimental data. Journal of Public Policy & Marketing 18(1):89–105.

Roy Morgan Research (2008) An investigation into the impact of nutrition content claims on packaging in relation to consumer purchase intention, nutrition attitude and health benefit. Report prepared for Food Standards Australia New Zealand. Brisbane: Roy Morgan Research. Accessed on 18 November 2011.
http://www.foodstandards.gov.au/_srcfiles/P293_Attach_10_2_RMR.pdf

Roy Morgan Research (2009) Consumers and nutrition content claims. A study of responses to vitamin, mineral and other claims. Report prepared for Food Standards Australia New Zealand. Brisbane: Roy Morgan Research.

Attachments

A. Approved variations to the *Australia New Zealand Food Standards Code*
B. Explanatory Statements

Attachment A – Approved variations to the *Australia New Zealand Food Standards Code*

Standard 1.2.7 – Nutrition, Health and Related Claims

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on gazettal.

Dated XXXX

[Signature to be inserted]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

STANDARD 1.2.7

NUTRITION, HEALTH AND RELATED CLAIMS

Table of Provisions

Part 1 – Purpose and interpretation
1 Purpose
2 Interpretation
Part 2 – Claims framework and general principles
3 Nutrition content claims or health claims not to be made about certain foods
4 Standard does not apply to certain foods
5 Standard does not apply to certain claims and declarations
6 Form of food to which provisions of this Standard apply
7 Claims not to be therapeutic in nature
8 Claims not to compare vitamin or mineral content
9 Standard does not prescribe words
Part 3 – Requirements for nutrition content claims and health claims
Division 1 – Nutrition content claims
10 Presentation of nutrition content claims
11 Nutrition content claims about properties of food in Schedule 1
12 Nutrition content claims about properties of food not in Schedule 1
13 Nutrition content claims about choline, fluoride or folic acid
14 Nutrition content claims must not imply slimming effects
15 Comparative claims
Division 2 – Health claims
16 Application or proposal to vary Schedule 3 taken to be a high level health claims variation
17 Conditions for making health claims
18 Requirement when making a general level health claim under paragraph 17(4)(b)
19 How health claims are to be made
20 Split health claims
21 Statements for claims about phytosterols, phytostanols and their esters
Division 3 – Endorsements
22 Endorsing bodies
23 Criteria for endorsements
Division 4 – Additional labelling of food required to meet the NPSC
24 Method for calculating a nutrient profiling score
25 Labelling of food required to meet the NPSC
26 Labelling exemptions for certain foods

Schedule 1 Conditions for nutrition content claims
Schedule 2 Conditions for permitted high level health claims
Schedule 3 Conditions for permitted general level health claims
Schedule 4 Nutrient profiling scoring criterion
Schedule 5 Nutrient profiling scoring method
Schedule 6 Process of systematic review

Part 1 – Purpose and interpretation

Editorial Note:

Standard 1.1A.2 is a transitional standard that operates concurrently with this Standard 1.2.7 for a period of three years. During the three-year period Standard 1.1A.2 operates unchanged by this Standard and related variations made by the *Food Standards (Proposal P293 – Nutrition, Health & Related Claims – Consequential) Variation*. A supplier can rely on this Standard or Standard 1.1A.2, but not both. At the end of the three-year period, Standard 1.1A.2 will cease to operate. There is no stock-in-trade period at the end of the three-year period.

1 Purpose

This Standard –

(a) sets out the claims that can be made on labels or in advertisements about the nutritional content of food (described as nutrition content claims) and the claims that can be made on labels or in advertisements about the relationship between a food or a property of a food, and a health effect (described as health claims); and
(b) describes the conditions under which such claims can be made, and
(c) describes the circumstances in which endorsements can be provided on labels or in advertisements.

2 Interpretation

In this Standard –

average energy content is as defined in Standard 1.2.8.

biologically active substance is as defined in Standard 1.2.8.

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.

carbohydrate is as defined in Standard 1.2.8.

dietary fibre is as defined in Standard 1.2.8.

endorsement means a nutrition content claim or a health claim that is made with the permission of an endorsing body.

endorsing body is a not-for-profit entity which has a nutrition- or health-related purpose or function that permits a supplier to make an endorsement.

fat is as defined in Standard 1.2.8.

food group means any of the following groups –

(a) bread (both leavened or unleavened), grains, rice, pasta and noodles;
(b) fruit, vegetables, herbs, spices and fungi;
(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;
(d) meat, fish, eggs, nuts, seeds and dried legumes;
(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, legumes and seeds.

fvnl is as defined in item 4 of Schedule 5 for the purpose of calculating V points.

general level health claim means a health claim that is not a high level health claim.

gluten means the main protein in wheat, rye, oats, barley, triticale and spelt relevant to the medical conditions coeliac disease and dermatitis herpetiformis.

glycaemic index (GI) means a measure of the blood glucose raising ability of the digestible carbohydrates in a given food as determined by a recognised scientific method.

Editorial note:

A 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.

health claim means a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect.

Editorial note:

For the definition of claim, see clause 2 of Standard 1.1.1.

health effect means an effect on the human body, including an effect on one or more of the following –

(a) a biochemical process or outcome;
(b) a physiological process or outcome;
(c) a functional process or outcome;
(d) growth and development;
(e) physical performance;
(f) mental performance;
(g) a disease, disorder or condition.

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

meets the NPSC means that the nutrient profiling score of a food described in Column 1 of Schedule 4 is less than the number specified for that food in Column 2 of that Schedule.

monounsaturated fatty acids is as defined in Standard 1.2.8.

NPSC means the nutrient profiling scoring criterion.

nutrient profiling score means the final score calculated pursuant to the method described in Schedule 5.

nutrition content claim means a claim about –

(a) the presence or absence of –

(i) a biologically active substance; or
(ii) dietary fibre; or
(iii) energy; or
(iv) minerals; or
(v) potassium; or
(vi) protein; or
(vii) carbohydrate; or
(viii) fat; or

(ix) the components of any one of protein, carbohydrate or fat; or
(x) salt; or
(xi) sodium; or
(xii) vitamins; or

(b) glycaemic index or glycaemic load;

that does not refer to the presence or absence of alcohol, and is not a health claim.

Editorial note:

For the definition of claim, see clause 2 of Standard 1.1.1.

polyunsaturated fatty acids is as defined in Standard 1.2.8.

property of food means a component, ingredient, constituent or other feature of food.

reference food means a food that is –

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

Editorial note:

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

salt is as defined in Standard 2.10.2.

saturated fatty acids is as defined in Standard 1.2.8.

serious disease means a disease, disorder or condition which is generally diagnosed, treated or managed in consultation with or with supervision by a health care professional.

small package is as defined in Standard 1.2.1.

sugars is as defined in Standard 1.2.8.

trans fatty acids is as defined in Standard 1.2.8.

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 legumes (including dried legumes that have been cooked or rehydrated) and seeds.

Part 2 – Claims framework and general principles

3 Nutrition content claims or health claims not to be made about certain foods

A nutrition content claim or health claim must not be made about –

(a) kava; or
(b) a food that contains more than 1.15% alcohol by volume, other than a nutrition content claim about energy content or carbohydrate content; or
(c) an infant formula product.

Editorial note:

Kava is standardised in Standard 2.6.3.

Infant formula product is standardised in Standard 2.9.1.

4 Standard does not apply to certain foods

This Standard does not apply to food that is –

(a) intended for further processing, packaging or labelling prior to retail sale; or
(b) delivered to a vulnerable person by a delivered meal organisation; or
(c) provided to a patient in a hospital or other similar institution, other than food in a package.

Editorial Note:

The facilities that are 'other similar institutions' are described in the table to clause 8 of Standard 1.2.1.

5 Standard does not apply to certain claims or declarations

This Standard does not apply to –

(a) a claim that is expressly permitted by another Standard in this Code; or
(b) a claim about the risks or dangers of alcohol consumption or about moderating alcohol intake; or
(c) a declaration that is required by the Act.

6 Form of food to which provisions of this Standard apply

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

Table to clause 6

Form of the food
The food as sold if the food can be either prepared with other food or consumed as sold.
The food as prepared if the food is required to be prepared and consumed according to directions.
The food after it is reconstituted with water and ready for consumption if the food requires reconstituting with water.
The food after it is drained and ready for consumption if the food requires draining before consuming.

Editorial note:

Clause 11A of Standard 1.2.8 provides additional nutrition information panel (NIP) requirements where a claim is based on food as prepared.

7 Claims not to be therapeutic in nature

A claim must not –

(a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or
(b) compare a food with a good that is –

(i) represented in any way to be for therapeutic use; or
(ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.

8 Claims not to compare vitamin or 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 the claim is permitted by another Standard in this Code.

9 Standard does not prescribe words

(1) Nothing in this Standard is to be taken to prescribe the words that must be used when making a claim.

(2) Any statement or information required by this Standard may be modified if the modification does not alter or contradict the effect of the required statement or information.

Part 3 – Requirements for nutrition content claims and health claims

Division 1 – Nutrition content claims

10 Presentation of nutrition content claims

A nutrition content claim must be stated together with a statement about the form of the food to which the claim relates, unless the form of the food to which the claim relates is the food as sold.

11 Nutrition content claims about properties of food in Schedule 1

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

(2) If a claim is made in relation to a food about a property of food mentioned in Column 1 of Schedule 1 the food must meet the corresponding general claim conditions, if any, in Column 2 of that Schedule.

(3) If a claim made in relation to a food about a property of food mentioned in Column 1 of Schedule 1 uses a descriptor mentioned in Column 3 of that Schedule or a synonym of that descriptor the food must meet –

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

(4) If, in relation to a claim mentioned in subclause (3), there is an inconsistency between a general claim condition in Column 2 of Schedule 1 and a specific claim condition in Column 4 of that Schedule, the specific claim condition prevails.

(5) A descriptor must not be used in a nutrition content claim about lactose or trans fatty acids unless the descriptor –

(a) is mentioned in Column 3 of Schedule 1 and corresponds with that property of food, or
(b) is a synonym of the descriptor mentioned in paragraph (a).

(6) A descriptor must not be used in a nutrition content claim about glycaemic load unless that descriptor is expressed as a number or in numeric form.

(7) A nutrition content claim in relation to gluten may only –

(a) use a descriptor that is mentioned in Column 3 of Schedule 1 in conjunction with gluten, or a synonym of such a descriptor; or
(b) state that a food contains gluten or is high in gluten.

(8) Subject to this clause and clause 14 (*Nutrition content claims must not imply slimming effects*) any descriptor that is not mentioned in Column 3 of Schedule 1, including a descriptor

expressed as a number or in numeric form, may be used in conjunction with a property of food that is mentioned in Column 1 of that Schedule.

12 Nutrition content claims about properties of food not in Schedule 1

(1) A nutrition content claim about a property of food that is not mentioned in Schedule 1 may only state –

(a) that the food contains or does not contain the property of food, or
(b) that the food contains a specified amount of the property of food in a specified amount of that food, or
(c) a combination of (a) and (b).

