



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

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CONSULTATION PAPER

PROPOSAL P293

NUTRITION, HEALTH AND RELATED CLAIMS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 1 February 2008
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

FSANZ is seeking comment on three issues relating to the proposed Standard for Nutrition, Health and Related Claims. These issues are:

- the food eligibility criteria for nutrition content and general level health claims about vitamins and minerals;
- the Scientific Substantiation Framework; and
- criteria for nutrition content claims about saturated fatty acids as a low proportion of total fatty acid content, and ‘free’ of *trans* fatty acids.

Under the approach proposed in the Draft and Preliminary Final Assessment Reports for Proposal P293 – Nutrition, Health and Related Claims, there are differing ‘food vehicle eligibility criteria’ for foods carrying nutrition content and health claims, depending on the subject of the claim. Health claims relating to vitamins and minerals can only be made on ‘claimable’ foods as defined in Standard 1.3.2, whereas health claims relating to macronutrients and biologically active substances can only be made on foods which are considered eligible on the basis of their overall nutrient profile, as determined by the Nutrient Profiling Scoring Criteria (NPSC). The NPSC take account of energy, saturated fat, sugar, sodium, protein, fruit and vegetable content. Nutrition content claims relating to vitamins and minerals can only be made on claimable foods.

However, nutrition content claims relating to other properties of a food can be made on any food, unless specific food eligibility criteria are defined for that particular claim. The dual approach for the food eligibility criteria were intended to be an interim measure, subject to further consideration as part of the review of the new Nutrient Reference Values. However, FSANZ now recommends that this issue is addressed as part of Proposal P293 in order to address inconsistencies between different types of claims, to prevent consumer confusion and to ease any enforcement difficulties relating to different approaches and transition times.

The final Scientific Substantiation Framework for health claims has not previously been made available for public consultation. FSANZ has amended the Scientific Substantiation Framework as published in the Draft Assessment Report so that it now only sets out the options for the scientific substantiation of food-health relationships that underpin general level health claims i.e. detail relating to the substantiation of nutrition content claims and high level health claims and detailed guidance material have been removed. These changes have been introduced to address concerns relating to the enforceability of the substantiation of general level health claims and also remove redundancy in the documentation. The list of scientific source documents which can be used as one of the methods for substantiating general level health claims has been modified to remove ambiguities around acceptable sources. The drafting in the proposed Standard has been amended to clearly reflect that the Scientific Substantiation Framework must be relied upon to substantiate a general level health claim and that the supplier of the food has records that substantiate the claim making those records available to relevant enforcement authorities upon request.

The third area for consultation is the proposal to include a new nutrition content claim relating to the proportion of fatty acids in a food and to amend the conditions for *trans* fatty acid ‘free’ claims to allow products with a more beneficial fatty acid profile to carry such claims.

These amendments have arisen from submissions received from industry and public health to improve the information available so that consumers are able to choose products with a preferable fatty acid profile.

Preferred Approach

Food vehicle eligibility criteria for general level health claims:

- All health claims, whether about micronutrients, macronutrients or biologically active substances are subject to the Nutrient Profiling Scoring Criteria.
- Foods carrying nutrition content claims are not subject to food vehicle eligibility criteria i.e. the 'claimable food' requirement for nutrition content claims about vitamins and minerals is removed.

Substantiation of a general level health claim can be made by any of the following four methods:

Method 1	List of nutrient function statements.
Method 2	Prescribed list of pre-approved high level food-health relationships.
Method 3	Prescribed list of scientific source documents.
Method 4	Systematic review

Nutrition content claims in relation to the overall fatty acid profile:

- For nutrition content claims about saturated fatty acids as a low proportion of total fatty acids content:
 - the food must make an associated mono or polyunsaturated fatty acid claim; and
 - the food must contain, as a proportion of the total fatty acid content no more than 28% saturated fatty acids and *trans* fatty acids and no less than 40% of monounsaturated or polyunsaturated fatty acids, as applicable.
- Alternative criteria applied to *trans* fatty acid 'free' claims to permit them on foods that contain no more than 28% saturated fatty acids as a proportion of the total fatty acid content.

Consultation

The issue of food vehicle eligibility criteria for vitamin and mineral claims has previously been consulted on in the Draft Assessment Report and the proposed recommendation (unamended) was included in the Preliminary Final Assessment Report. FSANZ has had targeted consultations on the issue with industry and public health stakeholders, representatives of the jurisdictions and the health claims Standard Development Advisory Committee.

The Scientific Substantiation Framework was developed with the assistance of the Scientific Advisory Group for health claims, building on the experience gained from the pre-approval of the high level health claims which are included in the proposed health claims standard.

An earlier version was consulted on in the Draft Assessment Report and submitters' comments have been taken into account in preparing the revised framework document.

The specific proposals relating to the fatty acid claims have not previously been consulted on, but have arisen from stakeholder concerns relating to providing consumers with adequate information to make informed choices relating to the fatty acid composition of foods, including *trans* fatty acid levels.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Consultation paper for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment of this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as confidential commercial information. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

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

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
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Submissions need to be received by FSANZ by 6pm (Canberra time) 1 February 2008.

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

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

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

INTRODUCTION

Food Standards Australia New Zealand (FSANZ) issued a Draft Assessment Report in December 2005 setting out a proposed approach to the regulation of nutrition, health and related claims together with the proposed new Standard 1.2.7 – Nutrition, Health and Related Claims (available from the FSANZ website at <http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm>). A Preliminary Final Assessment Report was released in April 2007 (available from the FSANZ website at the above link) asking for submissions on a number of aspects which had been amended as a result of submitters' comments to the Draft Assessment Report. As a result of submissions to the two preceding Reports, targeted consultations and further consideration within FSANZ, we have amended our recommendation on the specification of the food vehicle eligibility criteria in relation to nutrition content claims and general level health claims about vitamins and minerals and propose to include a new nutrition content claim relating to the fatty acid profile of foods and to amend the conditions for making a *trans* fatty acid 'free' claim. The substantiation framework for health claims in its final form has not been made available for public consultation previously and submitters responding to the Draft Assessment Report commented that they would like to see this before finalisation of the Proposal. Therefore, stakeholder comments are also sought on the proposed approach for substantiation of general level health claims and the Scientific Substantiation Framework document.

The development of Standard 1.2.7 is guided by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) policy guidance on the regulation of nutrition, health and related claims (referred to as the Policy Guideline), which is available on the FSANZ website at <http://www.foodstandards.gov.au/standardsdevelopment/ministerialcouncilpo1603.cfm>.

1. CLAIMABLE FOOD CRITERIA OR NUTRIENT PROFILING SCORING CRITERIA FOR CLAIMS ABOUT VITAMINS AND MINERALS

1.1 Recommendation

FSANZ proposes the following for food vehicle eligibility criteria for nutrition content and health claims about vitamins and minerals:

Nutrition content claims will not be subject to food vehicle eligibility criteria, i.e. the claimable food requirement is removed. This is consistent with the approach for nutrition content claim about other nutrients and biologically active substances.

General level health claims All general level health claims, whether about vitamins, minerals, macronutrients or biologically active substances, are subject to the nutrient profiling scoring criteria. The claimable food requirement is removed from claims about vitamins and minerals.

High level health claims Criteria for the composition of foods carrying high level health claims will be developed on a case-by-case basis as part of the approval process for the claim. Nutrient profiling scoring criteria apply to each of the high level health claims that have been proposed so far (including claims about vitamins and minerals).

1.2 The issue

Under the approach proposed in the Draft and Preliminary Final Assessment Reports there are differing ‘food vehicle eligibility criteria’ for foods carrying nutrition content and health claims, depending on the subject of the claim. Concern has been raised that this situation creates confusion and a number of anomalies; for example, there are additional food vehicle eligibility criteria for nutrition content claims about vitamins and minerals compared with nutrition content claims about other nutrients or substances. Also, because the food vehicle eligibility criteria for health claims about vitamins and minerals differ to those for health claims about other nutrients, a food may be eligible to carry a health claim about a vitamin or mineral but not about another nutrient, or vice versa.

1.3 Draft Assessment Report and Preliminary Final Assessment Report - approach taken and submitter comments

The proposed Nutrition, Health and Related Claims Standard comprises two types of claims; nutrition content claims and health claims. A nutrition content claim is a claim about the presence or absence of a property of a food. A health claim is a claim that refers to a relationship between a food or a property of a food, and a health effect. There are two levels of health claims; general level health claims and high level health claims.

High level health claims are health claims that make reference to a serious disease or a biomarker of a serious disease whereas a general level health claim does not. High level health claims require pre-market assessment and approval by FSANZ.

Both nutrition content claims and health claims must comply with certain pre-requisite compositional conditions. There are two sets of compositional conditions that foods must meet in order to make a claim (depending on the type of claim being made):

- qualifying criteria – the food must contain a certain quantity of the nutrient or substance that is the subject of the claim; and
- food vehicle eligibility criteria – the food itself must be eligible to carry a claim.

Specific qualifying criteria have been determined for each of the different types of claims and are not under consideration, however, the food vehicle eligibility criteria differ depending on the subject of the claim and this is the issue for consultation.

