

**REGULATORY FRAMEWORK FOR NUTRITION, HEALTH AND  
RELATED CLAIMS**

**Generic Application**

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## Purpose of Document

Attachment 5 explains the general application of the Regulatory Framework for Nutrition, Health and Related Claims. It discusses generic issues regarding nutrition content claims and the establishment of qualifying and disqualifying criteria and wording conditions for general level health claims. It also provides a synopsis of each substantiation review for the diet-disease relationships that are the basis of several high level claims, which have been pre-approved by FSANZ. Recommendations in relation to the conditions around the use of these pre-approved high level claims, including the application of qualifying and disqualifying criteria and wording conditions, are also discussed.

Recommendations in relation to how endorsements and cause-related marketing (which are considered to be related claims) will be treated are also included in this attachment.

Attachment 6 should be read in conjunction with Attachment 5 as it deals with specific issues in relation to the regulation of nutrition, health and related claims. Attachment 6 is in two parts:

- **Part 1** provides the background, assessment and rationale, and the proposed regulatory approach at draft assessment for content claims on macronutrients (fats, protein, carbohydrate, fibre), alcohol, energy, specific sub-categories of nutrients (fatty acids, cholesterol, sugar, salt, gluten, lactose) and specific types of claims ('free', comparative, diet, light/lite, wholegrain, lean/extra-lean).
- **Part 2** discusses the exclusions of some foods and nutrients from generic disqualifying criteria for general level health claims (gluten, lactose, food for infants, vitamins and minerals) as well as the eligibility of some foods to carry general level health claims (alcohol, infant formula). It also provides the background, assessment and rationale, and the proposed regulatory approach at draft assessment for a number of specific categories of general level health claims (biologically active substances, dietary interaction claims, life stage claims, weight management, Glycaemic Index/Glycaemic Load, whole foods) and on general dietary information.

# CHAPTER 1: Conceptual Framework for Nutrition Health and Related Claims

## 1.1 Proposed approach at Draft Assessment

- Claims will be classified as general level (including nutrition content claims and general level health claims) and high level.
- Claims must meet pre-requisite conditions to be permitted.
- Qualifying criteria and disqualifying criteria will apply to certain claims.
- Wording conditions will apply to general level health claims and high level claims.
- There will be a step-up in regulation from nutrition content claims to general level claims to high level claims (relating to criteria, wording and pre approval).
- The definition of ‘claim’ includes implied claims.

## 1.2 Background

At Initial Assessment FSANZ developed a Conceptual Framework to guide the development of the Standard for Nutrition, Health and Related Claims. The Conceptual Framework was based on the principle that regulatory intervention is required where risks to public health and safety and/or the risk of consumers being misled or confused by claims is likely to occur.

The objective of the FSANZ Conceptual Framework as described in the Initial Assessment Report was to illustrate the key components of the regulatory framework for nutrition, health and related claims and to guide decision making in relation to the regulatory parameters to be developed for inclusion in the new Standard. The FSANZ Conceptual Framework, underpinned by the Substantiation Framework, consisted of three interrelated elements: the Claims Classification Framework,<sup>1</sup> the FSANZ Claim Descriptors, and the FSANZ Regulatory Model for Nutrition, Health and Related Claims.

Figure 5.1 below is a diagrammatical representation of the FSANZ Conceptual Framework. FSANZ has now further refined the three key elements of the conceptual framework, particularly in relation to the FSANZ Claim Descriptors and the components that comprise the FSANZ Regulatory Model. Further information regarding the Substantiation Framework can be found in Attachment 8 of this report.

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<sup>1</sup> This is the terminology used in the Policy Guideline.