(2) A statement made for the purposes of paragraph (1)(a) must not use a descriptor listed in Column 3 of Schedule 1 or any other descriptor except a descriptor that indicates that the food does not contain the property of food.

13 Nutrition content claims about choline, fluoride or folic acid

(1) A nutrition content claim about choline, fluoride or folic acid may only state –

(a) that the food contains choline, fluoride or folic acid, or
(b) that the food contains a specified amount of choline, fluoride or folic acid in a specified amount of that food, or
(c) a combination of (a) and (b).

(2) A statement made for the purposes of paragraph (1)(a) must not use a descriptor listed in Column 3 of Schedule 1 or any other descriptor.

(3) A nutrition content claim about choline, fluoride or folic acid may be made only if a health claim about that substance is made in relation to the same food.

14 Nutrition content claims must not imply slimming effects

A nutrition content claim that meets the conditions to use the descriptor diet must not use another descriptor that directly or indirectly refers to slimming or a synonym for slimming.

15 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 include together with the claim –

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

Division 2 – Health claims

16 Application or proposal to vary Schedule 3 taken to be a high level health claims variation

An application or a proposal to add a general level health claim to Schedule 3 is taken to be an application or proposal for a **high level health claims variation**.

Editorial Note:

High level health claims variation is defined in section 4 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

The effect of this provision is that an application or a proposal to add a general level health claim to Schedule 3 will be assessed under the provisions in Subdivision G of each of Divisions 1 and 2 of Part 3 of the FSANZ Act, as appropriate.

17 Conditions for making health claims

(1) A health claim must not be made unless it complies with subclause (2) and either subclause (3) or (4), whichever applies.

(2) The food to which the health claim relates meets the NPSC.

(3) If the health claim is a high level health claim –

(a) the food or the property of food is mentioned in Column 1 of Schedule 2; and
(b) the health effect claimed for that food or property of food is mentioned in the corresponding row in Column 2 of Schedule 2; and
(c) the food complies with the relevant conditions in Column 5 of Schedule 2.

(4) If the health claim is a general level health claim, either –

(a) each of the following –

(i) the food or the property of food is mentioned in Column 1 of Schedule 3;
(ii) the health effect claimed for that food or property of food is mentioned in the corresponding row in Column 2 of Schedule 3; and
(iii) the food complies with the relevant conditions in Column 5 of Schedule 3; or

(b) the person who is responsible for making the health claim has notified the Chief Executive Officer of the Authority of the details of a relationship between a food or property of food and a health effect that has been established by a process of systematic review that is described in Schedule 6.

(5) Despite subclause (2) a food that is standardised in Part 2.9 of this Code does not need to meet the NPSC.

18 Requirement when making a general level health claim under paragraph 17(4)(b)

A person who gives the notice mentioned in paragraph 17(4)(b) is required to –

(a) provide the name of the person that is giving the notice and the address in Australia or New Zealand of that person; and
(b) consent to the publication by the Authority of the information given for the purposes of paragraph 17(4)(b) and subparagraph 18(1)(a); and
(c) certify that the notified relationship between a food or property of food and a health effect has been established by a process of systematic review that is described in Schedule 6; and
(d) if requested by a relevant authority, provide records to the relevant authority that demonstrate that –

(i) the systematic review was conducted in accordance with the process of systematic review described in Schedule 6; and
(ii) the notified relationship is a reasonable conclusion of the systematic review.

(2) A certificate provided for a body corporate must be signed by a senior officer of the body corporate.

19 How health claims are to be made

(1) If a health claim is a high level health claim based on a relationship described in Schedule 2 or a general level health claim based on a relationship described in Schedule 3, the health claim must –

(a) state –

(i) the food or the property of food mentioned in Column 1 of Schedule 2 or Column 1 of Schedule 3; and
(ii) the specific health effect mentioned in Column 2 of Schedule 2 or Column 2 of Schedule 3 that is claimed for the food or the property of food; and

(b) if Column 3 of Schedule 2 or Column 3 of Schedule 3 refers to a relevant population group to which the specific health effect relates, include a statement of that population group in conjunction with the health claim.

(2) If a health claim is a general level health claim based on a relationship that has been notified under paragraph 17(4)(b), the health claim must –

(a) state the food or the property of food and the specific health effect; and
(b) include together with the health claim a statement about the relevant population group, if any, that is a reasonable conclusion of the systematic review mentioned in paragraph 17(4)(b).

(3) In addition to the requirements under subclause (1) or (2), whichever applies, the health claim must also include together with the health claim –

(a) a dietary context statement according to the principles for a dietary context statement set out in subclause (4); and
(b) a statement of the form of the food to which the health claim relates.

(4) A dietary context statement must –

(a) state that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods; and
(b) be appropriate to the type of food or the property of food that is the subject of the claim and the health effect claimed; and
(c) either –

(i) if the health claim is a high level health claim based on a relationship described in Schedule 2 or a general level health claim based on a relationship described in Schedule 3, include words to the effect of the relevant dietary context statement in the corresponding row of Column 4 of Schedule 2 or Column 4 of Schedule 3, if any; or
(ii) if the health claim is a general level health claim based on a relationship that has been notified under paragraph 17(4)(b), include words to the effect of a relevant dietary context statement that is a reasonable conclusion of the systematic review.

(5) Despite paragraph (3)(a), a dietary context statement need not be included on a label on a food product that is contained in a small package.

(6) Despite paragraph (3)(b), 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 stated.

20 Split health claims

If the statements required by subclauses 19(1) and (3) or 19(2) and (3) appear on a label or in an advertisement, the matters referred to in paragraph 19(1)(a) or (2)(a), as appropriate, may also appear in another statement on the label or in the advertisement if that other statement indicates where on the label or advertisement the statements required by subclauses 19(1) and (3) or 19(2) and (3) are located.

21 Statements for claims about phytosterols, phytostanols and their esters

A dietary context statement for a claim about phytosterols, phytostanols and their esters need not include a statement required by paragraph 19(4)(a) if the claim appears together with the mandatory advisory statement required by clause 2 of Standard 1.2.3.

Division 3 – Endorsements

22 Endorsing bodies

(1) An endorsing body must –

(a) not be related to; and
(b) be independent of; and
(c) be free from influence by;

the supplier of food in relation to which an endorsement is made.

(2) 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.

23 Criteria for endorsements

(1) A supplier of food may make or include an endorsement on a label or in an advertisement for the food, or otherwise use the endorsement, if:

(a) the supplier keeps the required records for the information period; and
(b) the supplier upon request by the relevant authority, makes the required records available for inspection within the time specified by the relevant authority; and
(c) the endorsement complies with clause 7; and
(d) the endorsing body complies with clause 22.

(2) If a label on, or an advertisement for, imported food makes or includes an endorsement, the importer of the food must –

(a) keep the required records for the information period as if the importer of the food were the supplier of the food; and
(b) upon request by the relevant authority, make the required records available for inspection within the time specified by the relevant authority.

(3) An endorsement must not refer to a serious disease except in a reference to the endorsing body if the serious disease is part of the name of the endorsing body.

(4) Part 2 (other than clause 7) and Part 3 Divisions 1, 2 and 4 do not apply to an endorsement.

(5) In this clause –

information period, in relation to food, means the period –

(a) during which the food is available for sale or advertised for sale; and
(b) the period of 2 years after the food was last sold, or advertised or available for sale, whichever is the latest.

required records means a document or documents that demonstrate that –

(a) a supplier using an endorsement has obtained the permission of the endorsing body to use the endorsement; and
(b) the endorsing body has a nutrition- or health-related function or purpose; and
(c) the endorsing body is a not-for-profit entity; and
(d) the endorsing body is not related to the supplier using the endorsement.

Division 4 – Additional labelling of food required to meet the NPSC

24 Method for calculating a nutrient profiling score

The method for calculating a nutrient profiling score is described in Schedule 5.

25 Labelling of food required to meet the NPSC

(1) This clause applies if a food must meet the NPSC in order to make a claim.

(2) The particulars of a property of food must be declared in the nutrition information panel if –

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

(3) The calcium content of a food must be declared in the nutrition information panel if the food –
(a) is classified in Category 3 of Schedule 4 for the purposes of determining the food's nutrient profiling score; and
(b) is a cheese or processed cheese.

(4) If a food scores V points under item 4 of Schedule 5, the percentage of each element of fvnl that is relied on to meet the NPSC must be declared on the label, unless the claim is a health claim about fruits and vegetables.

(5) If food is not required to bear a label under subclause 2(1) of Standard 1.2.1, the information prescribed in subclause (2), (3) or (4) of this clause must be provided to the purchaser of the food on request by the purchaser or –

(a) in the case of information prescribed in subclause (2) or (3), declared in a nutrition information panel displayed on or in connection with the display of the food; or
(b) in the case of information prescribed in subclause (4), declared on a label displayed on or in connection with the display of the food.

26 Labelling exemptions for certain foods

The declaration required by subclauses 25(2), (3) or (4) is not required if food is in a small package.

SCHEDULE 1

Conditions for nutrition content claims

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions that must be met**	**Specific descriptor**	**Conditions that must be met if using specific descriptor in column 3**
Carbohydrate		Reduced or light/lite	The food contains at least 25% less carbohydrate than in the same quantity of reference food.
		Increased	The food contains at least 25% more carbohydrate than in 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 in 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.
		Excellent source	A serving of the food contains at least 7 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 in the same quantity of reference food.
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 in the same quantity of reference food.
		Diet	(a) the food meets the NPSC, unless the food is a food standardised by Part 2.9 of the Code; and (b) (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 in the same quantity of reference food.

SCHEDULE 1 (continued)

Conditions for nutrition content claims

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions that must be met**	**Specific descriptor**	**Conditions that must be met if using specific descriptor in column 3**
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 in the same quantity of reference food.
Gluten		Free	The food must not contain – (a) detectable gluten; or (b) oats or their products; or (c) 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.
Glycaemic Index	(a) the food meets the NPSC, unless the food is a food standardised by Part 2.9 of the Code; 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	The numerical value of the glycaemic index of the food is 55 or below.
		Medium	The numerical value of the glycaemic index of the food is at least 56 and not exceeding 69.
		High	The numerical value of the glycaemic index of the food is 70 or above.
Glycaemic load	The food meets the NPSC, unless the food is a food standardised under Part 2.9 of the Code.		
Lactose	The nutrition information panel indicates the lactose and galactose content.	Free	The food contains no detectable lactose.
		Low	The food contains no more than 2 g of lactose per 100 g of the food.
Monounsaturated fatty acids	The food contains, as a proportion of the total fatty acid content – (a) no more than 28% saturated fatty acids and trans fatty acids; and (b) no less than 40% monounsaturated fatty acids.	Increased	(a) the food contains at least 25% more monounsaturated fatty acids than in the same quantity of reference food; and (b) the reference food meets the general claim conditions for a nutrition content claim about monounsaturated fatty acids.