Two types of food vehicle eligibility criteria have been proposed in previous consultation documents:

- nutrient profiling scoring criteria (NPSC) (referred to as disqualifying criteria in the Draft Assessment Report); and
- the claimable food criteria.

The application of the food vehicle eligibility criteria was dependent on the type of claim being made (see Figure 1).

Nutrition content claims: For claims about vitamins and minerals, the food was subject to the ‘claimable food’¹ criteria as currently defined in Standard 1.3.2. For claims about macronutrients and other substances, there were no food vehicle eligibility criteria.

General level health claims: For claims about vitamins and minerals, the food remained subject to the ‘claimable food’ criteria as currently defined in Standard 1.3.2 and were specifically exempt from the NPSC. For claims about macronutrients and other substances, foods were subject to the NPSC.

High level health claims:- Criteria for the composition of foods carrying high level health claims will be developed on a case-by-case basis as part of the approval process for the claim. NPSC apply to each of the high level health claims that have been proposed so far (including claims about vitamins and minerals) as it was considered that these fulfil the objective of ensuring that foods bearing health claims are consistent with national nutrition guidelines. However, for future high level health claims it may be determined that additional or different food vehicle eligibility criteria are required.

Nutrition content claims		General level health claims		High level health claims
		Vitamin and mineral claims	Other	
Vitamin and mineral claims	Other			
Qualifying criteria	Qualifying criteria Some specific food composition criteria for certain claims only	Qualifying criteria Claimable food criteria Wording conditions	Qualifying criteria NPSC Wording conditions	
Claimable food criteria				

Figure 1: Food vehicle eligibility criteria proposed in the Preliminary Final Assessment Report

As indicated in Figure 1, the conditions for making claims (excluding high level health claims) about vitamins and minerals differed from the conditions for making claims about other nutrients or substances.

¹ **Claimable food** means a food which consists of at least 90% by weight of –

- (a) (i) primary foods; or
(ii) foods listed in the Table to clause 3; or
- (b) (i) a mixture of primary foods; and/or
(ii) water; and/or;
(iii) foods listed in the Table to clause 3 excluding butter, cream and cream products, edible oils, edible oil spreads and margarine.

Primary food means fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish.

For claims about substances and nutrients other than vitamins and minerals it was considered that to overlay any further requirements in relation to foods able to carry nutrition content claims would be overly prescriptive. Following consideration of the findings of consumer research FSANZ is maintaining this approach. In both the Draft and Preliminary Final Assessment Reports it was proposed that food vehicle eligibility criteria would be applied to foods carrying general level health claims in order to avoid the promotion, through the use of general level health claims, of certain categories of foods that are inconsistent with national dietary guidelines. This approach will be maintained.

The rationale for the above approach for claims about vitamins and minerals was explained as follows in the Draft Assessment Report:

Vitamins and minerals covered under Standard 1.3.2 of the Code present a particular case in relation to disqualifying criteria. These nutrients are subject to 'claimable food' criteria, which in essence, serve the same purpose as disqualifying criteria. At the time of developing the concept of 'claimable foods', FSANZ devised the above definition to act as a criterion that ensured claims made in relation to vitamins and minerals were placed only on foods consistent with healthy eating guidelines. Therefore, the 'claimable food' criterion is acting in a similar way to the generic disqualifying criteria that have been developed for general level health claims.

Whilst there are merits in having a consistent approach to the application of disqualifiers across all general level health claims, including claims in relation to vitamins and minerals, FSANZ considers that this is an issue that would be more appropriately considered once the new Nutrient Reference Values are adopted. At this time there is likely to be a review of several standards in the Code which are underpinned by nutrient reference values, including Standard 1.3.2 and FSANZ will need to consider general level health claims (and high level claims) made in relation to vitamins and minerals and determine whether the 'claimable food' criterion should be replaced by the generic disqualifying criteria. Subsequently for the time being, general level health claims in relation to vitamins and minerals will not be subject to generic disqualifying criteria but will be required to meet the claimable food criterion.

Submitters that commented on this approach were mainly from industry and the jurisdictions. There was general opposition to use of the claimable food criteria for claims about vitamins and minerals, with the lack of consistency between the regulation of vitamin and mineral claims with claims about other nutrients or substances cited as the main reason. It was considered that if a food contains a claimable amount of a vitamin or mineral, then it should be able to declare this. There was objection to the use of the claimable food criteria providing an advantage to foods that are permitted to be fortified over those that are not, in being able to make truthful and substantiated claims about their vitamin and mineral content.

Some submitters noted concern about the current definition of 'claimable food' including that it is difficult to work out and understand, is outmoded, and the appropriateness of butter, cream, edible oils and spreads as claimable foods needs to be reconsidered.

1.4 Nutrient Reference Values proposal and review of ‘claimable food’ approach

New Nutrient Reference Values (NRVs) for Australia and New Zealand were published in May 2006 (NHMRC and Ministry of Health, 2006). Currently, the *Australia New Zealand Food Standards Code* (Code) prescribes nutrient reference values (Recommended Dietary Intakes and Estimated Safe and Adequate Daily Dietary Intakes) for three age groups as the basis for various criteria for vitamin and mineral claims for nutrition labelling.

The new NRVs developed by the National Health and Medical Research Council (NHMRC) and the New Zealand Ministry of Health have an expanded range of values encompassing Estimated Average Requirements and Recommended Dietary Intakes, or alternatively Adequate Intakes, for most nutrients as well as Upper Levels of Intake for some nutrients. Values for these requirements are stipulated for several age/sex groups and the life stages of pregnancy and lactation. Many factors will need to be considered during the process of updating the reference values contained in the Code to reflect the new NRVs, since one value per nutrient will need to be selected from the broad range of NRV values for each of the specified population groups. It is not FSANZ’s intention to review which foods can be fortified as part of the process to incorporate the new NRVs into the Code. However, some consideration may be given to the level of fortification, and to the basis of any claims related to fortification.

As outlined in section 1.3, it was stated in the Draft Assessment Report that FSANZ intended to address the conditions for vitamin and mineral claims when Standard 1.3.2 was to be reviewed as part of the proposal(s) to adopt the new NRVs into the Code. In so doing, we would seek consistency within the regulation of nutrition and health claims more broadly, including qualifying criteria and disqualifying criteria (now referred to as NPSC). At the time this decision was made, the NRVs were in draft form and it was considered that to wait until their release before doing this work would delay the planned release of the Draft Assessment Report for Proposal P293. The issue of incorporating the NRVs into health claims regulations was revisited after the new NRVs were released in May 2006. Although the decision remained the same, the rationale for not expanding the scope of Proposal P293 to incorporate the new NRVs was that the NRV work was too large in its own right and should be considered separately. It was agreed that NRV work is of high priority and should if possible be undertaken prior to the end of the transition period for implementation of Proposal P293, to minimise costs to industry resulting from further regulatory changes.

FSANZ has revisited this decision in light of the altered timelines for Proposal P293 and the initial scoping of the NRV review. It is now considered that the component of the NRV review relating to the food eligibility in relation to vitamin and mineral claims can be partitioned into Proposal P293 and progressed within current planned timelines (refer to section 5).

1.5 Analysis of options

The following options can be considered for the food vehicle eligibility criteria for nutrition content claims and health claims about vitamins and minerals.

Option 1: Retain the claimable food criteria as proposed in the Draft Assessment Report and Preliminary Final Assessment Report:

- (a) foods carrying nutrition content claims about vitamins and minerals must be ‘claimable’ foods;
- (b) foods carrying general level health claims about vitamins and minerals must be ‘claimable’ foods.

Option 2: Amend claimable food approach (hybrid):

- (a) foods carrying nutrition content claims about vitamins and minerals must be ‘claimable’ foods;
- (b) foods carrying general level health claims must meet the NPSC.

Option 3: Amend claimable food approach (remove claimable food criteria):

- (a) no food vehicle eligibility criteria for foods carrying nutrition content claims;
- (b) foods carrying general level health claims must meet the NPSC.

Notes:

1. Under each of these options, the approach proposed in the Preliminary Final Assessment Report for claims about other nutrients or biologically active substances (not vitamins or minerals) remains, i.e. for nutrition content claims there are no food vehicle eligibility criteria, and for general level health claims the food must be eligible under the NPSC.
2. The exemption from the NPSC for general level health claims about gluten and lactose, and on foods for infants, as proposed in previous consultation documents, will be retained.
3. There are additional qualifying criteria that a food must meet in order to carry a claim, for example, the food must contain at least 10% of the RDI for the vitamin or mineral that is the subject of the claim. These additional criteria will remain and are not under consideration in this report. They are therefore not included in the options above.
4. Food vehicle eligibility criteria for high level health claims are not included in the options above as these would be considered on a case-by-case basis for each claim.