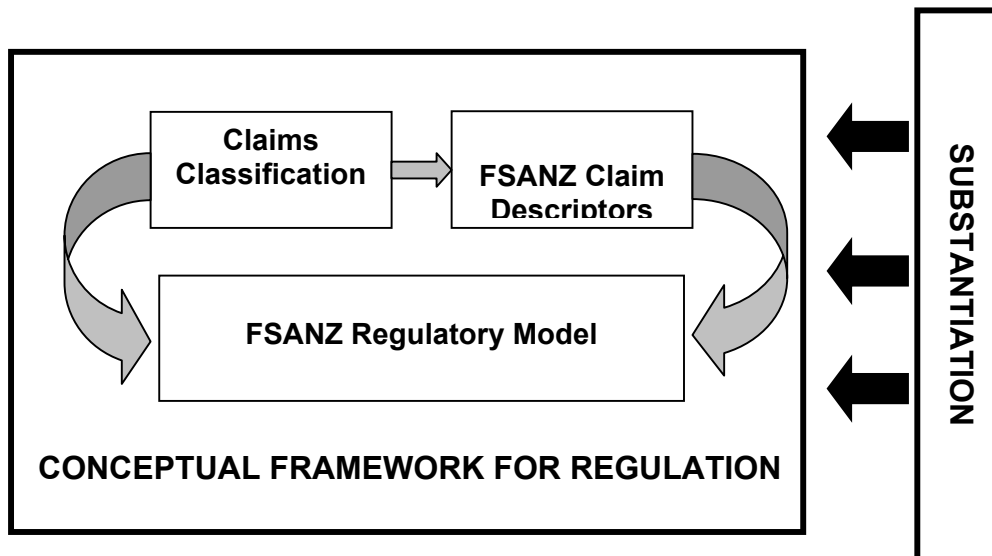
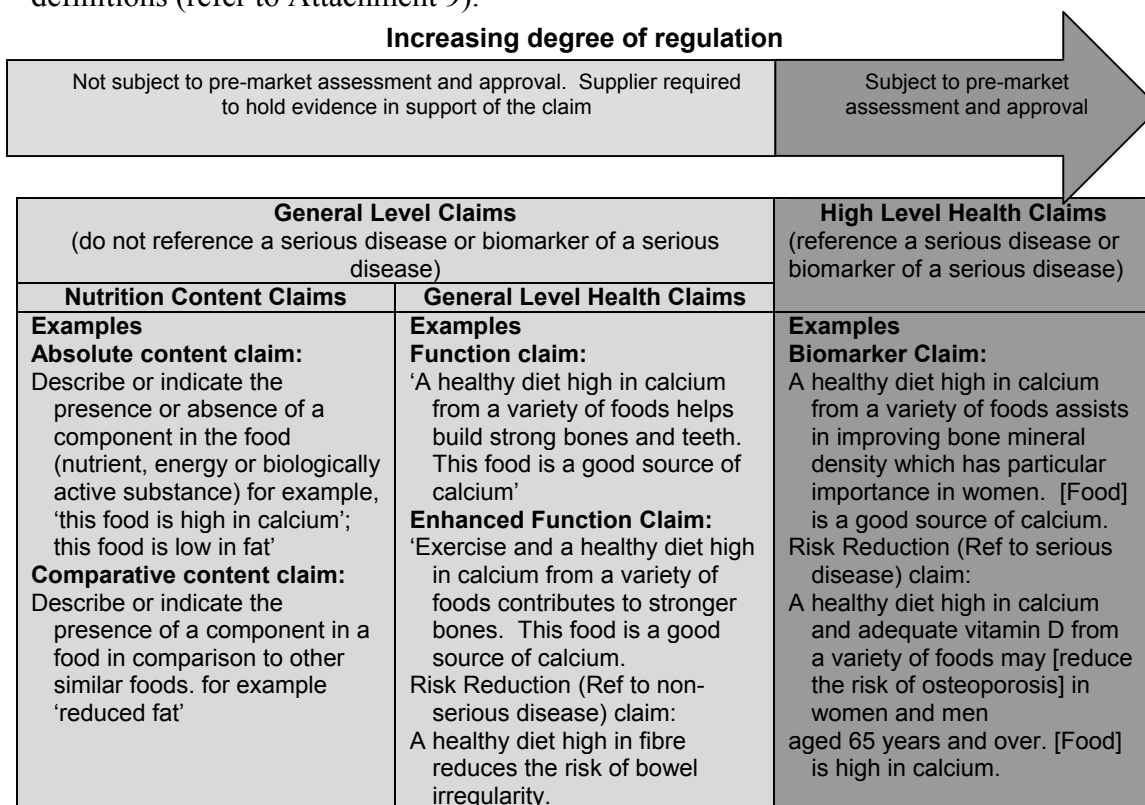