SCHEDULE 1 (continued)

Conditions for nutrition content claims

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions that must be met**	**Specific descriptor**	**Conditions that must be met if using specific descriptor in column 3**
Omega fatty acids (any)	The type of omega fatty acid is specified immediately after the word 'omega'.		
Omega-3 fatty acids	(a) the food meets the conditions for a nutrition content claim 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 type and amount of omega-3 fatty acids, that is, alpha-linolenic acid, docosahexaenoic acid or eicosapentaenoic acid, or a combination of the above.	Good Source	(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.
		Increased	(a) the food contains at least 25% more omega-3 fatty acids than in the same quantity of reference food; and (b) the reference food meets the general claim conditions for a nutrition content claim about omega-3 fatty acids.

SCHEDULE 1 (continued)

Conditions for nutrition content claims

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions that must be met**	**Specific descriptor**	**Conditions that must be met if using specific descriptor in column 3**
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 in the same quantity of reference food; and (b) the reference food meets the general claim 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 in the same quantity of reference food; and (b) the reference food meets the general claim conditions for a nutrition content claim about omega-9 fatty acids.
Polyunsaturated fatty acids	The food contains, as a proportion of the total fatty acid content – (a) no more than 28% saturated fatty acids and trans fatty acids; and (b) no less than 40% polyunsaturated fatty acids.	Increased	(a) the food contains at least 25% more polyunsaturated fatty acids than in the same quantity of reference food; and (b) the reference food meets the general claim conditions for a nutrition content claim about polyunsaturated fatty acids.
Potassium	The nutrition information panel indicates the sodium and potassium content.		

SCHEDULE 1 (continued)

Conditions for nutrition content claims

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions that must be met**	**Specific descriptor**	**Conditions that must be met if using specific descriptor in column 3**
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 in the same quantity of reference food; and (b) the reference food meets the general claim 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 in 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 or sodium.
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 than in 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'.

SCHEDULE 1 (continued)

Conditions for nutrition content claims

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions that must be met**	**Specific descriptor**	**Conditions that must be met if using specific descriptor in column 3**
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	The food contains – (a) at least 25% less saturated fatty acids than in the same quantity of reference food, and (b) no more trans fatty acids than in 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 the total fatty acid content'.
Sugar or Sugars		% Free	The food meets the conditions for a nutrition content claim about low sugar.
		Low	The food contains no more sugars 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 than in 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, or 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.

SCHEDULE 1 (continued)

Conditions for nutrition content claims

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions that must be met**	**Specific descriptor**	**Conditions that must be met if using specific descriptor in column 3**
Sugar or Sugars (continued)		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.
Trans fatty acids		Free	The food contains no detectable trans fatty acids, and contains – (a) no more than 0.75 g saturated fatty acids per 100 mL of liquid food or 1.5 g saturated fatty acids per 100 g of solid food; or (b) no more than 28% saturated fatty acids as a proportion of the total fatty acid content.
		Reduced or Light/Lite	The food contains – (a) at least 25% less trans fatty acids than in the same quantity of reference food, and (b) no more saturated fatty acids than in the same quantity of reference food.
Vitamin or mineral (not including potassium or sodium)	(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 or clause 5 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 1 (continued)

Conditions for nutrition content claims

Column 1	Column 2	Column 3	Column 4
Property of food	**General claim conditions that must be met**	**Specific descriptor**	**Conditions that must be met if using specific descriptor in column 3**
Vitamin or mineral (not including potassium or sodium) (continued)	If the food is a food standardised under Standard 2.9.2, the food meets the conditions for making a claim about vitamins and minerals in subclause 8(2) of Standard 2.9.2.		
	If the food is a formulated meal replacement standardised under Standard 2.9.3, the food meets the conditions for making a claim about vitamins and minerals in subclause 3(2) of Standard 2.9.3.		
	If the food is a formulated supplementary food standardised under Standard 2.9.3, the food meets the conditions for making a claim about vitamins and minerals in subclause 5(2) of Standard 2.9.3.		
	If the food is a formulated supplementary food for young children standardised under Standard 2.9.3, the food meets the conditions for making a claim about vitamins and minerals in subclause 7(2) of Standard 2.9.3.		

SCHEDULE 2

Conditions for permitted high level health claims

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Context claim statements**	**Conditions**
A high intake of fruit and vegetables	Reduces risk of coronary heart disease		Diet containing a high amount of both fruit and vegetables	(a) claims are not permitted on – (i) fruit juice or vegetable juice as standardised in Standard 2.6.1; or (ii) a food standardised in Standard 2.6.2; and (b) the food must contain no less than 90% fruit or vegetable by weight.
Beta-glucan	Reduces blood cholesterol		Diet low in saturated fatty acids Diet containing 3 g of beta-glucan per day	The food must contain – (a) one or more of the following oat or barley foods – (i) oat bran; (ii) wholegrain oats; or (iii) wholegrain barley; and (b) at least 1 g per serving of beta-glucan from the foods listed in (a).
Calcium	Enhances bone mineral density		Diet high in calcium	The food must contain no less than 200 mg of calcium per serving.
	Reduces risk of osteoporosis	Persons 65 years and over	Diet high in calcium, and adequate vitamin D status	The food must contain no less than 290 mg of calcium per serving
	Reduces risk of osteoporotic fracture			

SCHEDULE 2 (continued)

Conditions for permitted high level health claims

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Context claim statements**	**Conditions**
Calcium and Vitamin D	Reduces risk of osteoporosis Reduces risk of osteoporotic fracture	Persons 65 years and over	Diet high in calcium, and adequate vitamin D status	The food must – (a) contain no less than 290 mg of calcium per serving; and (b) meet the general claim conditions for making a nutrition content claim about vitamin D
Folic acid (but not folate)	Reduces risk of foetal neural tube defects	Women of child bearing age	Consume at least 400 µg of folic acid per day, at least the month before and three months after conception	The food must – (a) contain 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) food containing added phytosterols, phytostanols and their esters; or (v) food standardised in Standards 2.6.4 and 2.9.4; or (vi) a formulated meal replacement standardised in Division 2 of Standard 2.9.3

SCHEDULE 2 (continued)

Conditions for permitted high level health claims

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Context claim statements**	**Conditions**
Increased intake of fruit and vegetables	Reduces risk of coronary heart disease		Diet containing an increased amount of both fruit and vegetables	(a) claims are not permitted on – (i) fruit juice or vegetable juice as standardised in Standard 2.6.1; or (ii) a food standardised in Standard 2.6.2; and (b) the food must contain no less than 90% fruit or vegetable by weight
Phytosterols, phytostanols and their esters	Reduces blood cholesterol		Diet low in saturated fatty acids Diet containing 2 g of phytosterols, phytostanols and their esters per day	The food must – (a) meet the relevant conditions specified in Columns 1 and 2 of the Table to clause 2 in Standard 1.5.1; and (b) contain a minimum of 0.8 g total plant sterol equivalents content per serving
Saturated fatty acids	Reduces total blood cholesterol or blood LDL cholesterol		Diet low in saturated fatty acids	The food must meet the conditions for making a nutrition content claim about low saturated fatty acids
Saturated and trans fatty acids	Reduces total blood cholesterol or blood LDL cholesterol		Diet low in saturated and trans fatty acids	The food must meet the conditions for making a nutrition content claim about low saturated and trans fatty acids
Sodium or salt	Reduces blood pressure		Diet low in salt or sodium	The food must meet the conditions for making a nutrition content claim about low sodium or salt

SCHEDULE 3

Conditions for permitted general level health claims
Part 1 – Minerals

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Calcium	Necessary for normal teeth and bone structure			The food must meet the general claim conditions for making a nutrition content claim about calcium
	Necessary for normal nerve and muscle function			
	Necessary for normal blood coagulation			
	Contributes to normal energy metabolism			
	Contributes to the normal function of digestive enzymes			
	Contributes to normal cell division			
	Contributes to normal growth and development	Children		
Chromium	Contributes to normal macronutrient metabolism			The food must meet the general claim conditions for making a nutrition content claim about chromium
Copper	Contributes to normal connective tissue structure			The food must meet the general claim conditions for making a nutrition content claim about copper
	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	Children		
Fluoride	Contributes to the maintenance of tooth mineralisation			The food must contain no less than 0.6 mg fluoride per L

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 1 – Minerals (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Iodine	Necessary for normal production of thyroid hormones			The food must meet the general claim conditions for making a nutrition content claim about iodine
	Necessary for normal neurological function			
	Necessary for normal energy metabolism			
	Contributes to normal cognitive function			
	Contributes to the maintenance of normal skin			
	Contributes to normal growth and development	Children		
Iron	Necessary for normal oxygen transport			The food must meet the general claim conditions for making a nutrition content claim about iron
	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 cognitive function			
	Contributes to the reduction of tiredness and fatigue			
	Necessary for normal cell division			
	Contributes to normal growth and development	Children		
	Contributes to normal cognitive development	Children		
Manganese	Contributes to normal bone formation			The food must meet the general claim conditions for making a nutrition content claim about manganese
	Contributes to normal energy metabolism			
	Contributes to cell protection from free radical damage			
	Contributes to normal connective tissue structure			
	Contributes to normal growth and development	Children		

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 1 – Minerals (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Magnesium	Contributes to normal energy metabolism			The food must meet the general claim conditions for making a nutrition content claim about magnesium
	Necessary for normal electrolyte balance			
	Necessary for normal nerve and muscle function			
	Necessary for teeth and bone structure			
	Contributes to a reduction of tiredness and fatigue			
	Necessary for normal protein synthesis			
	Contributes to normal psychological function			
	Necessary for normal cell division			
	Contributes to normal growth and development	Children		
Molybdenum	Contributes to normal sulphur amino acid metabolism			The food must meet the general claim conditions for making a nutrition content claim about molybdenum
Phosphorus	Necessary for normal teeth and bone structure			The food must meet the general claim conditions for making a nutrition content claim about phosphorus
	Necessary for the normal cell membrane structure			
	Necessary for normal energy metabolism			
	Contributes to normal growth and development	Children		
Selenium	Necessary for normal immune system function			The food must meet the general claim conditions for making a nutrition content claim about selenium
	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 sperm production			
	Contributes to the maintenance of normal hair and nails			
	Contributes to normal growth and development	Children		

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 1 – Minerals (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Zinc	Necessary for normal immune system function			The food must meet the general conditions for making a nutrition content claim about zinc
	Necessary for normal cell division			
	Contributes to normal skin structure and wound healing			
	Contributes to normal growth and development	Children		
	Contributes to normal acid-base metabolism			
	Contributes to normal carbohydrate metabolism			
	Contributes to normal cognitive function			
	Contributes to normal fertility and reproduction			
	Contributes to normal macronutrient metabolism			
	Contributes to normal metabolism of fatty acids			
	Contributes to normal metabolism of vitamin A			
	Contributes to normal protein synthesis			
	Contributes to the maintenance of normal bones			
	Contributes to the maintenance of normal hair and nails			
	Contributes to the maintenance of normal testosterone levels in the blood			
	Contributes to cell protection from free radicals			
	Contributes to the maintenance of normal vision			