1.5.1 Pros and cons of each option

<p>Option 1: Retain claimable food criteria as proposed in the Draft Assessment Report and Preliminary Final Assessment Report:</p> <ul style="list-style-type: none"> (a) foods carrying nutrition content claims about vitamins and minerals must be ‘claimable’ foods; (b) foods carrying general level health claims about vitamins and minerals must be ‘claimable’ foods. 	
Pros	Cons
<ul style="list-style-type: none"> • Strongly maintains link between permission for fortification and all types of claim permissions about vitamins and minerals • <i>Status quo</i> – less industry impact in the short term • Consistent risk management (food vehicle eligibility criteria) approach for nutrition content claims and health claims about vitamins and minerals (excluding case by case for high level health claims) 	<ul style="list-style-type: none"> • Some high saturated fat/sugar/sodium foods e.g. some breakfast cereals, ice cream, cheese, etc may carry health claims about vitamins and minerals (but not about other nutrients/substances) • Different risk management system for claims about vitamins and minerals compared to other nutrients/substances:

<ul style="list-style-type: none"> • Allows vitamin and mineral nutrition content claims on a broad range of foods, for example all cereals, ice cream, soups, cheese 	<ul style="list-style-type: none"> – lack of sound rationale for different approaches – undermines approach for nutrition content claims about other substances based on consumer research that additional risk management for nutrition content claims is not needed – inequitable for nutrition content and health claims about vitamins and minerals compared to other nutrients/substances – confusion for industry, consumers and enforcement regarding conditions for claims <ul style="list-style-type: none"> • Would take a long time to achieve a common approach for food eligibility for health claims due to transition times for NRVs and eventual withdrawal of claimable food approach
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<p>Option 2: Amend claimable food approach (hybrid): (a) foods carrying nutrition content claims about vitamins and minerals must be ‘claimable’ foods; (b) foods carrying general level health claims must meet the NPSC.</p>	
<p>Pros</p>	<p>Cons</p>
<ul style="list-style-type: none"> • Consistent risk management (food vehicle eligibility criteria) approach for health claims about all nutrients (excluding case by case for high level health claims) • Health claims about vitamins and minerals cant be made on some claimable foods which do not meet NPSC because of their saturated fat/sugar/sodium content – less misleading for consumers in considering ‘health attributes’ of a product • Maintains link between permission to fortify and permission to make a nutrition content claim (but not a health claim). 	<ul style="list-style-type: none"> • Different risk management system for nutrition content claims about vitamins and minerals compared to other nutrients/substances: <ul style="list-style-type: none"> – lack of sound rationale for different approaches – undermines approach for nutrition content claims about other substances based on consumer research that additional risk management for nutrition content claims is not needed – inequitable for nutrition content claims about vitamins and minerals compared to other nutrients – confusion for industry, consumers and enforcement regarding conditions for claims • Some claimable foods can not make health claims because of their saturated fat/sugar/sodium content, resulting in loss of claims and labelling changes²

² Of the 1399 food labels collected in 2005 for the Label Monitoring Survey, 18 (1.3%) were ‘claimable foods’ featuring function claims about vitamins and/or minerals. Approximately 28% of these foods would not be eligible to carry those claims under the proposed NPSC (FSANZ, 2007a)

<p>Option 3: Amend claimable food approach (remove claimable food criteria): (a) no food vehicle eligibility criteria for foods carrying nutrition content claims; (b) foods carrying general level health claims must meet the NPSC.</p>	
Pros	Cons
<ul style="list-style-type: none"> • Consistent and equitable risk management approach (food vehicle eligibility) for claims about nutrition content and health claims about all nutrients • Less confusion for industry, consumers and enforcement regarding conditions for making claims • Health claims about vitamins and minerals can not be made on some claimable foods which do not meet NPSC because of their saturated fat/sugar/sodium content – less misleading for consumers in considering ‘health attributes’ of a product • Transition period for change in approach to claimable food would be aligned to the health claims transition period • More potential for industry to make nutrition content claims about vitamins and minerals • Supported by the approach for nutrition content claims based on consumer research that additional risk management for nutrition content claims is not needed. 	<ul style="list-style-type: none"> • Loss of additional risk management for nutrition content claims about vitamins and minerals • Permission to fortify is disconnected from permission to make health claims (but not nutrition content claims) • Potentially less fortification uptake • Some claimable foods can not make health claims because of their saturated fat/sugar/sodium content, resulting in loss of claims and labelling changes²

1.5.2 Impact of the different approaches

FSANZ has undertaken some initial modelling to assess the impact of option 3 on food products contained within our nutrient profiling database.

1.5.2.1 Health claims

The following table lists current ‘claimable foods’ (from the Table to clause 3 of Standard 1.3.2) and indicates how their eligibility for making health claims would be affected, should they become subject to the NPSC (using the NPSC model proposed in the Preliminary Final Assessment Report). Eligibility was assessed using food products included in the FSANZ database (n>10 000).

Table 1: Estimates of ‘claimable foods’ affected by change in food vehicle eligibility criteria to NPSC

‘Claimable food’ as defined in Standard 1.3.2	Eligible under NPSC	Ineligible under NPSC
Biscuits & crackers (not more than 200g/kg fat and not more than 50g/kg sugars)	About 20% of crackers	About 80% of crackers All sweet biscuits
Breads	Most	A few (due to higher levels of any of the baseline nutrients)
Breakfast cereals	Lower sugar and salt varieties, rolled oats,	Those with higher salt or sodium content; some high fibre cereals have high sugar and salt levels

‘Claimable food’ as defined in Standard 1.3.2	Eligible under NPSC	Ineligible under NPSC
Cereal flours	All	
Pasta	Dried pasta	Some minute noodles or other pasta with salty sauces
Milk powders	All (when reconstituted) ¹	Except possibly a small number with unusually high fat levels
Modified and skim milks	Skim and low fat milk	Full fat milk with added omega-3 etc
Cheeses and cheese products	Most cottage and ricotta cheese Reduced fat varieties which do not have excessive sodium levels if they also have >320 mg calcium	Regular fat hard cheese, some lower fat cheeses with high sodium levels, processed cheese if sodium levels are very high Fruit and nut cheeses
Yoghurts	Most (variety of whole, reduced fat, sweetened types)	Some (due to higher saturated fat and/or sugar levels)
Dairy desserts (with no less than 3.1% mass per mass milk protein)	Low fat mousse, custard etc Many full fat varieties	Some, depends on saturated fat and sugar levels
Ice cream and ice confections (with no less than 3.1% mass per mass milk protein)	98% fat free Ice confections depending in saturated fat and sugar content	Most full fat varieties (due to saturated fat levels)
Cream and cream products (no more than 40% mass per mass milk fat)		All
Butter ²		All
Edible oil spreads and margarines ² (no more than 28% total saturated fatty acids and trans fatty acids)	Most, including those with phytosterols	Some (due to saturated fat levels) Some polyunsaturated margarines with higher sodium levels
Edible oils ² (no more than 28% total saturated fatty acids and trans fatty acids)	If saturated fat is less than approximately 21%	Oils with higher saturated fat levels)
Extracts (of meat, vegetables or yeast) and foods containing no less than 800g/kg of these extracts	Peanut butter with lower amounts of salt and sugar Cashew and almond spreads	Those with high sodium levels e.g. yeast spreads, meat and fish pastes, olive tapenade. Regular peanut butter Chocolate hazelnut spread
Fruit juice, vegetable juice (see table to Clause 3 Standard 1.3.2 for specifics)	If 100% juice and sodium levels are not excessive	
Fruit drink (see table to Clause 3 Standard 1.3.2 for specifics)		All with less than 80% juice content
Fruit cordial ³	Low joule cordial	Sugar sweetened cordial
Composite products - soups	Most eligible (when reconstituted)	A few (due to higher sodium levels)
Analogues derived from cereals (beverages containing no less than 0.3% mass per mass protein derived from cereals)	Rice milk with protein content similar to cow milk	Low protein rice milks
Analogues derived from legumes		
i. Beverages (no less than 3% mass per mass derived from legumes)	Plain soy milks	Higher sugar soy milks

‘Claimable food’ as defined in Standard 1.3.2	Eligible under NPSC	Ineligible under NPSC
ii. Analogues of meat (no less than 12% energy values from protein and food contains 5g protein per serve)	unclear as have limited data available for these products.	unclear as have limited data available for these products.
iii. Analogues of yoghurts and dairy desserts (no less than 3.1% mass per mass derived from legumes)	Some (e.g. soy yoghurts and tofu desserts), depends on saturated fat and sugar content	
iv. Ice cream (no less than 3.1% mass per mass derived from legumes)		Some (e.g. tofu ice creams)
v. Cheese analogues (must contain no less than 15% mass per mass protein derived from legumes)	Unclear as have no data available for these products.	Unclear as have no data available for these products.
Primary foods (fruit, vegetable, grain, legume, meat, milk, eggs, nuts, seeds, fish)	Fruit Vegetables Most nuts Fresh eggs Legumes, baked beans Smoked and canned fish with lower salt levels Leaner cuts of meat, chicken Skim, low fat and most whole milk (plain) Flavoured skim and low fat milk	Macadamia nuts are unclear as there are several different composition data Roasted salted nuts Fattier cuts of meat, sausages Smoked and canned fish with higher salt levels Some whole milks; flavoured whole milk
Foods which are a mixture of primary foods, water, and those listed in the table to Clause 3 (as above)	Eligibility unclear as have no specific data for these products.	

¹ Most whole, reduced and skim milks are currently eligible under Category 2 of the nutrient profiling scoring criteria

² Cheese, edible oils, edible oil spreads, margarines and butter fall within category 3 of the nutrient profiling scoring criteria

³ Nutrient profiling scoring criteria will apply to cordials in their diluted form

1.5.2.2 Nutrition content claims

Permissions for vitamin and mineral nutrition content claims would also change if the claimable food criteria were removed. Instead of being restricted to claimable foods, vitamin and mineral content claims could be made on any food meeting the relevant qualifying criteria; for example, potato crisps that contain a sufficient level of vitamin C could carry a ‘good source of vitamin C’ claim.