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 2 – Vitamins

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Biotin	Contributes to normal fat metabolism and energy production			The food must meet the general conditions for making a nutrition content claim about biotin
	Contributes to normal functioning of the nervous system			
	Contributes to normal macronutrient metabolism			
	Contributes to normal psychological function			
	Contributes to maintenance of normal hair			
	Contributes to maintenance of normal skin and mucous membranes			
Choline	Contributes to normal homocysteine metabolism			The food must contain no less than 50 mg choline per serve
	Contributes to normal fat metabolism			
	Contributes to the maintenance of normal liver function			
Folate	Necessary for normal blood formation			The food must meet the general conditions for making a nutrition content claim about folate
	Necessary for normal cell division			
	Contributes to normal growth and development	Children		
	Contributes to maternal tissue growth during pregnancy			
	Contributes to normal amino acid synthesis			
	Contributes to normal homocysteine metabolism			
	Contributes to normal psychological function			
	Contributes to normal immune system function			
	Contributes to the reduction of tiredness and fatigue			

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 2 – Vitamins (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Folic acid (but not folate)	Contributes to normal neural tube structure in the developing foetus	Women of child bearing age	Consume at least 400 µg of folic acid per day, at least the month before and three months after conception	(a) the food must contain 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) food containing added phytosterols, phytostanols and their esters; or (v) a food standardised in Standards 2.6.4 and 2.9.4; or (vi) a formulated meal replacement standardised in Division 2 of Standard 2.9.3
Niacin	Necessary for normal neurological function			The food must meet the general claim conditions for making a nutrition content claim about niacin
	Necessary for normal energy release from food			
	Necessary for normal structure and function of skin and mucous membranes			
	Contributes to normal growth and development	Children		
	Contributes to normal psychological function			
	Contributes to the reduction of tiredness and fatigue			

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 2 – Vitamins (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Pantothenic acid	Necessary for normal fat metabolism			The food must meet the general claim conditions for making a nutrition content claim about pantothenic acid
	Contributes to normal growth and development	Children		
	Contributes to normal energy production			
	Contributes to normal mental performance			
	Contributes to normal synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters			
	Contributes to the reduction of tiredness and fatigue			
Riboflavin	Contributes to normal iron transport and metabolism			The food must meet the general claim conditions for making a nutrition content claim about riboflavin
	Contributes to normal energy release from food			
	Contributes to normal skin and mucous membrane structure and function			
	Contributes to normal growth and development	Children		
	Contributes to normal functioning of the nervous system			
	Contributes to the maintenance of normal red blood cells			
	Contributes to the maintenance of normal vision			
	Contributes to the protection of cells from oxidative stress			
	Contributes to the reduction of tiredness and fatigue			

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 2 – Vitamins (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Thiamin	Necessary for normal carbohydrate metabolism			The food must meet the general claim conditions for making a nutrition content claim about thiamin
	Necessary for normal neurological and cardiac function			
	Contributes to normal growth and development	Children		
	Contributes to normal energy production			
	Contributes to normal psychological function			
Vitamin A	Necessary for normal vision			The food must meet the general claim conditions for making a nutrition content claim about vitamin A
	Necessary for normal skin and mucous membrane structure and function			
	Necessary for normal cell differentiation			
	Contributes to normal growth and development	Children		
	Contributes to normal iron metabolism			
	Contributes to normal immune system function			
Vitamin B_6	Necessary for normal protein metabolism			The food must meet the general claim conditions for making a nutrition content claim about vitamin B_6
	Necessary for normal iron transport and metabolism			
	Contributes to normal growth and development	Children		
	Contributes to normal cysteine synthesis			
	Contributes to normal energy metabolism			
	Contributes to normal functioning of the nervous system			
	Contributes to normal homocysteine metabolism			
	Contributes to normal glycogen metabolism			
	Contributes to normal psychological function			
	Contributes to normal red blood cell formation			

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 2 – Vitamins (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Vitamin B_6 (continued)	Contributes to normal immune system function			The food must meet the general claim conditions for making a nutrition content claim about vitamin B_6
	Contributes to the reduction of tiredness and fatigue			
	Contributes to the regulation of hormonal activity			
Vitamin B_{12}	Necessary for normal cell division			The food must meet the general conditions for making a nutrition content claim about vitamin B_{12}
	Contributes to normal blood formation			
	Necessary for normal neurological structure and function			
	Contributes to normal growth and development	Children		
	Contributes to normal energy metabolism			
	Contributes to normal homocysteine metabolism			
	Contributes to normal psychological function			
	Contributes to normal immune system function			
	Contributes to the reduction of tiredness and fatigue			
Vitamin C	Contributes to iron absorption from food			The food must meet the general claim conditions for making a nutrition content claim about vitamin C
	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	Children		
	Contributes to normal collagen formation for the normal structure of cartilage and bones			

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 2 – Vitamins (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary context**	**Conditions**
Vitamin C (continued)	Contributes to normal collagen formation for the normal function of teeth and gums			The food must meet the general claim conditions for making a nutrition content claim about vitamin C
	Contributes to normal collagen formation for the normal function of skin			
	Contributes to normal energy metabolism			
	Contributes to normal psychological function			
	Contributes to the normal immune system function			
	Contributes to the reduction of tiredness and fatigue			
Vitamin D	Necessary for normal absorption and utilisation of calcium and phosphorus			The food must meet the general claim conditions for making a nutrition content claim about vitamin D
	Contributes to normal cell division			
	Necessary for normal bone structure			
	Contributes to normal growth and development	Children		
	Contributes to normal blood calcium levels			
	Contributes to the maintenance of normal muscle function			
	Contributes to the maintenance of normal teeth			
	Contributes to the normal function of the immune system			
Vitamin E	Contributes to cell protection from free radical damage			The food must meet the general claim conditions for making a nutrition content claim about vitamin E
	Contributes to normal growth and development	Children		
Vitamin K	Necessary for normal blood coagulation			The food must meet the general claim conditions for making a nutrition content claim about vitamin K
	Contributes to normal bone structure			
	Contributes to normal growth and development	Children		

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 3 – Other

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary Context**	**Conditions**
Beta-glucan	Reduces dietary and biliary cholesterol absorption		Diet low in saturated fatty acids Diet containing 3 g of beta-glucan per day	The food must contain – (a) one or more of the following oat or barley foods – (i) oat bran; (ii) wholegrain oats; or (iii) wholegrain barley; and (b) at least 1 g per serving of beta-glucan from the foods listed in (a)
Carbohydrate	Contributes energy for normal metabolism			(a) carbohydrate must contribute at least 55% of the energy content of the food; or (b) the food must – (i) be a formulated meal replacement or a formulated supple-mentary food; and (ii) have a maximum 10% of carbo-hydrate content from sugars
	Contributes energy for normal metabolism	Young children aged 1-3 years		The food must – (a) be a formulated supplementary food for young children (as standardised in Standard 2.9.3 Division 4); and (b) have a maximum 10% of carbohydrate content from sugars

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 3 – Other (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary Context**	**Conditions**
Dietary fibre	Contributes to regular laxation			The food must meet the general conditions for making a nutrition content claim about dietary fibre
Eicosapentaenoic acid (EPA) and Docosa-hexaenoic acid (DHA) (but not Omega-3)	Contributes to heart health		Diet containing 500 mg of EPA and DHA per day	(a) the food must contain 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.
Energy	Contributes energy for normal metabolism			The food must contain a minimum of 420 kJ of energy per serving
	Contributes energy for normal metabolism	Young children aged 1-3 years		The food must be a formulated supplementary food for young children (as standardised in Standard 2.9.3 Division 4)

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 3 – Other (continued)

Column 1	Column 2	Column 3	Column 4	Column 5

Food or property of food	Specific health effect	Relevant population	Dietary Context	Conditions
Energy (continued)	Contributes to weight loss or weight maintenance		Diet reduced in energy and including regular exercise	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 and contains no more than 1200 kJ per serving
Live yoghurt cultures	Improves lactose digestion	Individuals who have difficulty digesting lactose		The food must – (a) be yoghurt or fermented milk and (b) contain at least 10^8 cfu/g (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*)
Phytosterols, phytostanols and their esters	Reduces dietary and biliary cholesterol absorption		Diet low in saturated fatty acids Diet containing 2 g of phytosterols, phytostanols and their esters per day	The food must – (a) meet the relevant conditions specified in Columns 1 and 2 of the Table to clause 2 in Standard 1.5.1; and (b) contain a minimum of 0.8 g total plant sterol equivalents content per serving

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 3 – Other (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Dietary Context**	**Conditions**
Potassium	Necessary for normal water and electrolyte balance			The food contains no less than 200 mg of potassium per serving
	Contributes to normal growth and development	Children		
	Contributes to normal functioning of the nervous system			
	Contributes to normal muscle function			
Protein	Necessary for tissue building and repair			The food must meet the general conditions for making a nutrition content claim about protein
	Necessary for normal growth and development of bone	Children and adolescents aged 4 years and over		
	Contributes to the growth of muscle mass			
	Contributes to the maintenance of muscle mass			
	Contributes to the maintenance of normal bones			
	Necessary for normal growth and development	Children aged 4 years and over		The food must meet the general conditions for making a nutrition content claim about protein.
	Necessary for normal growth and development	Infants aged 6 months to 12 months		The food must be a food for infants and meet the conditions in subclause 6(3) of Standard 2.9.2

Conditions for permitted general level health claims
Part 4 – Foods

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Context claim statements**	**Conditions**
Fruits and vegetables	Contributes to heart health		Diet containing an increased amount of fruit and vegetables; or Diet containing a high amount of fruit and vegetables	(a) the food is not – (i) fruit juice or vegetable juice as standardised in Standard 2.6.1; or (ii) a food standardised in Standard 2.6.2; and (b) the food contains no less than 90% fruit or vegetable by weight
Sugar or sugars	Contributes to dental health		Good oral hygiene	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

SCHEDULE 3 (continued)

Conditions for permitted general level health claims
Part 4 – Foods (continued)

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	**Specific health effect**	**Relevant population**	**Context claim statements**	**Conditions**
Chewing gum	Contributes to the maintenance of tooth mineralisation		Chew the gum for at least 20 minutes after eating or drinking	The food is chewing gum and either – (a) contains 0.2% or less starch, dextrins, mono-, di- and oligosaccharides, or other fermentable carbohydrates combined; or (b) 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
	Contributes to the neutralisation of plaque acids			
	Contributes to the reduction of oral dryness		Chew the gum when the mouth feels dry	

SCHEDULE 4

Nutrient profiling scoring criterion

	Column 1	Column 2
Category	**NPSC category**	**The nutrient profiling score must be less than**
1	Beverages	1
2	Any food other than those included in Category 1 or 3.	4
3	(a) cheese and processed cheese as defined in Standard 2.5.4 (with calcium content >320 mg/100 g)*; and (b) edible oil as defined in Standard 2.4.1; and (c) edible oil spreads as defined in Standard 2.4.2; and (d) margarine as defined in Standard 2.4.2; and (e) butter as defined in Standard 2.5.5. *All other cheeses (with calcium content ≤320 mg/100 g) are classified as a category 2 food product.	28

SCHEDULE 5

Nutrient profiling scoring method

1 Steps in determining a nutrient profiling score

(1) For a food in Category 1 in Schedule 4, 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 in Schedule 4, 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 in Schedule 4, 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 subitem (2) to work out the baseline points, for the content of energy and 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 or 100 mL	Average saturated fatty acids (g) per 100 g or 100 mL	Average total sugars (g) per 100 g or 100 mL	Average 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

Table 1 (continued)
Baseline Points for Category 1 or 2 Foods

Baseline points	Average energy content (kJ) per 100 g or 100 mL	Average saturated fatty acids (g) per 100 g or 100 mL	Average total sugars (g) per 100 g or 100 mL	Average sodium (mg) per 100 g or 100 mL
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 average saturated fatty acids) + (points for average total sugars) + (points for average sodium)

3 Baseline points for Category 3 foods

(1) Use the information in Table 2 and the formula in subitem (2) to work out the baseline points, for the content of energy and 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

Baseline Points	Average energy content (kJ) per 100 g or 100 mL	Average saturated fatty acids (g) per 100 g or 100 mL	Average total sugars (g) per 100 g or 100 mL	Average sodium (mg) per 100 g or 100 mL
0	≤ 335	≤1.0	≤ 5.0	≤ 90
1	>335	>1.0	>5.0	>90
2	>670	>2.0	>9.0	>180
3	>1005	>3.0	>13.5	>270
4	>1340	>4.0	>18.0	>360
5	>1675	>5.0	>22.5	>450
6	>2010	>6.0	>27.0	>540
7	>2345	>7.0	>31.0	>630
8	>2680	>8.0	>36.0	>720
9	>3015	>9.0	>40.0	>810
10	>3350	>10.0	>45.0	>900
11	>3685	>11.0		>990
12		>12.0		>1080
13		>13.0		>1170
14		>14.0		>1260
15		>15.0		>1350
16		>16.0		>1440
17		>17.0		>1530
18		>18.0		>1620
19		>19.0		>1710
20		>20.0		>1800
21		>21.0		>1890
22		>22.0		>1980
23		>23.0		>2070

Table 2 (continued)
Baseline Points for Category 3 Foods

Baseline Points	Average energy content (kJ) per 100 g or 100 mL	Average saturated fatty acids (g) per 100 g or 100 mL	Average total sugars (g) per 100 g or 100 mL	Average sodium (mg) per 100 g or 100 mL
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 average saturated fatty acids) + (points for average total sugars) + (points for average 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 –

(a) fvnl that are fresh, cooked, frozen, canned, pickled or preserved; and
(b) fvnl that have been peeled, diced or cut (or otherwise reduced in size), puréed or dried.

(2) V points cannot be scored for –

(a) a constituent, extract or isolate of a food mentioned in subitem (1); or
(b) 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 coconut oil; 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 6 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 6 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 fruit or vegetables and non-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 vegetables**	**% 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 fruit or vegetables and non-concentrated fvnl sources, the percentage of total fvnl must be worked out as follows –

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

where –

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

(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 V points.

Table 4
P Points

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

6 Fibre points (F 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 100 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)

SCHEDULE 6

Required elements of a systematic review

A systematic review must include the following elements –

1 A description of the food or property of food, the health effect and the proposed relationship between the food or property of food and the health effect.

2 A description of the search strategy used to capture the scientific evidence relevant to the proposed relationship between the food or property of food and the health effect, including the inclusion and exclusion criteria.

3 A final list of studies based on the inclusion and exclusion criteria. Studies in humans are essential. A relationship between a food or property of food and the health effect cannot be established from animal and *in vitro* studies alone.

4 A table with key information from each included study. This must include information on:

(a) the study reference
(b) the study design
(c) the objectives
(d) the sample size in the study groups and loss to follow-up or non-response
(e) the participant characteristics
(f) the method used to measure the food or property of food including amount consumed
(g) confounders measured
(h) the method used to measure the health effect
(i) the study results, including effect size and statistical significance
(j) any adverse effects.

5 An assessment of the quality of each included study based on consideration of, as a minimum:

(a) a clearly stated hypothesis
(b) minimisation of bias
(c) adequate control for confounding
(d) the study participants' background diets and other relevant lifestyle factors
(e) study duration and follow-up adequate to demonstrate the health effect
(f) the statistical power to test the hypothesis.

6 An assessment of the results of the studies as a group by considering whether:

(a) there is a consistent association between the food or property of food and the health effect across all high quality studies
(b) there is a causal association between the consumption of the food or property of food and the health effect that is independent of other factors (with most weight given to well-designed experimental studies in humans)
(c) the proposed relationship between the food or property of food and the health effect is biologically plausible
(d) the amount of the food or property of food to achieve the health effect can be consumed as part of a normal diet of the Australian and New Zealand populations.

7 A conclusion based on the results of the studies that includes:

(a) whether a causal relationship has been established between the food or property of food and the health effect based on the totality and weight of evidence; and
(b) where there is a causal relationship between the food or property of food and the health effect:

(i) the amount of the food or property of food required to achieve the health effect
(ii) whether the amount of the food or property of food to achieve the health effect is likely to be consumed in the diet of the Australian and New Zealand populations or by the target population group, where relevant.

8 An existing systematic review may be used if it is updated to include –

(a) the required elements 1 to 6 above for any relevant scientific data not included in the existing systematic review
(b) the required element 7 above incorporating the new relevant scientific data with the conclusions of the existing systematic review.

Food Standards (Proposal P293 – Nutrition, Health & Related Claims – Consequential) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated XXXX

[Signature to be inserted]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Proposal P293 – Nutrition, Health & Related Claims – Consequential) Variation.*

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

These variations, other than Items [2.3], [4] and [13], commence **on the date of gazettal.** Items [2.3], [4] and [13.1] commence **3 years from gazettal**. Items [13.2] to [13.4] commence immediately after the commencement of Standard 2.9.5.

SCHEDULE

[1] ***Standard 1.1.1 i****s varied by –*

[1.1] *omitting from subclause 1(6) –*

a Standard for which a corresponding transitional Standard in part 1.1A applies

substituting –

Standard 1.1A.6

[1.2] *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] ***Standard 1.1A.2*** *is varied by –*

[2.1] *omitting* the Purpose statement*, substituting –*

Editorial Note

Standard 1.1A.2 is a transitional standard that operates concurrently with Standard 1.2.7 for a period of three years. During the three-year period Standard 1.1A.2 operates unchanged by the *Food Standards (Proposal P293 – Nutrition, Health & Related Claims – Consequential) Variation* and a supplier can rely on Standard 1.2.7 or Standard 1.1A.2, but not both. If Standard 1.1A.2 is relied on in that period, the changes made to other Standards by that variation are to be treated as if they have no effect. At the end of the three-year period Standard 1.1A.2 ceases to operate. There is no stock-in-trade period at the end of the three-year period.

[2.2] *omitting* two years *from subclause (1B), substituting* three years.

[2.3] *repealing* the Standard

[3] **Standard 1.2.1** *is varied by inserting –*

(da) subclause 24(5) of Standard 1.2.7 – Nutrition, Health and Related Claims.

after paragraph 2(2)(d).

[4] ***Standard 1.2.7*** *is varied by omitting the* editorial note *preceding clause 1*

[5] ***Standard 1.2.8*** *is varied by –*

[5.1] *omitting* the Purpose statement*, 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.

Editorial Note:

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.

[5.2] *omitting the definitions of* gluten *and* nutrition claim *in subclause 1(1)*

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

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

[5.4] *inserting in alphabetical order in subclause 1(1)* –

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

[5.5] *renumbering subclause 1(2) as 1(4)*

[5.6] *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.

[5.7] *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. Standard 2.9.1 prescribes specific nutrition information requirements for those foods.

[5.8] *omitting clause 4, substituting* –

4 Requirements for nutrition information panels when certain claims made

(1) A claim requiring nutrition information means –

(a) a nutrition content claim; or
(b) a health claim;

but does not include –

(c) a declaration that is required by the Act, or
(d) an endorsement.

(2) Subject to subclauses (3) and (4), if 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) If 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.

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

subject to clause 12,

substituting –

subject to subclause (1A),

[5.10] *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.

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

(1A) If 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 properties set out in subclause (1B) may be set out in the panel as a minimum or maximum quantity in a serving of the food and per 100 g/mL.

(1B) The properties are –

(a) saturated fatty acids; and
(b) polyunsaturated fatty acids; and
(c) monounsaturated fatty acids; and
(d) trans fatty acids.

[5.12] *omitting from the* editorial note *after subclause 5(2)* –

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

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

nutrition claim is made in respect of

substituting –

claim requiring nutrition information is made about or based on

[5.14] *omitting from subclause 5(5)* –

nutrition claim is made in respect of

substituting –

claim requiring nutrition information is made about or based on

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

(2) If 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;
(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'.

[5.16] *inserting after clause 7* –

7A Percentage recommended dietary intake information

(1) This clause applies if–

(a) a claim requiring nutrition information is made about or based on a vitamin or mineral (the relevant vitamin or mineral); and
(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 RDIs 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 dietary 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.

[5.17] *omitting clause 8, substituting* –

8 Food in small packages

(1) This clause applies if 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 acids, trans fatty acids, polyunsaturated fatty acids and monounsaturated fatty acids 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 acids	(a) Saturated fatty acids, trans fatty acids, polyunsaturated fatty acids and monounsaturated fatty acids content per serving of the food; and (b) Type and amount of omega-3 fatty acids per serving of the food, namely alpha-linolenic acid, or docosahexaenoic acid, or eicosapentaenoic acid, or a combination of the above
Lactose	Galactose content per serving of the food
Potassium	Sodium and potassium content per serving of the food

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

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

(a) must be set out as minimum, maximum or average quantities unless specified in the Table to subclause (3); and
(b) must clearly indicate whether the particulars are minimum, maximum 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 Additional declarations for food in small packages

(1) This clause applies if a claim requiring nutrition information is made about carbohydrate, dietary fibre, sugars or any other carbohydrate on or about food in a small package.

(2) The label must include a declaration of unavailable carbohydrate if 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 Table 2 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;

the presence of the relevant substances must be declared on the label.

[5.18] *inserting in clause 11*, *the word* 'in' *after* 'as set out'.

[5.19] *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 or consumed with at least one other food–

(a) the nutrition information panel must include an additional column at the right hand side of the panel, specifying, in the same manner as set out in the panel –

(i) a description of the additional food or foods; and
(ii) the quantity of the additional food or foods; and
(iii) the average energy content of the combined foods; and
(iv) the average quantities of nutrients contained in the combined foods; and
(v) the average quantities of biologically active substances contained in the combined foods; and

(b) the weight or volume of the serving size of the food as prepared must be declared in the panel.

[5.20] *omitting Division 3, substituting –*

Division 3 – Deleted

[5.21] *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) dietary fibre if the food contains less than 2 g of dietary fibre per serving; or
(ii) trans fatty acid content; or
(iii) lactose 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 a nutrition content claim.