1.6 Recommended approach

The recommended approach is option 3 i.e. to remove the ‘claimable food’ criteria so that there are no food vehicle eligibility criteria for foods carrying nutrition content claims, and foods carrying general level health claims must meet the NPSC. The reasons for this recommendation are that:

- FSANZ now considers that the claimable food approach can be reviewed under Proposal P293, separately from the NRV proposal;
- any resulting changes to labels and associated costs to industry could be made collectively with any other labelling changes arising out of Proposal P293;
- this approach provides more consistency across all claims about different nutrients, and is therefore less confusing for industry, consumers and enforcement; and
- the NPSC are more effective at restricting health claims to foods consistent with dietary guidelines and more consistent with the Ministerial Council Policy Guideline on Nutrition, Health and Related Claims, than the claimable food criteria.

2. CRITERIA FOR NUTRITION CONTENT CLAIMS ABOUT 'SATURATED FATTY ACIDS AS A LOW PROPORTION OF THE TOTAL FATTY ACIDS CONTENT' AND ABOUT 'TRANS FAT FREE'

2.1 Criteria for nutrition content claims about saturated fatty acids as a low proportion of the total fatty acids content

2.1.1 Recommendation

FSANZ proposes the following criteria for nutrition content claims about saturated fatty acids as a low proportion of total fatty acids content:

- the food must make an associated mono or polyunsaturated fatty acid claim; and
- the food must contain, as a proportion of the total fatty acid content no more than 28% saturated fatty acids and *trans* fatty acids and no less than 40% of monounsaturated or polyunsaturated fatty acids, as applicable.

2.1.2 The issue

Under the proposed Standard 1.2.7, 'low in saturated fatty acids' nutrition content claims are limited to foods that contain no more saturated and *trans* fatty acids than 0.75 g per 100 mL of liquid food and 1.5 g per 100 g of solid food. As a result, some foods have a fatty acid profile that is comparatively low in saturated fatty acids (e.g. vegetable oils, edible oil spreads, nuts, avocados) but do not meet the conditions for a 'low saturated fatty acid' nutrition content claim. Under the draft Standard proposed in the Preliminary Final Assessment Report, there was lack of clarity around the requirements for claims such as 'low proportion of saturated fat'. Concern has been raised by some stakeholders that this situation would leave consumers without adequate information to make informed choices and does not allow suppliers to effectively promote the consumption of foods with a comparatively beneficial fatty acid profile.

This situation has implications on a broad range of foods (see Table 2).

Table 2: Food categories that contain some foods with less than 28% saturated fatty acids as a proportion of total fatty acid content

Food Categories	
Beverages	Ice Cream
Breakfast cereals	Legumes
Biscuits	Meal and main dishes
Breads	Meat & Alternatives
Cakes	Noodles
Cereal Snack foods	Nuts & Seeds
Cheeses	Pasta
Confectionery	Rice
Convenience foods	Sandwiches
Cooked seafood	Sauces
Crackers	Snack foods
Dressings	Soups
Eggs	Spreads
Fats and oils	Vegetables
Fish & Seafood	Yoghurts
Fruits	

2.1.3 Draft Assessment Report and Preliminary Final Assessment Report – approach taken and submitter comments

The regulation of claims regarding a low proportion of saturated fatty acids of the total fatty acids content has not been formally considered during the assessment of Proposal P293 until now. Under the drafting proposed in the Draft Assessment Report and Preliminary Final Assessment Report, conditions were not prescribed for the use of these claims.

The conditions proposed in the Draft Assessment Report and Preliminary Final Assessment Report for a ‘low saturated fatty acid’ claim were as follows:

- ≤0.75 g in total of saturated and *trans* fatty acids per 100 ml of liquid food; and
- ≤1.5 g in total of saturated and *trans* fatty acids per 100 g of solid food.

A number of stakeholders (from the industry and public health sectors) expressed concern about the conditions proposed for ‘low’ saturated fatty acid claims in response to both the Draft Assessment Report and the Preliminary Final Assessment Report. There were requests for the use of an alternative condition of no more than 28% saturated fatty acids and *trans* fatty acids as a proportion of the total fatty acid content. Reasons for this included that the proposed approach failed to recognize that fats as eaten comprise a mixture of saturated and unsaturated fatty acids; and that the proposed conditions disadvantage foods high in fat, even if they are high in monounsaturated and polyunsaturated fatty acids, such as nuts, seed bread, some vegetable oils, and avocados. It was suggested that consumers will be confused when information relating to low saturated fat intake (including the associated high level health claim) is not permitted to appear in association with or on foods that are recommended in dietary guidelines and which are good sources of unsaturated fats (e.g. oils, dressings, nuts, seeds and margarines). Further to this, it was felt that restricting claims to those about unsaturated fats on these types of foods will restrict the provision of information that could otherwise be provided about the most useful dietary changes for achieving heart health.

One submitter noted that the public health messages regarding the ratio of unsaturated fats to saturated is of value, but considered that total saturated fat intake still needs to be reduced and many people are unaware that fats with higher levels of unsaturated fats still contain saturated fats.

2.1.4 Further information

According to the *Dietary Guidelines for Australian Adults*, saturated fatty acids are the strongest dietary determinant of plasma LDL cholesterol concentration. This has been demonstrated repeatedly in controlled human experiments (NHMRC, 2003).

FSANZ has been concerned that 'low' saturated fat claims should not mislead consumers regarding the absolute saturated fatty acid content of the food they are purchasing and therefore 'low' saturated fatty acid claims have been limited to foods that contain no more saturated fatty acids than 0.75 g per 100 mL of liquid food and 1.5 g per 100 g of solid food. In addition, claims should not result in an increased consumption of saturated fatty acids.

The Dietary Guidelines for Australian Adults (NHMRC, 2003) recommend limiting saturated fat and moderating total fat intake. To assist consumers in achieving this, the Guidelines suggest a number of practices to optimise the fat profile of the diet. These include choosing predominantly unsaturated vegetable oils, unsaturated margarines rather than butter or hard margarine, unsaturated salad creams and dressings and other suggestions that rely on consumers having adequate information to choose foods with a healthier fatty acid profile. The New Zealand Food and Nutrition Guidelines make similar recommendations (Ministry of Health, 2003).

Recent discussions with stakeholders have highlighted the possibility that the current requirements for low saturated fatty acid claims may not provide consumers with enough information to make informed decisions when purchasing foods such as oils, edible oil spreads, nuts, salad dressings, avocados, olives, dips, high seed content breads, eggs, and fresh and processed fish and other seafood. Stakeholders have argued that a claim with words to the effect 'polyunsaturated margarine, low proportion of saturated fatty acids of the total fatty acid content' would inform consumers about the whole fatty acid profile of a product.

2.1.5 Analysis of options

The following options can be considered for claims about saturated fatty acid as a low proportion of the total fatty acid content the food:

Option 1 – Status quo

Remain silent on claims about saturated fatty acids as a low proportion of the total fatty acids. Claims regarding 'saturated fatty acids as a low proportion of total fatty acids' could be made in isolation of any other claim.

2.1.5.2 Option 2 – New category of claim to the effect that a food has a low proportion of saturated fatty acids of total fatty acid content, to be made as an extension to the polyunsaturated/monounsaturated fatty acid claim

Foods can make a claim to the effect of a 'low proportion of saturated fatty acids' if:

- the food makes an associated mono or polyunsaturated fatty acid content claim; and
- the food contains, as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and *trans* fatty acids and no less than 40% of monounsaturated or polyunsaturated fatty acids, as applicable.

Option 3 – New category of claim to the effect that a food has a low proportion of saturated fatty acids of total fatty acid content, limited to foods with more than 30 g fat per 100 g of food

Foods can make a claim to the effect of a ‘low proportion of saturated fatty acids’ if:

- the food contains, as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and *trans* fatty acids; and
- the food contains at least 30 g of fat per 100 g.

Option 4 – New category of claim to the effect that a food has a low proportion of saturated fatty acids of total fatty acid content, limited to foods that meet the nutrient profiling scoring criteria (NPSC)

Foods can make a claim to the effect of a ‘low proportion of saturated fatty acids’ if:

- the food contains, as a proportion of the total fatty acid content no more than 28% saturated fatty acids and *trans* fatty acids; and
- the food meets the NPSC.