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

[6] ***Standard 1.3.2*** *is varied by –*

[6.1] *omitting from the first sentence of the* Purpose –

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

[6.2] *omitting the definitions of* claimable food, primary food *and* reference quantity *from 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.

[6.3] *omitting clause 4, substituting* –

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

If a vitamin or mineral has been added to a food listed in Column 1 of the Table to clause 3, 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.

[6.4] *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) If a final food contains more than one ingredient and at least one ingredient contains an added vitamin or mineral pursuant to a permission in Standard 1.3.2, the maximum claim permitted in relation to that vitamin or mineral in a reference quantity of the final food is calculated by summing the quantity of that vitamin or mineral calculated for each ingredient according to the formula set out below and rounded to the nearest 2 significant figures.

(2) In this subclause –

M_{rq} means the maximum quantity of a vitamin or mineral permitted to be claimed in a reference quantity of the final food calculated in accordance with the formula –

$M_{rq} = Q_1 + Q_2 + \ldots\ldots Q_i$

where –

$Q_{1,\ is}$ the quantity of a vitamin or mineral permitted to be claimed for the first ingredient in a reference quantity of the final food, Q_2 is the quantity of a vitamin or mineral permitted to be claimed for a second ingredient in a reference quantity of the final food, and so forth for all ingredients containing that vitamin or mineral.

(3) The amount used for the quantity permitted to be claimed means either the –

(a) average quantity of the vitamin or mineral present in the amount of unfortified ingredient in a reference quantity of the final food; or
(b) maximum permitted claim for the vitamin or mineral in the amount of fortified ingredient in a reference quantity of the final food.

Editorial note:

Example calculations

(a) Vitamin C claim for an apple and blackcurrant fruit drink comprised of 80 mL apple juice and 4 mL blackcurrant juice 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

Q_1 (apple juice) = 120 mg x 80/200 = 48 mg vitamin C/200 mL
Q_2 (blackcurrant juice) = 500 mg x 4/200 = 10 mg vitamin C/200 mL

M_{rq} = 48 + 10 = 58 mg vitamin C/200 mL apple and blackcurrant fruit drink

The calculated maximum quantity of vitamin C that may be claimed in 200 mL of apple and

blackcurrant fruit drink rounded to the nearest 2 significant figures = 58 mg (no change)

(b) Iron claim for an uncooked beef schnitzel comprised of 115 g raw beef and 30 g iron-fortified breadcrumbs, in a reference quantity of 145 g –

Average quantity of iron in raw beef = 2.5 mg/100 g (from analysis or nutrient composition tables)

Maximum claim per reference quantity for iron in fortified breadcrumbs = 3 mg/50 g bread

Q_1 (raw beef) = 2.5 x 115/100 = 2.875 mg iron/115 g
Q_2 (iron-fortified breadcrumbs) = 3 mg x 30/50 = 1.8 mg iron/30 g

M_{rq} = 2.875 + 1.8 = 4.675 mg iron/145 g uncooked beef schnitzel

The calculated maximum quantity of iron that may be claimed in 145 g of uncooked beef schnitzel rounded to the nearest 2 significant figures = 4.7 mg

[6.5] *omitting clauses 6 to 9*

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

[7] ***Standard 2.6.2*** *is varied by omitting* nutrition claim for the purposes of Standard 1.2.8 *in subclause 2B(4), and substituting* nutrition content claim for the purposes of Standard 1.2.7

[8] ***Standard 2.6.4*** *is varied by omitting subclause 3(6*)

[9] ***Standard 2.9.1*** *is varied by –*

[9.1] *omitting clause 28, substituting –*

28 Required statements for products under this Subdivision

The label on an infant formula 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.

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

[10] ***Standard 2.9.2*** *is varied by –*

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

(e) clause 9.

[10.2] i*nserting after subclause 9(1) –*

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

[11] ***Standard 2.9.3*** *is varied by –*

[11.1] *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; and
(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.

[11.2] *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.

[11.3] *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

[11.4] *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; and
(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.

[11.5] *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.

[11.6] *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

[11.7] *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; and
(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.

[12] ***Standard 2.9.4*** *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).

[13] ***Standard 2.9.5*** *is varied by:*

[13.1] *omitting* 1.1A.2, *from paragraph 3(1)(b); and*

[13.2] *omitting subparagraph 9(e)(iv), substituting –*

(iv) subject to subclauses 14(4) and 15(5) of this Standard, any other substance if a nutrition content claim as defined in Standard 1.2.7 is made in relation to that substance.

[13.3] *omitting clause 14, substituting –*

(1) A claim in relation to the lactose content of a food for special medical purposes is prohibited unless expressly permitted by this clause.

(2) A claim to the effect that a food for special medical purposes is lactose free may be made if the food contains no detectable lactose.

(3) A claim to the effect that a food for special medical purposes is low lactose may be made if the food contains not more than 2 g of lactose per 100 g of the food.

(4) If a claim in relation to the lactose content of a food for special medical purposes is made the label on the package of food must include the average quantity of the lactose and galactose in the food, expressed per given quantity of the food.

[13.4] *omitting the editorial note after subclause 15(5).*

[14] **Standard *2.10.2*** *is varied by omitting subclause 5(2) and the following editorial note, substituting –*

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

[15] **Transitional Provisions**

[15.1] **Transition period** means the period starting on the date of commencement of Standard 1.2.7 and ending on the date of repeal of Standard 1.1A.2.

[15.2] During the transition period, a food must comply with:

(a) Standard 1.2.7; or
(b) Standard 1.1A.2, and the rest of the Australia New Zealand Food Standards Code as if items [1] to [14] of this Schedule had not commenced,

but not a combination of both.

[15.3] Subclause 1(2) of Standard 1.1.1 does not apply to the variation of the *Australia New Zealand Food Standards Code* made by item [2.3].

Attachment B – Explanatory Statements

Standard 1.2.7 – Nutrition, Health and Related Claims

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P293 to implement the then Australia and New Zealand Food Regulation Ministerial Council[15] Policy Guideline for the development of the regulatory framework for the management of nutrition, health and related claims. The Authority considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act and has approved a draft Standard.

On 6 June 2008, the then Australia and New Zealand Food Regulation Ministerial Council asked FSANZ to review its decision in relation to the new Standard. FSANZ has reviewed its decision and has re-affirmed the approval of Standard 1.2.7 subject to amendments in response to the review request and to additional advice in July 2012 from the COAG Legislative and Governance Forum on Food Regulation[16], regarding the regulatory approach for general level health claims.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

The Authority has approved a new Standard 1.2.7 – Nutrition, Health and Related Claims. The purpose of this Standard is to regulate the use of nutrition content claims and health claims on food labels and in advertisements for food. It will consolidate 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 will replace the transitional standard – Standard 1.1A.2 – Transitional Standard – Health Claims.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

---

[15] Now known as the COAG Legislative and Governance Forum on Food Regulation
[16] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

4. Consultation

The Authority's consideration of P293 has included six rounds of public consultation following assessments, the preparation of a draft Standard, a draft variation and associated reports. Public submissions were called for in 2004, 2005, 2007, 2009 and 2012. In addition, targeted consultation about the regulation of general level health claims was undertaken in 2011 and 2012 with key stakeholders.

A Standards Development Advisory Committee (SDAC) was established with representatives from the industry sector, the relevant State and Territory government agencies and consumer organisations to provide ongoing advice to the Authority throughout the standard development process. The SDAC contributed a broad spectrum of knowledge and expertise covering industry, government, research and consumers. The SDAC was involved in the initial development of the new Standard, however it was not active during the review of the Standard that commenced in 2008.

A Regulation Impact Statement was required because the proposed variation, Standard 1.2.7, is likely to have an impact on businesses and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Commencement

Standard 1.2.7 commences on gazettal. There will be a transition period of three years, starting when Standard 1.2.7 commences and ending when Standard 1.1A.2 is repealed. During that period Standard 1.1A.2 will operate concurrently with Standard 1.2.7.

During the transition period, if Standard 1.1A.2 is relied on, the changes made to other Standards under Proposal P293 have no effect. For a particular food, either Standard 1.2.7 and the changes made to other Standards, or the Code (including Standard 1.1A.2) as it was immediately prior to the commencement of Standard 1.2.7 can be relied on, but not a combination of both.

Three years after the gazettal of Standard 1.2.7 and associated variations, the Transitional Standard 1.1A.2 ceases to operate and the conditions in Standard 1.2.7 must be met. All food labels and advertising in the marketplace at that time must comply with Standard 1.2.7 and the variations to other standards made under Proposal P293.

7. Variations

Part 1 —Purpose and interpretation

Clause 1 outlines the purpose of the Standard.

Clause 2 sets out definitions for terms used in the Standard. In particular, a nutrition content claim is defined as a claim about the presence or absence of certain properties of food (the properties are listed in the definition). A health claim is a claim that a food or property of food has or may have a health effect. These definitions depend on the definition of a 'claim' as defined in Standard 1.1.1, which includes implied claims.

Part 2 — Claims framework and general principles

Clause 3 prohibits nutrition content claims and health claims from being made about kava (as standardised in Standard 2.6.3), an infant formula product (as standardised in Standard 2.9.1) and food containing more than 1.15% alcohol by volume. However a nutrition content claim about the energy content or carbohydrate content of a food containing more than 1.15% alcohol by volume is permitted.

Clause 4 lists the foods that do not need to comply with the Standard. For example, food delivered to a vulnerable person by a delivered meal organisation does not need to comply with the Standard. The definition of 'vulnerable person' in Standard 3.3.1 does not apply to the use of this term in Standard 1.2.7.

Clause 5 makes it clear that the Standard does not apply to certain claims or declarations, for example, claims permitted by other standards in the Code.

Clause 6 describes how the requirements of the Standard apply to different forms of food. The Table to clause 6 sets out different types of food and the form of the food to which the requirements of the Standard apply. To determine the form of the food to which the requirements of the Standard apply, the following should be taken into account:

- the information on the label for the food, including the directions for use
- any information provided in an advertisement for the food.

Clause 7 prohibits therapeutic claims. A prohibition on therapeutic claims assists to clarify the interface between foods and goods for therapeutic use, given that therapeutic claims are characteristically a feature of goods for therapeutic use. This prohibition maintains the existing prohibition on making claims of therapeutic or prophylactic action currently in the transitional standard 1.1A.2.

A claim that compares a food with a good that is represented to be for therapeutic use, or is likely to be taken to be for therapeutic use, is also not permitted. An exception to this prohibition exists if a statement is permitted by another provision of the Code. Subclause 8(3) of Standard 2.6.2 permits a claim about the treatment of a condition (namely, mild dehydration). This is currently the only express permission for a statement that refers to the alleviation of a condition.

Clause 8 is designed to prohibit any claim that compares the vitamin or mineral content of one food with that of any other food. This is an existing provision in Standard 1.3.2 that has been moved to Standard 1.2.7.

Clause 9 clarifies that there is flexibility in the actual wording that can be used in a nutrition content claim or health claim, i.e. the wording of a claim is not prescribed. The statements or information that are required to be on a label or in an advertisement can be worded as desired, as long as the effect of the required statement or information, as described in the Standard, is not altered or contradicted.