2.1.5.1 Pros and cons of options

Option 1: <i>Status quo</i>. Remain silent on claims about saturated fatty acids as a low proportion of the total fatty acid content.	
Pros	Cons
<ul style="list-style-type: none"> • Provision to make the claim is retained. 	<ul style="list-style-type: none"> • Conditions for the claim not regulated, meaning consumers could be misled by such claims • Consumers may not get adequate information to make informed choices if claims are made on foods with inappropriate fatty acid profile • Does not provide industry with certainty around the claim and therefore doesn't encourage innovation

<p>Option 2: New category of claim to the effect that a food has a low proportion of saturated fatty acids of total fatty acid content, to be made as an extension to the polyunsaturated/ monounsaturated fatty acid claim</p> <ul style="list-style-type: none"> the food must make an associated mono or polyunsaturated fatty acid content claim; and the food must contain, as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and <i>trans</i> fatty acids and no less than 40% of monounsaturated or polyunsaturated fatty acids, as applicable. 	
Pros	Cons
<ul style="list-style-type: none"> Claims on foods with a low proportion of saturated fatty acids of the total fatty acid content are permitted on a wider range of foods than any of the other options giving consumers wider informed choice Claims are restricted to foods that are also proportionally high in poly or monounsaturated acids Where a claim is made, consumers are informed about the whole fatty acid profile of a product which would aid understanding and reduce consumer confusion about the claim Approach consistent with other fatty acid claims 	<ul style="list-style-type: none"> Claims can be carried on foods that are high in saturated fat and these may be chosen in preference to foods that are lower in saturated fat Claims can be carried on foods that are very low in total fat content, potentially misleading consumers that the fatty acid profile is significant in these products Consumers may be confused between ‘low saturated fat’ and ‘proportionately low in saturated fat’ claims

<p>Option 3: New category of claim to the effect that a food has a low proportion of saturated fatty acids of total fatty acid content, limited to foods with certain fat content:</p> <ul style="list-style-type: none"> the food must contain, as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and <i>trans</i> fatty acids; and the food must contain at least 30 g of fat per 100 g 	
Pros	Cons
<ul style="list-style-type: none"> Claims cannot be carried on foods that are low in total fat content, preventing consumers from being misled that the fatty acid profile is significant in these products Allows for provision of information to consumers about the proportion of saturated fatty acid and restricts such claims to foods where the fatty acid profile is significant Claims are restricted to foods that are also proportionally high in poly or monounsaturated fatty acids 	<ul style="list-style-type: none"> Claims on foods with a low proportion of saturated fatty acids of the total fatty acid content are permitted on a narrower range of foods than Option 2 giving consumers less informed choice Claims can be carried on foods that are high in saturated fat and these may be chosen in preference to foods that are lower in saturated fat overall Consumers may be confused between ‘low saturated fat’ and ‘proportionately low in saturated fat’ claims Approach inconsistent with other fatty acid claims

<p>Option 4: New category of claim to the effect that a food has a low proportion of saturated fatty acids of total fatty acid content, limited to foods that meet the NPSC:</p> <ul style="list-style-type: none"> the food must contain, as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and <i>trans</i> fatty acids; and the food must meet the NPSC 	
Pros	Cons
<ul style="list-style-type: none"> Claim is allowed on a broader range of foods not limited by total fat content The broader nutritional profile of the food is also taken into account Claims are restricted to foods that are also proportionally high in poly or monounsaturated fatty acids 	<ul style="list-style-type: none"> Claims on foods that are low in saturated fatty acids as a proportion of the total fatty acid content are allowed on a narrower range of foods than Option 2 giving consumers fewer choices Approach inconsistent with other fatty acid claims Consumers may be confused between ‘low saturated fat’ and ‘proportionately low in saturated fat’ claims

2.1.5.2 Impact of the different approaches

The analysis below is based on foods containing, as a proportion of the total fatty acid content, no more than 28% saturated and *trans* fatty acids, and a total saturated fatty acid content of more than 1.5 g per 100 g, i.e. it is assumed that foods that have less than 1.5 g saturated fat per 100 g of food would make a ‘low in saturated fatty acids’ claim rather than the proposed ‘low proportion of saturated fatty acids’ claim. For example, milk and alternatives would be unlikely to make a proportionate claim because all the milks in the FSANZ database that are low in saturated fatty acids as a proportion of the total fatty acid content (less than 28%) would be eligible to make a ‘low saturated fatty acid’ claim.

Option 1

Option 1 follows the *status quo*: claims about ‘low proportion of saturated fatty acids’ remain unregulated and would only be subject to the general requirements for nutrition content claims and fair trade legislation. Foods containing more than 1.5 g saturated fatty acids per 100 g of solid food or 0.75 g per 100 mL of liquid food can not make a ‘low saturated fatty acid’ claim.

Option 2

The qualifying criteria for Option 2 are the same as those for poly and monounsaturated fatty acid claims. A wide range of foods would be able to carry claims about ‘low proportion of saturated fatty acids’. Ten per cent, that is 1084 foods, of the foods in FSANZ’s nutrient profiling database (which contains data on 10 761 foods) would qualify for the proposed nutrition content claim but not for a ‘low saturated fatty acid’ claim. The food categories that are represented are listed in Table 2. It is possible that a small number of these foods may have less than 40% poly or monounsaturated fatty acids as a proportion of total fatty acids and therefore, not be able to make the proportional saturated fatty acid claim. The current database used by FSANZ has limited information on poly and monounsaturated fatty acid content therefore, we are interested in obtaining further relevant data from industry.

Option 3

The food must contain, as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and *trans* fatty acids; and a 30 g minimum fat content per 100 g of food is required for the food to be permitted to carry the claim. Almost all fats and oils and edible oil spreads that meet the fatty acid qualifying criteria would also meet this additional criterion for fat content. However, a small number of fat modified cheeses and non dairy cheese analogues have less than 30 g of fat per 100 g. Some foods from most of the categories listed in Table 2 would not be able to make claims, with the exception of cheeses and fats and oils. However, a wide range of foods other than fats and oils across many categories would be able to carry claims about a 'low proportion of saturated fatty acids'. Examples include chocolate jam cookies, chocolate nut slice, chocolate coated hazelnuts, creamy mayonnaise, poppy seeds, peanuts, hollandaise sauce, pesto sauce, potato crisps, chocolate hazelnut spread, peanut butter, and olive tapenade.

Option 4

The food must contain, as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and *trans* fatty acids; and in addition the food must be rated eligible according to the NPSC.

Foods that meet the qualifying criteria were checked against the NPSC (excluding oils, edible oils spreads and cheeses). About 50% of those foods were eligible to make a claim, for example, muesli, currant bun, apricot breakfast bar, boiled egg, canned salmon, avocado, falafel, cashew nuts, peanuts, couscous, peanut butter, tahini, potato chips fried in canola oil. Examples of the 50% of foods (excluding oils, edible oils spreads and cheeses) not eligible under the NPSC include savoury muffin, carrot cake with cream cheese icing, pita crisps with sesame, Caesar dressing, sardines in oil, lemon sorbet, salted peanuts roasted in oil, potato crisps, chocolate hazelnut spread, peanut butter, and potato chips.

Of the 113 fats, oils and cheeses that qualified for the claim, 75% were found to be eligible to make the claim when checked against the NPSC, for example, light canola spread, some polyunsaturated margarines, canola margarine, canola oil, corn oil, olive oil, peanut oil, safflower oil, sunflower oil, and margarine with phytosterols. Examples of the 25% not eligible to make the claim under the NPSC include some polyunsaturated margarines and spreads, and hardened shortening.

2.1.6 Recommended approach

FSANZ recommends option 2 i.e. a new category of claim to the effect that a food has a low proportion of saturated fatty acids of total fatty acid content, whereby the food must make an associated mono or polyunsaturated fatty acid nutrition content claim; and the food must contain, as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and *trans* fatty acids and no less than 40% of monounsaturated or polyunsaturated fatty acids (as applicable to the claim).

Permission for this claim will facilitate provision of adequate information for consumers to choose foods with a healthier fatty acid profile as recommended in dietary guidelines. Provision of criteria in the draft Standard for this claim will also provide greater certainty for both industry and enforcement.

Under the recommended approach, consumers' understanding of the 'low proportion of saturated fat' claim will be facilitated compared with the other options because the wording of the claim must include information about the beneficial fatty acids in the food, thus providing more complete information about the whole fatty acid profile of the food. This additional wording will also help to distinguish the claim from a 'low saturated fatty acid' claim. As for all fatty acid claims, the total *trans*, poly, monounsaturated and saturated fatty acids will be required to be declared in the nutrition information panel, thus providing further information to support the claim.

It is acknowledged that these claims will be permitted on foods that contain an overall high saturated fat content per serve and these may compete with foods that are lower in saturated fat overall. In addition, these claims could be carried on foods that are overall very low in total fat content potentially misleading consumers that the fatty acid profile is significant in these products. However, requests for the use of these claims from industry and public health stakeholders has been directed at their use on foods such as oils, spreads, and nuts where the overall fatty acid profile is appropriate for such claims. The compositional criteria for making the claim are the same as the current criteria for making claims about monounsaturated and polyunsaturated fatty acids in the Code, and FSANZ is not aware of any inappropriate usage of these claims in the marketplace.

2.2 Criteria for 'free of *trans* fatty acids' nutrition content claims

2.2.1 Recommendation

FSANZ recommends the following criteria for 'free of *trans* fatty acids' nutrition content claims:

- the food is free of *trans* fatty acids; and
- the food contains no more saturated fatty acids than 0.75 g per 100 mL of liquid food and 1.5 g per 100 g of solid food, or
- the food contains no more than 28% saturated fatty acids as a proportion of the total fatty acid content of the food.

2.2.2 The issue

Under the proposed Standard 1.2.7, a food carrying a claim that it is '*trans* fatty acid free' must not contain any detectable *trans* fatty acids. In addition, the food must contain no more saturated fatty acids than 0.75 g per 100 ml of liquid food and 1.5 g per 100 g of solid food. As a result, some foods (e.g. some plant oils) that are free of *trans* fatty acids and have a fatty acid profile that is comparatively low in saturated fatty acids, but which have a total saturated fat content higher than 1.5 g per 100 g of food (i.e. the criterion for a low saturated fat claim) cannot make '*trans* fatty acid free' claims. Concern has been raised that this situation would leave consumers without adequate information regarding the *trans* fatty acid content of food and would disadvantage certain products against others that are also free of *trans* fatty acids.

2.2.3 Preliminary Final Assessment Report - approach taken and submitter comments

There is consistent and robust evidence linking *trans* fatty acid intake with risk factors for coronary heart disease, including raised total cholesterol concentrations (FSANZ, 2007b). FSANZ has been concerned that claims that a food is ‘free’ of *trans* fatty acids should not mislead consumers regarding the saturated fatty acid content of the food making the claim and therefore conditions for such claims have included the saturated fatty acid content.

The intention for ‘*trans* fatty acid free’ claims in the Preliminary Final Assessment Report was that in addition to the food being free of *trans* fatty acids, it must also contain no more than 0.75 g of saturated fatty acids per 100 mL of liquid food and 1.5 g of saturated fatty acids per 100 g of solid food. However, the drafting of the conditions for this claim in draft Standard 1.2.7 stated ‘0.75 g of saturated and *trans* fatty acids per 100 mL of liquid food and 1.5 g of saturated and *trans* fatty acids per 100 g of solid food’. This will be corrected in the draft Standard in the Final Assessment Report to reflect the intention that food must be free of *trans* fatty acids.

Submitter comments in response to this approach that are applicable to this consultation included that the approach supported claims on manufactured food over less processed food. For example, dairy products and fruit can not be totally free of *trans* fatty acids whereas products like confectionery can. It was also suggested that foods that contain no *trans* fatty acids (e.g. nuts, seeds, avocado, olive oils) should be able to make the claim even if they are not ‘low’ in saturated fatty acids.

2.2.4 Analysis of options

The following options can be considered for the conditions for ‘*trans* fatty acid free’ claims:

Option 1: *Status quo*

Foods that claim to be ‘free’ of *trans* fatty acids must be free of *trans* fatty acids and:

- the food must contain no more saturated fatty acids than 0.75 g per 100 mL of liquid food and 1.5 g per 100 g of solid food.

Option 2: *Trans* fatty acid ‘free’ claims permitted on foods that are free of *trans* fatty acids and that contain:

- no more saturated fatty acids than 0.75 g per 100 mL of liquid food and 1.5 g per 100 g of solid food, or
- no more than 28% saturated fatty acids as a proportion of the total fatty acid content.

2.2.4.1 Pros and cons of each option

Option 1: <i>Status quo</i> , food carrying ' <i>trans</i> fatty acid free' claims must be free of <i>trans</i> fatty acids and contain no more saturated fatty acids than 0.75 g per 100 mL of liquid food and 1.5 g per 100 g of solid food.	
Pros	Cons
<ul style="list-style-type: none"> • <i>Trans</i> fatty acid claims restricted to foods that are also low in saturated fatty acids 	<ul style="list-style-type: none"> • Foods that are free of <i>trans</i> fatty acids and have a low proportion of saturated fatty acids of the total fatty acids content cannot make a <i>trans</i> fatty acid 'free' claim. The claim would not be permitted on a wide range of foods, particularly less processed foods. • Consumers may not get adequate information to make informed choices when purchasing foods that are free of <i>trans</i> fatty acids but cannot make that claim • Does not encourage industry to supply products that are free of <i>trans</i> fatty acids

Option 2: <i>Trans</i> fatty acid 'free' claims permitted on foods that are free of <i>trans</i> fatty acids and that contain	
<ul style="list-style-type: none"> • no more saturated fatty acids than 0.75 g per 100 ml of liquid food and 1.5 g per 100 g of solid food, <u>or</u> • no more than 28% saturated fatty acids as a proportion of the total fatty acid content. 	
Pros	Cons
<ul style="list-style-type: none"> • <i>Trans</i> fatty acid 'free' claims are permitted on a wide range of foods that have low saturated fatty acids or low proportion of saturated fatty acids of the total fatty acids content giving consumers improved informed choice • Claims are restricted to foods that are proportionally low in saturated fatty acids, i.e. foods with a beneficial fatty acid profile • Approach consistent with other fatty acid claims • Encourages industry to supply products that are free of <i>trans</i> fatty acids 	<ul style="list-style-type: none"> • Claims can be carried on foods that are higher in saturated fat per serve

2.2.4.2 Impact of the different approaches

Option 1

Option 1 follows the *status quo*: claims that foods are *trans* fatty acid 'free' must be true and the food must contain no more saturated fatty acids than 0.75 g per 100 mL of liquid food and 1.5 g per 100 g of solid food. Foods high in fat and high in absolute saturated fatty acid content would not be able to make a *trans* fatty acid 'free' claim, including vegetable oils, nuts, seeds and other foods high in total fat, including those that have a low proportion of saturated fatty acids of the total fatty acid content.

Option 2

The alternative qualifying criteria for Option 2, which limit claims to food with less than 28% saturated fatty acid as a proportion of total fatty acids, would allow a wide range of foods to carry ‘*trans* fatty acid free’ claims, as long as they are free of *trans* fatty acids.

2.2.5 Recommended approach

FSANZ recommends Option 2 – ‘*trans* fatty acid free’ claims are permitted on foods that are free of *trans* fatty acids and that contain no more saturated fatty acids than 0.75 g per 100 mL of liquid food and 1.5 g per 100 g of solid food, or no more than 28% saturated fatty acids as a proportion of the total fatty acid content.

Under this option, the claim is permitted on a wider range of foods than under Option 1, including foods such as oils and nuts with a beneficial overall fatty acid profile, i.e. the claim would not be limited to manufactured foods or foods that do not naturally contain fat as is largely the case with current provisions around saturated fatty acid claims.

3. SUBSTANTIATION OF FOOD-HEALTH RELATIONSHIPS FOR USE AS A BASIS OF GENERAL LEVEL HEALTH CLAIMS

3.1 Recommendation

FSANZ proposes that the Scientific Substantiation Framework will be inserted into draft Standard 1.2.7 as a Schedule; and relate only to general level health claims. The following methods for the substantiation of general level health claims apply:

Method 1 List of nutrient function statements. These are pre-approved and may be used without further substantiation.

Method 2 Prescribed list of pre-approved high level food-health relationships. These are pre-approved and may be used as the basis of a general level health claim without further substantiation providing that the general level health claim does not refer to a serious disease or to a biomarker of serious disease.

Method 3 Prescribed list of scientific source documents. Two corroborating sources are required in which the food-health relationship is clear, confident and definitive. No further substantiation is needed.

Method 4 Systematic review. This method may be used including if food-health relationships cannot be obtained using one of the previous methods. A systematic review may be particularly useful for substantiating recent food-health relationships that have not yet been published in textbooks or undergone a formal published systematic review.

3.1.1 Summary of changes since the Draft and Preliminary Final Assessment Reports

The strength of evidence required to substantiate a health claim was not explicitly stated in the Draft Assessment Report. In the Preliminary Final Assessment Report, a strength of evidence of ‘probable’ was proposed for the substantiation of general level health claims and ‘convincing’ for high level health claims. In response to jurisdictional concerns, there is now one strength of evidence that applies to general and high level health claims.

In the Draft Assessment Report, it was suggested that general level health claims could be substantiated by using a relatively ‘open’ list of source documents. In response to jurisdictional concerns, the use of source documents is now more prescriptive.

In the Draft Assessment Report, the Scientific Framework (Attachment 8) included chapters on content claims, high level health claims, and a guideline to applicants. These topics have been taken out of the framework and will be presented in other FSANZ documents.

3.2 Introduction

In the Draft Assessment Report, two high level principles were described. These principles are maintained and reiterated below:

- General level health claims will not be subject to pre-market assessment and approval by FSANZ because they do not reference a serious disease or a biomarker of a serious disease; and
- General level health claims will nonetheless be required to be scientifically substantiated. This requires the supplier to assess the evidence supporting the claim prior to market, holding this evidence and producing it at the request of enforcement officials.

3.3 The issue

A process for substantiating nutrition, health and related claims on foods was expressed in Attachment 8 of the Draft Assessment Report (available from the FSANZ website at <http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm>). This Scientific Substantiation Framework document was released for public comment and attracted a large number of submissions. Concerns were raised over the enforceability of the substantiation requirements of health claims and levels of evidence required for the substantiation of general level health claims which were not explicitly stated in the Draft Assessment Report. A Preliminary Final Assessment Report on Nutrition, Health and Related claims was subsequently prepared and released for public comment. Although the substantiation framework document was not included in the Preliminary Final Assessment Report, FSANZ recommended that the minimum level of evidence to support a general level health claim be established at ‘probable’. Several government agencies did not support a ‘probable’ level of evidence, again citing lack of clarity and unenforceability as key objections.