Part 3 – Requirements for nutrition content claims and health claims

Division 1 – Nutrition content claims

A nutrition content claim, as defined in clause 2, is a claim about the presence or absence of certain properties of food, which are listed in the definition.

Clause 10 provides that, if a nutrition content claim is made, it must be presented together with a description of the form of the food to which the claim relates, unless the claim relates to the food in the form in which it is sold. This requirement relates back to clause 6 which describes how the requirements of the Standard apply to different forms of food.

Clause 11 deals with nutrition content claims about the properties of food set out in Schedule 1, e.g. nutrition content claims about the fat content of a food.

Schedule 1 has two types of conditions in it: general claim conditions and specific claim conditions. Subclause 11(2) provides that foods carrying nutrition content claims about a property of food listed in Column 1 must meet the general claim conditions in Column 2 that correspond with that property of food, if there are any. Subclause 11(3) provides that foods carrying nutrition content claims using a specific descriptor (e.g. 'good source', 'free', 'reduced') listed in Column 3 (or a similar descriptor) must meet the general claim conditions in Column 2 as well as the specific claim conditions in Column 4 that align with the descriptor and the property of food that is the subject of the claim.

Subclause 11(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 11(4) makes it clear that the 7 g requirement prevails.

Subclause 11(5) provides that only certain nutrition content claims about lactose and trans fatty acids can be made. Only the descriptors listed in Column 3 of Schedule 1 (or similar descriptors) corresponding to lactose or trans fatty acids, as applicable, can be used. For example, the claims 'free of trans fatty acids' and 'no trans fatty acids' can be made but 'low in trans fatty acids' is prohibited.

Subclause 11(6) has the effect that descriptors, for example 'high', 'low' or 'medium', cannot be used in relation to glycaemic load claims, however numbers of the measure can be used, for example, GL = 30.

Subclause 11(7) has the effect that the only nutrition content claims that can be made about gluten are 'low', 'free', 'high' and 'contains' (or claims using similar wording).

Subclause 11(8) makes it clear that in addition to the descriptors listed in Column 3 of Schedule 1, any other descriptor can also be used in a nutrition content claim to describe the amount of a property of food listed in Schedule 1. However the restrictions mentioned in earlier subclauses still apply. For example, a 'high energy' claim is permitted even though the descriptor 'high' or similar is not listed in Column 3 adjacent to energy. If descriptors other than those listed in Column 3 (or similar descriptors to those in Column 3) are used, the general claim conditions adjacent to the property of food that is the subject of the claim must be met (if any), but there are no specific conditions that apply. For example, a 'good source of polyunsaturated fatty acids' claim could be made if the food meets the conditions in Column 2 that apply to claims about polyunsaturated fatty acids.

Clause 12 sets out the conditions for making nutrition content claims about properties of food that are not mentioned in Schedule 1, e.g. biologically active substances. The descriptors listed in Column 3 of Schedule 1 cannot be used in these nutrition content claims, e.g. 'good source of x', 'increased x'; except for descriptors indicating the food does not contain the property of the food, e.g. 'free'.

Claims that the food contains (e.g. ‘source of x’, ‘contains x’) or does not contain (e.g. ‘free of x’) the property of food can be made. In addition, paragraph 12(1)(b) permits nutrition content claims that specify the presence of a certain amount of the property of food in a specified amount of the food, e.g. ‘contains 10 g of x per serving’.

Clause 13 permits certain nutrition content claims about choline, fluoride or folic acid to be made about a food, but only if a health claim about that substance is made about that same food. Claims that the food contains choline, fluoride or folic acid (e.g. ‘source of choline’) can be made in this instance. In addition, paragraph 13(1)(b) permits nutrition content claims that specify the presence of a certain amount of choline, fluoride or folic acid in a specified amount of the food. The descriptors listed in Column 3 of Schedule 1 cannot be used in these nutrition content claims, e.g. ‘good source’, ‘increased’. Specific permission for nutrition content claims about choline, fluoride and folic acid (a synthetic form of the vitamin folate) is necessary because they are not permitted by the conditions for making nutrition content claims about vitamins and minerals in Schedule 1 (as they are vitamins or minerals but are not listed in Column 1 of the Schedule to Standard 1.1.1). However nutrition content claims about folate are permitted by the conditions for making nutrition content claims about vitamins in Schedule 1.

Clause 14 provides that words which imply slimming cannot be used in a nutrition content claim about energy, instead of the descriptor ‘diet’. ‘Diet’ claims have been permitted under the transitional standard and it is not intended to prohibit the use of ‘diet’ as a descriptor if the conditions of use are satisfied. However, the use of other terms that suggest slimming properties is not permitted.

Clause 15 deals with nutrition content claims that are ‘comparative’. Subclauses (1) and (2) describe what comparative claims are. Subclause (3) sets out some additional labelling information that must be provided with a comparative claim.

Division 2 – Health claims

Health claims are claims (including implied claims) that a food or property of food has or may have a health effect. A health effect means an effect on the human body. A high level health claim is a health claim that refers to a serious disease or a biomarker of a serious disease. A general level health claim is any other health claim that is not a high level health claim. These definitions are in clause 2.

Clause 16 has the effect that an application or proposal to add a new general level health claim to Schedule 3 will be subject to the provisions in the FSANZ Act that apply to high level health claims variations.

Subclause 17(1) requires that for all health claims, the conditions in subclause 17(2) must be met. In addition, for high level health claims, the conditions in subclause 17(3) must be met, and for general level health claims, the conditions in subclause 17(4) must be met.

Subclause 17(2) requires that if a health claim is made about a food, that food must meet the nutrient profiling scoring criterion (NPSC). This requirement does not apply to foods standardised in Part 2.9 of the Code (Special Purpose Foods) (subclause 17(5)). Instructions on how to calculate the nutrient profiling score of a food are provided in Schedule 5. In order to meet the NPSC, the score of a food must meet the nutrient profiling score specified in Schedule 4.

Subclause 17(3) prohibits high level health claims unless they are derived from a relationship between a food or property of food and a corresponding health effect listed in Schedule 2.

The food about which the high level health claim is made must meet any applicable conditions that are specified in Column 5 of Schedule 2. For example, for a health claim about salt and blood pressure, the food must meet the conditions for salt or sodium nutrition content claims specified in Column 4 of Schedule 1 corresponding to 'low'.

For general level health claims, subclause 17(4) specifies the two ways in which a claim is permitted to be made. The general level health claim can be derived from a relationship between a food or property of food and a corresponding health effect listed in Schedule 3. The food about which the general level health claim is made must meet any applicable conditions that are specified in Column 5 of Schedule 3.

Alternatively, a general level health claim can be based on a relationship between a food or property of food and a health effect that has been established by a process of systematic review. Under this option, paragraph 17(4)(b) requires that the person responsible for making the general level health claim must have notified the Chief Executive Officer (CEO) of Food Standards Australia New Zealand (FSANZ) of the actual relationship that has been established between a food or property of food and a health effect (upon which the general level health claim is based). The notified relationship must have been established by the process for systematic review as outlined in Schedule 6.

Clause 18 sets out the requirements that must be met if a general level health claim is based on a relationship between a food or property of food and a health effect that has been notified to the CEO of FSANZ under paragraph 17(4)(b). The person giving this notification must provide their name and the Australian or New Zealand address of that person, and certify that the relationship that has been notified has been established by a process of systematic review as described in Schedule 6. Further, if requested by a relevant authority, records must be provided to it that demonstrate the systematic review was conducted in accordance with the requirements for systematic review outlined in Schedule 6. Those records must also demonstrate that the notified relationship is a reasonable conclusion of the systematic review. 'Relevant authority' is defined in clause 2 of Standard 1.1.1 as the authority responsible for the enforcement of the Code.

Subclause 18(2) clarifies that if the certificate required by subclause 18(1)(c) is provided for a body corporate, the certificate must be signed by a senior officer of that body corporate.

Clause 19 sets out what a health claim must say and the statements that must be made together with the health claim.

Subclause 19(1) applies to high level health claims and general level health claims based on relationships between a food or a property of food and a health effect listed in Schedules 2 and 3 respectively. The health claim must state the food or property of food and the specific health effect claimed for that food or property of food, as mentioned in the applicable Schedule. Paragraph 19(1)(b) requires that the relevant population group from Column 3 of the applicable Schedule (if any) must be stated together with the health claim.

Subclause 19(2) applies to general level health claims that are based on a relationship between a food or property of food and a health effect that has been notified to the CEO of FSANZ. The general level health claim must state the food or property of food and the specific health effect, based on the notified relationship. It must also state the relevant population group, if a target population group is identified in the conclusion of the systematic review.

Subclause 19(3) provides that the health claim must also be presented together with a dietary context statement and a description of the form of the food to which the claim relates.

Subclause 19(5) provides an exemption from the dietary context statement if the health claim is on a label of a small package. Subclause 19(6) specifies that the form of the food does not need to be stated if the claim relates to the food in the form in which it is sold.

Subclause 19(4) outlines what must be included in the dietary context statement. The dietary context statement must state that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods and must be appropriate for the claim being made. For health claims based on a relationship described in Schedules 2 or 3, words to the effect of the relevant dietary context statement in Column 4 of those Schedules must also be used. For general level health claims based on a relationship notified to the CEO of FSANZ, the dietary context statement must be consistent with the conclusions of the systematic review.

As outlined in clause 9, the actual wording that is used in the health claim can be modified from the wording mentioned in Schedules 2 or 3 as long as the effect is not altered.

Clause 20 allows some elements of a health claim to be presented as a separate statement in what is called a split health claim. However, those elements must appear on the same label or in the same advertisement as the complete statement required by clause 19. An indication of where the complete statement is located must be provided with the separate elements. For example, the split health claim 'calcium for normal bone and teeth structure' can be presented on the main panel of a food package, accompanied by a directive statement such as 'see back of pack', with the complete claim 'calcium for normal bone and teeth structure when consumed as part of a healthy diet including a variety of foods' provided on the back of the same package.

The effect of clause 21 is that an additional 'healthy diet' context statement is not required if a health claim about phytosterols, phytostanols or their esters is presented together with the advisory statement required by clause 2 of Standard 1.2.3.

Division 3 – Endorsements

Endorsements are nutrition content claims or health claims that are made with the permission of an endorsing body.

Clause 22 imposes conditions on endorsing bodies. The terms 'endorsing body' and 'endorsement' are defined in clause 2.

Clause 23 sets out the requirements for an endorsement to be validly made. An endorsing body must satisfy criteria set out in clause 22. Endorsements are exempt from the other requirements of the Standard (except clause 7), to allow for endorsement programs which use the criteria set by the endorsing body. Clause 23 also contains record-keeping requirements for suppliers who use endorsements. Required records must be kept for a certain period of time and presented to the relevant authority (defined in clause 2 of Standard 1.1.1) on request. Subclause (2) is designed to deal with an endorsement that is placed on a label prior to importation. It provides that the importer of the food must comply with the record-keeping requirements of this clause.