3.4 Amended approach to substantiation

3.4.1 Strength of scientific evidence

Some submitters were concerned about the strength of scientific evidence required to substantiate a health claim. The strength of evidence required was not explicitly stated in the Draft Assessment Report in which it was indicated that an assessment of the overall strength of evidence would have to be made and assigned a rating as ‘convincing’, ‘probable’, ‘possible’, or ‘insufficient’. In the Preliminary Final Assessment Report, FSANZ recommended that the minimum level of evidence to support a general level health claim could be established at ‘probable’ and that of a high level health claim at ‘convincing’. There was concern from some jurisdictions around a tiered approach to substantiation. However, as health claims are not required to refer to the strength of scientific evidence underpinning the claim, both general and high level health claims should be based on clear and definitive food-health relationships. In addition, the use of the descriptors ‘probable’ and ‘convincing’ has been discontinued because of possible confusion between the scientific and the legal use of these terms.

In assessing the strength of the evidence to substantiate general or high level health claims, the following must be applied:

- (a) the evidence must support a consistent association between the property of a food and the claimed health effect; and
- (b) the evidence must comprise a number of supportive, good quality human studies including some experimental studies; and
- (c) the evidence must support a food-health relationship that is biologically plausible; and there must be a causal relationship in which it is shown that consumption of a specifically characterised diet, food or component causes the health effect independent of other factors; and
- (d) to assess causality and the weight of evidence, most weight is given to well-designed experimental studies in humans.

This strength of evidence can be achieved through application of any of the listed four methods of substantiation. Method 1 uses a list of ‘well-established’ nutrient function statements with a high degree of certainty around the nutrient function. Method 2 is based on a rigorous pre-approval procedure conducted by FSANZ. Method 3 refers to criteria to be applied in assessing information found in listed authoritative documents in which definite food-health relationships may be used providing that the relationship is found in at least two corroborating sources. Method 4 directly applies the strength of scientific evidence.

Supporting documentation will be developed to assist stakeholders with the process of substantiation for all methods but particularly as it relates to Method 4.

3.4.2 Changes to methods of substantiation

A list of well-established nutrient function statements, generally sourced from the United Kingdom Joint Health Claims Initiative, was included in the Draft Assessment Report as a ‘pre-approved’ list. This list remains largely unchanged, although two changes have been made.

These are the nutrient function statement for docosahexaenoic acid (DHA) has been removed because there are no criteria for claims about DHA in the Code on which to base a general level health claim; and a vitamin A nutrient function statement has been added. The use of this list as a basis for making a general level health claim is referred to as Method 1. It was developed to assist smaller industry in selecting a nutrient function in the knowledge that these statements were sufficiently substantiated.

The Initial Assessment Report sought opinion as to which high level health claims might be of interest to stakeholders. Seven were selected and investigating these allowed the proposed substantiation framework to be tested. Details of the substantiation of four of the potential claims were released in the Draft Assessment Report and the remaining three were described in the Preliminary Final Assessment Report. Of these seven relationships, a convincing food-health relationship could not be substantiated for ‘wholegrains and coronary heart disease’ or for ‘long chain omega-3 fatty acids and cardiovascular disease’ and as a consequence these proposed relationships did not provide sufficient evidence to support a high level health claim.

However, in the Preliminary Final Assessment Report, FSANZ suggested that the relationship of long-chain omega-3 fatty acids with cardiovascular disease was ‘probable’ and therefore could be used to support a general level health claim. In submissions to the Preliminary Final Assessment Report, some jurisdictions objected to a general level health claim being made based on a relationship that was found not to be ‘convincing’. As previously indicated, the strength of the scientific evidence used to make a general level health claim should be based on clear and definitive food-health relationships. General level health claims may be based on food-health relationships that have been substantiated and pre-approved by FSANZ for high level health claims. These relationships are listed in the substantiation framework and may be used according to the conditions stated in Method 2.

Another approach given in the Draft Assessment Report for substantiating general level health claims was the use of published information. FSANZ had proposed a fairly ‘open’ list of information and in submissions to the Draft Assessment Report there was concern that this did not provide a consistent evidence base. The sources listed in the Draft Assessment Report are replicated below:

- national diet policy publications such as the Australian and New Zealand National Dietary Guidelines and review of Nutrient Reference Values;
- position papers and scientific reviews conducted by peak³ medical, nutrition, scientific or public health non-government authoritative organisations from Australia, New Zealand, and, where relevant, overseas countries;
- reviews conducted by internationally recognised scientific bodies;
- authoritative, current, science texts presently used in university dietetics courses; and
- reports of health claims assessed by overseas governments.

Comments indicated that this approach was too open to interpretation and that documents of very different scientific rigour could be used. The jurisdictions viewed this approach as unable to be enforced. FSANZ has reviewed the list of documents and made the following changes:

³ A “peak” organisation is an overarching body that is a lead representative for the interest it represents.

- Scientific reviews have been restricted to the Cochrane database of systematic reviews and the UK Joint Health Claims Initiative. Cochrane systematic reviews are recognised for their high standard in evidence-based analysis. The strength of evidence required as the basis of a general level health claim is consistent with the Cochrane systematic review process. The strength of evidence required to substantiate a general level health claim is also consistent with Joint Health Claims Initiative document that lists ‘well-established’ nutrient functions. Position papers and review articles are not always founded on a formal and transparent systematic review process. This is likely to lead to variable strengths of evidence among these reviews and for this reason FSANZ proposes that position papers and review articles appearing in the general scientific literature are not permissible as source materials on which to base general level health claims.
- In the Draft Assessment Report there was no indication as to what might constitute an ‘internationally recognised scientific body’. Some jurisdictions expressed reservations of having relatively loosely defined criteria for source documents as it could permit the use of inappropriate work. Acceptable scientific reviews conducted by internationally recognised bodies have been restricted to three World Health Organization (WHO) documents and the United States Institute of Medicine Dietary Reference Intake series. The WHO and Institute of Medicine documents are highly regarded and cover a broad range of foods and nutrients.
- In the Draft Assessment Report it was proposed that science texts used in dietetic courses be used for substantiating general level health claims. However, submitters commented that these texts cover a wide range of topics, some of which were not relevant to substantiating general level health claims. This approach also would have excluded appropriate textbooks that were not used in the dietetics courses. Thus, we have been more prescriptive in the type of textbook that could be used whilst broadening the range. Suggested textbooks are those in human nutrition whose authors are specialists in the topics covered. It is also a requirement that the textbook is edited by a specialist or specialists in human nutrition as this level of oversight provides a degree of peer-review. Nutritional science is evolving and to maintain relevance it is suggested that the textbooks used as the basis of a general level health claim should have been published within 10 years of the claim under consideration.

In addition, there is now a requirement that a food-health relationship must be found in at least two corroborating sources. The use of credible source documents is referred to as Method 3 for the substantiation of general level health claims.

The fourth method of substantiating general level health claims is to conduct a systematic review of the current scientific literature. This method may be useful for the substantiation of relatively recent food-health relationships that have not yet been published in textbooks or undergone an independent systematic review. Conducting a systematic review is complex and FSANZ will produce supporting documentation to assist in the process.

3.4.3 Re-structuring the framework document

FSANZ has found it necessary to restructure the document for the following reasons:

- The Scientific Substantiation Framework attached to the Draft Assessment Report had been drafted in a descriptive manner and broadly described the process to undertake when applying a scientific methodology to substantiating the basis for a content or health claim. The language in the document needed to be more prescriptive in order for (i) jurisdictions to make clear decisions about whether enforcement action needs to be taken on the basis that a claim could not be substantiated and (ii) for stakeholders to follow a specific and clear process in order to substantiate the claim.
- Much of the practical explanatory detail on how to review the scientific evidence has been moved out of the Scientific Substantiation Framework and incorporated into supporting documentation that is being developed to accompany the release of the Standard. This documentation will primarily describe how to conduct a systematic review (Method 4) although some additional information will be given on the use of methods one to three.
- Substantiation of nutrition content claims has been taken out of the substantiation framework because this type of claim is verified by analysing or calculating the value of the nutrient content of the food and the criteria for compliance are specified in the Standard.
- Substantiation of high level health claims has been removed from the framework because these types of claims are subject to pre-approval by FSANZ. The substantiation requirements will be specified in a guideline for applicants that will be incorporated into the Application Handbook following public consultation in early 2008.

4. IMPLEMENTATION [FOR INFORMATION ONLY]

Substantiation of general level health claims will be implemented as a post-market system, i.e. the supplier of the food in question is required to hold evidence, as discussed above, to substantiate the claim, and jurisdictional enforcement officers will be responsible for requesting access to that evidence as and when required. As food standards are enforced at jurisdictional level (i.e. the Australian states and territories, the Australian border and New Zealand), the jurisdictional response to a potential breach of the standard may vary among the jurisdictions. In conjunction with the development of the new nutrition and health claims standard, a ‘health claims watchdog’ has been established within the auspices of the Implementation Sub-Committee (ISC). The health claims watchdog has established a working group that is currently addressing matters of consistency of implementation and enforcement of health claims generally and substantiation of general level health claims will be an important element within these considerations.

[Note that this section on implementation is provided for information only and is not part of the consultation as enforcement processes lie within the domain of the jurisdictions rather than FSANZ.]

5. TIMELINES FOR FINALISATION OF PROPOSAL P293

FSANZ is intending to notify the decision on the draft standard to Ministers for consideration at their meeting in May 2008. It is intended that the extra-ordinary round of consultation as presented in this consultation paper will not impact on the overall timelines.

References

FSANZ (2007a) *On-going Label Monitoring Survey in Australia and New Zealand. Report on the Assessment of 2005 Labels for Nutrition, Health and Related Claims*. Evaluation Report Series No 16. Food Standards Australia New Zealand, Canberra, ACT

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Ministry of Health (2003) *Food and Nutrition Guidelines for Healthy Adults: A Background Paper*. Ministry of Health, Wellington.

NHMRC (2003) *Dietary Guidelines for Australian Adults*. NHMRC, Commonwealth of Australia

NHMRC and Ministry of Health (2006). *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*. Commonwealth of Australia and New Zealand Government.

SCIENTIFIC SUBSTANTIATION FRAMEWORK

Purpose

This document describes the approach to scientific substantiation of food-health relationships that are proposed to form the subject of a general level health claim. Substantiation is the process of deciding whether a body of scientific evidence supports a relationship between food or a property of a food and a health effect.

Methods for substantiation

There are four methods that are available to substantiate a general level health claim:

- Method 1 List of nutrient function statements.
- Method 2 Prescribed list of pre-approved food-health relationships.
- Method 3 Prescribed list of scientific source documents.
- Method 4 Systematic review.

1. Method 1 – List of nutrient function statements

1.1 The food-health relationships mentioned in Table 1 may be used as the basis of a general level health claim.

1.2 The wording of the statement is not prescribed for the purpose of making a claim, however, the general level health claim must be based on the scientific intent of the food-health relationship.

Table 1

Nutrient	Nutrient function statement¹
Vitamin A	Vitamin A is necessary for normal vision
Vitamin D	Vitamin D is necessary for the normal absorption and utilisation of calcium and phosphorus
Vitamin E	Vitamin E is necessary for cell protection from the damage caused by free radicals (such as oxidation of polyunsaturated fatty acids in red blood cell membranes)
Vitamin K	Vitamin K is necessary for normal coagulation (blood clotting)
Thiamine	Thiamine is necessary for the normal metabolism of carbohydrates
Riboflavin	Riboflavin contributes to the normal release of energy from food
Niacin	Niacin is necessary for the normal release of energy from food
Pantothenic acid	Pantothenic acid is necessary for the normal metabolism of fat
Vitamin B ₆	Vitamin B ₆ is necessary for the normal metabolism of protein
Folate	Folate is necessary for normal blood formation
Vitamin B ₁₂	Vitamin B ₁₂ contributes to normal blood formation
Biotin	Biotin contributes to normal fat metabolism and energy production
Vitamin C	Vitamin C is necessary for normal structure and function of connective tissue (such as that required for normal gums, skin, healing processes, bone and cartilage)
Calcium	Calcium is necessary for normal structure of bones and teeth
Magnesium	Magnesium is necessary for normal energy metabolism
Iron	Iron contributes to normal blood formation
Copper	Copper is necessary for the normal function of the immune system
Iodine	Iodine is necessary for normal production of thyroid hormones
Iodine ²	Iodine is necessary for normal brain development in the unborn child, babies and young children
Zinc	Zinc contributes to the normal structure of skin and normal wound healing
Manganese	Manganese contributes to normal bone function

Table 1 (continued)

Nutrient	Nutrient function statement¹
Phosphorus	Phosphorus is necessary for the normal structure of bone and teeth
Selenium	Selenium is necessary for cell protection from some types of damage caused by free radicals
Protein ³	Protein helps to build and repair body tissues
Dietary fibre ⁴	Dietary fibre contributes to regular laxation

¹ The statements originate from the UK Joint Health Claims Initiative (JHCI) unless otherwise indicated.

² The statement originates from FSANZ based on work undertaken in the development of the proposal for iodine fortification (P230).

³ The statement originates from the Canadian Food Inspection Agency (CFIA).

⁴ The statement originates from the Australian Dietary Guidelines.

2. Method 2 Prescribed list of pre-approved food-health relationships

2.1 The food-health relationship supporting a pre-approved high level health claim may be used as the basis of a general level health claim. However, no reference must be made to the disease or biomarker in the general level health claim. For example, the general level health claim may refer to the benefit of fruit and vegetables and heart health, not coronary heart disease.

2.2 The food-health relationships mentioned in Table 2 are taken from the pre approved high level health claims mentioned in the Table to clause 7 of the Standard.

Table 2

Specifically characterised diet, food or food component	Disease/biomarker	Association
Fruits and vegetables	Coronary heart disease	Inverse
A diet rich in fruit and vegetables	Coronary heart disease	Inverse
Saturated fatty acids	Low density lipoprotein cholesterol	Positive
Saturated and <i>trans</i> fatty acids	Low density lipoprotein cholesterol	Positive
Calcium (with or without vitamin D)	Osteoporosis	Inverse
Calcium	Bone density	Positive
Sodium	Blood pressure	Positive
Folic acid	Neural tube defects	Inverse

3. Method 3 Prescribed list of scientific source documents

3.1 Subject to subclause 3.2, the food-health relationship used as the basis of a general level health claim can be substantiated using the scientific source documents mentioned in Table 3.

3.2 The following paragraphs apply to substantiate the general level health claim using the scientific source documents mentioned in Table 3 –

- (a) The food-health relationship must be substantiated from two or more corroborating sources mentioned in Table 3.
- (b) The most recent versions of the scientific source documents mentioned in Table 3 must be used.

- (c) To ensure that the food-health relationship is valid at the time of reliance on method 3, the relationship should be confirmed by comparison with current scientific literature.
- (d) If the authoritative source of a scientific source document originates external to Australia and New Zealand, the food-health relationship must be capable of being generalised to the Australian and New Zealand populations.
- (e) The food-health relationship must be confident and definitive and not rely on qualified, equivocal or unsupportive evidence.

Table 3

Authoritative sources	Most Recent Version of Documents
Australian and New Zealand government sources	Australian dietary guideline reports New Zealand food and nutrition background papers Nutrient Reference Values for Australia and New Zealand
World Health Organization	Vitamin and mineral requirements in human nutrition Trace elements in human nutrition and health Joint WHO/FAO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases
United States	Institute of Medicine Dietary Reference Intake series Food and Drug Administration: Health Claims that meet Significant Scientific Agreement
Scientific textbooks in human nutrition	Textbooks of university standard produced in the last 10 years. The books must have been written and edited by specialist academic authors. The textbook must include reference lists, bibliographies or further reading lists.
Scientific reviews	The Cochrane database of systematic reviews. The UK Joint Health Claims Initiative.

4. Method 4 Systematic Review

4.1 A systematic review can be relied on to substantiate a general level health claim and can be used if methods 1, 2 and 3 are not capable of substantiating the food-health relationship, if a food-health relationship is still under investigation or is an emerging food-health relationship, or the food-health relationship has not yet been published in textbooks or undergone a Cochrane systematic review.

4.2 To substantiate the general level health claim the following applies –

- (a) If mechanistic, laboratory and animal evidence is available this must be generally supportive of the human food-health relationship.
- (b) If the food-health relationship is found in people from countries other than Australia and New Zealand, the relationship must be able to be generalised to the Australian and New Zealand populations.

4.3 To assess the totality of the scientific evidence outlined in step 5 of subclause 4.4, the following applies –

- (a) the evidence must support a consistent association between the property of a food and the claimed health effect, and

- (b) the evidence must comprise a number of supportive, acceptable quality human studies including some experimental studies, and
- (c) the evidence must support a food-health relationship that is biologically plausible, and
- (d) there must be a causal relationship in which it is shown that consumption of a diet, food or component causes the health effect independent of other factors, and
- (e) to assess causality and the weight of evidence, most weight is given to well-designed experimental studies in humans.

4.4 The process of conducting a systematic review requires the following steps to be satisfied –

- Step 1 Develop a comprehensive search strategy that captures all of the evidence relevant to the food-health relationship.
- Step 2 Categorise studies into groups comprising experimental (interventional) studies of humans, observational studies of humans, systematic reviews and supporting evidence (animal and *in vitro* studies).
- Step 3 Assess study quality based on a number of factors. The study must have a clearly stated hypothesis and minimise bias and control confounding. Substantiation must be based on human data, primarily from intervention studies, the design of which includes –
 - (i) Study groups that are representative of the proposed target group
 - (ii) An appropriate control group
 - (iii) Durations of exposure and follow-up adequate to demonstrate the intended health effect.
 - (iv) An assessment of the participants' background diets and other relevant aspects of lifestyle.
 - (v) Monitoring of participants' compliance concerning intake of food or food component under test.
 - (vi) The statistical power to test the hypothesis.
- Step 4 Interpret the results of individual studies by completing the following:
 - (i) assess the relationship between the exposure and outcome under the study conditions, and
 - (ii) consider the relationship in the context of the effect in the general population or relevant subgroups within the population, and
 - (iii) assess the change in the outcome parameter which must be statistically significant and biologically meaningful for the target group consistent with the claim.
- Step 5 Assess the totality of scientific evidence in order to evaluate the weight of evidence supporting a food-health relationship.