Division 4 – Additional labelling of food required to meet the NPSC

Clause 24 indicates where the method for calculating the NPSC is described.

Clause 25 sets out some additional labelling requirements for food that is required to meet the NPSC in order to make a claim.

Subclause (5) outlines how this additional information must be provided if the food in question is exempt from the requirement to bear a label under clause 2 of Standard 1.2.1.

Clause 26 provides exemptions from these additional labelling requirements for food in small packages.

Explanatory Statement

Food Standards (Proposal P293 – Nutrition, Health & Related Claims - Consequential) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P293 to implement the COAG Legislative and Governance Forum on Food Regulation Policy Guideline for the development of the regulatory framework for the management of nutrition, health and related claims. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard.

On 6 June 2008, the then Australia and New Zealand Food Regulation Ministerial Council[17] asked FSANZ to review its decision in relation to the new Standard. FSANZ has reviewed its decision and has re-affirmed the approval of Standard 1.2.7 subject to amendments in response to the review request and to additional advice in July 2012 from the COAG Legislative and Governance Forum on Food Regulation[18], regarding the regulatory approach for general level health claims.

Following consideration by COAG Legislative and Governance Forum on Food Regulation section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

The purpose of this variation is to repeal Standard 1.1A.2 – Transitional Standard – Health Claims so that it can be replaced with a new Standard. The variation also makes a number of consequential amendments to Standards 1.1.1, 1.2.1, 1.2.8, 1.3.2, 2.6.2, 2.6.4, 2.9.1, 2.9.2, 2.9.3, 2.9.4, 2.9.5 and 2.10.2.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

[17] Now known as the COAG Legislative and Governance Forum on Food Regulation
[18] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

4. Consultation

The Authority's consideration of Proposal P293 has included six rounds of public consultation following assessments, the preparation of draft Standards, a draft variation and associated reports. Public submissions were called for in 2004, 2005, 2007, 2009 and 2012.

A Standards Development Advisory Committee (SDAC) was established with representatives from the industry sector, the relevant State and Territory government agencies and consumer organisations to provide ongoing advice to the Authority throughout the standard development process. The SDAC contributed a broad spectrum of knowledge and expertise covering industry, government, research and consumers. The SDAC was involved in the initial development of the new Standard, however it was not active during the review of the Standard that commenced in 2008.

A Regulation Impact Statement was required because the proposed variation, Standard 1.2.7, is likely to have an impact on businesses and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Commencement

Items [1] to [14] amend existing Standards. Each of these amendments other than items [2.3], [4] and [13] will commence on gazettal.

Items [2.3] and [4], which give effect to the repeal of the transitional health claims standard, commence three years after gazettal. Item [13.1], which removes the reference to the transitional health claims standard from Standard 2.9.5 when that transitional standard is repealed, also commences three years after gazettal.

Items [13.2] to [13.4] anticipate the commencement of Standard 2.9.5 and will commence immediately after the commencement of Standard 2.9.5.

Item [15] is a transition provision that establishes a regulatory framework that permits the co-existence of alternate forms of regulation during the transition period. The transition period is the period that ends when the transitional health claims standard is repealed. A supplier will be able to elect whether to comply with the new measures established in Standard 1.2.7 or the measures that had been established immediately prior to the commencement of Standard 1.2.7, but not a combination of those alternatives.

7. Variations

Item [1] Standard 1.1.1

Item [1.1] omits from subclause 1(6) the reference to transitional standards generally and replaces that reference with a reference to Standard 1.1A.6. The effect is to remove any application of subclause 1(6) to the transitional health claims standard, when it is repealed.

Item [1.2] amends the current definition of 'claim' to make it clear that a claim can be express or implied.

Item [2] Standard 1.1A.2

Item [2.1] replaces the Purpose statement in Standard 1.1A.2 with an editorial note which explains the transitional arrangements following the gazettal of Standard 1.2.7.

Item [2.2] amends the time in which Standard 1.1A.2 ceases to have effect, from two years to three years.

Item [2.3] repeals the transitional health claims standard—Standard 1.1A.2, at the end of the transition period.

Item [3] Standard 1.2.1

Item [3] inserts a reference to subclause 24(5) of Standard 1.2.7 in the list of labelling provisions in subclause 2(2) of Standard 1.2.1.

Item [4] Standard 1.2.7

This provision removes a transitional editorial note from Standard 1.2.7 at the end of the transition period during which Standard 1.1A.2 has parallel operation.

Item [5] Standard 1.2.8

Item [5] amends Standard 1.2.8.

Under item [5.1], the second paragraph of the current purpose statement is revised as an editorial note and updated to take account of the new Standard 1.2.7.

Item [5.2] removes the definitions of gluten and nutrition claim as these have been incorporated into Standard 1.2.7 (where the 'nutrition claim' definition has been revised and referred to as 'nutrition content claim').

Under items [5.3] and [5.6] the existing calculation for determining average energy content has been incorporated into subclause 1(3) and reformatted.

In item [5.6] subclause 1(2) is added to Standard 1.2.8, so that the definitions in Standard 1.2.7 also apply in Standard 1.2.8.

Item [5.7] inserts new clause 1A to clarify that Standard 1.2.8 does not apply to infant formula products, which are standardised in Standard 2.9.1.

Item [5.8] updates the existing clause 4 to refer to terminology used in the new Standard 1.2.7. The term 'claims requiring nutrition information' has been introduced and defined.

Items [5.10], [5.13] and [5.14] amend current paragraph 5(1)(g) and subclauses 5(4) and 5(5) to incorporate the new term 'claim requiring nutrition information' (see item [5.8] above). Declarations of certain substances must be declared in the nutrition information panel when 'claims requiring nutrition information' are made.

Item [5.11] inserts new subclauses 5(1A) and (1B). The new provision restates the current requirement in subclause 12(2), which is deleted by a later provision.

Item [5.15] amends existing subclause 7(2), which deals with declaring percentage daily intake (DI) information in a nutrition information panel.

The amendment maintains the current provision in the Code, however, the requirement for these declarations to be on a per serving basis has been added. Subparagraph 7(2)(b)(ii) requires certain statements to be included in the nutrition information panel if percentage daily intake information is provided. The amendment means these statements are shorter than the statement currently required.

Item [5.16] adds new clauses 7A and 7B. Clause 7A sets out the requirements for percentage recommended dietary intake (RDI) declarations in the nutrition information panel when certain claims are made. Requirements for percentage RDI declarations were previously in Standard 1.3.2. Clause 7B sets out the requirements if the percentage RDI or DI information required or permitted by clause 7 or 7A is also declared outside the nutrition information panel.

Item [5.17] revises the existing clause 8 to provide clarity about the nutrient declarations required on the label of a small package if a claim requiring nutrition information is made.

Item [5.18] corrects a typographical error in clause 11.

Item [5.19] adds a new clause 11A which requires that if a claim requiring nutrition information is made about a food that is required to be prepared and consumed according to directions, with at least one other food, the nutrition information panel must include an additional column at the right hand side, specifying certain information about the additional food or foods.

Item [5.20] deletes Division 3, which contained conditions for making nutrition claims. Most of these conditions have been moved to Standard 1.2.7.

Item [5.21] adds a new clause 19 which gives permission for certain nutrients to be declared voluntarily in the nutrition information panel, without requiring the declaration to meet the conditions for the applicable nutrition content claim in Standard 1.2.7. New subclause 19(4) allows a nutrition information panel to be provided voluntarily on a food containing more than 1.15% alcohol by volume. Such a declaration will not be regulated as a nutrition content claim.

Item [6] Standard 1.3.2 – Vitamins and Minerals

Item [6] amends Standard 1.3.2. Items [6.3], [6.4] and [6.5] omit the conditions for making claims about the presence of vitamins and minerals and good source claims about vitamins and minerals (clauses 4, 6 and 9) as these are now contained in Standard 1.2.7 or 1.2.8. The remaining clauses 5 and 8 have minor reformatting amendments and are renumbered.

Item [8] Standard 2.6.4 – Formulated Caffeinated Beverages

Item [8] amends Standard 2.6.4. This amendment deletes the current prohibition on making nutrition content claims about vitamins and minerals in formulated caffeinated beverages. This prohibition is restated in Standard 1.2.7 (conditions for making claims about vitamins and minerals in Schedule 1).

Item [9] Standard 2.9.1 – Infant Formula Products

Item [9] amends Standard 2.9.1. Item [9.1] removes the reference to ‘claims’ from the existing requirement in clause 28.

Item [10] Standard 2.9.2 – Foods for Infants

Item [10] amends Standard 2.9.2. It deletes the current cross reference to the exemption (in Standard 1.2.8) from the requirement to declare the sodium and potassium content of a food for infants when a claim about the salt, sodium or potassium content of that food is made. A new subclause is included to provide the exemption from declaring the potassium content. As the sodium content must be declared in the nutrition information panel on foods for infants, an exemption from the requirement to declare the sodium content when a claim about salt, sodium or potassium has not been included.

Item [11] Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods

Item [11] amends Standard 2.9.3. New subclauses are 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 on other foods.

Items [11.2], [11.3], [11.5] and [11.6] amend Standard 2.9.3 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.

Item [12] Standard 2.9.4 – Formulated Supplementary Sports Foods

Item [12] amends Standard 2.9.4. It removes the cross reference to the requirement in Standard 1.3.2 to declare certain information when a claim about the presence or absence of a vitamin or mineral is made about a formulated supplementary sports food. This requirement is now in Standard 1.2.8 (which applies to formulated supplementary sports foods).

Item [13]

Item [13.2] amends Standard 2.9.5, when that Standard commences, to refer to the definition of nutrition content claim in Standard 1.2.7.

Items [13.3] to [13.4] amend the conditions in Standard 2.9.5 for making claims about lactose content to be consistent with the claims in Standard 1.2.7.

Items [2.3] and [15]

Item [15] establishes a transition period starting when Standard 1.2.7 commences and ending when Standard 1.1A.2 is repealed. During that period of three years Standard 1.1A.2 will operate concurrently with Standard 1.2.7.

During the transition period, if Standard 1.1A.2 is relied on, the changes made to other Standards by the other items in this Variation have no effect. For a particular food, either Standard 1.2.7 and the changes made to other Standards, or the Code (including Standard 1.1A.2) as it was immediately prior to the commencement of Standard 1.2.7 can be relied on, but not a combination of both.

Three years after the gazettal of Standard 1.2.7 and associated variations, the Transitional Standard 1.1A.2 ceases to operate and the conditions in Standard 1.2.7 must be met. All food labels and advertising in the marketplace at that time must comply with Standard 1.2.7 and the variations to other standards outlined above.

Minor technical amendments

Items [5.4], [5.5], [5.9], [5.12], [5.22], [6.1], [6.2], [6.6], [7], [9.2], and [14] contain minor amendments that are necessary as a result of the new Standard and other amendments mentioned above. For example, in item [5.4] a cross reference to the definition of 'claim requiring nutrition information' is provided to clarify where this definition is located within the Standard; item [7] updates the existing clause to reflect new terminology and location of claim conditions in Standard 1.2.7.