Figure 5.1: The FSANZ Conceptual Framework

### 1.3 Claims Classification Framework

The Claims Classification Framework identifies two broad categories of claims, either general level claims or high level claims, on the basis of whether or not the claim references a serious disease or condition or a biomarker. The Policy Guideline states that the level of the claim, as established by the Claims Classification Framework, will determine the degree to which the claim is regulated.

Figure 5.2 outlines FSANZ’s interpretation of the Claims Classification Framework, based on the two broad categories of claims. This should be interpreted in the context of the proposed definitions (refer to Attachment 9).



Note – This is not an exhaustive list of examples

Figure 5.2: Claims Classification Framework

The classification of a claim determines whether it is subject to pre-market assessment and approval by FSANZ. All nutrition, health and related claims on foods sold or supplied in Australia and New Zealand will be required to be substantiated by scientific evidence, to ensure claims are soundly based and do not mislead consumers. FSANZ will evaluate high level claims on a claim-by-claim basis whereas, suppliers will be required to substantiate general level claims and hold the evidence. Some high level claims have already been evaluated and are included in this proposal.

As illustrated by Figure 5.2 there are two categories of claims within the general level claim classification: nutrition content claims and general level health claims<sup>2</sup>. Nutrition content claims are relatively simple nutrition messages that convey information about the amount of a nutrition related component in a food. General level health claims go beyond this and describe the relationship between a food, either singly or as a category, or a property of a food and a health effect within the context of a healthy diet.

The delineation between claims within the general level claim classification has allowed FSANZ to determine whether additional or different requirements for making general level health claims should be applied. Chapters 3 and 4 discuss the regulatory framework for general level health claims.

## **1.4 Claim Descriptors and Other Terminology**

At Initial Assessment FSANZ developed a number of descriptions and definitions (The FSANZ Claim Descriptors) to provide more detail around individual types of general level claims and high level claims particularly in terms of the way in which a claim might be structured or represented to consumers. FSANZ sought advice from stakeholders on these definitional issues. Following are key terms that have been defined in the Draft Standard 1.2.7. Attachment 9 provides the definitions for these key terms and the assessment and rationale relating to the wording of the definitions.

### *1.4.1 Key terms*

- biomarker
- cause related marketing statement
- dietary information
- endorsement
- endorsing organisation.
- general level claim
- health claim
- health effect
- high level claim
- national nutrition guidelines
- nutrition content claim
- property of a food
- reference food
- serious disease
- substantiate

## **1.5 Regulatory Model for Claims**

The Regulatory Model for Claims takes into account the need to set regulatory parameters to delineate between core regulatory requirements that apply to all claims, irrespective of the classification, and specific requirements which relate to where the claim is situated along the spectrum of claims according to the Claims Classification Framework.

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<sup>2</sup> Note drafting of Standard 1.2.7 refers to general level health claims as ‘general level claims, other than nutrition content claims’.



Draft Standard 1.2.7 includes a general prohibition on the use of nutrition and health claims unless these regulatory parameters are met.

At Initial Assessment, FSANZ proposed that the regulatory parameters take the form of prerequisite conditions, claim criteria and wording conditions, described as follows:

- **Pre-requisite** conditions are pre-conditions that must be met before a claim can be considered an eligible nutrition, health and related claim. Pre-requisite conditions apply to all claims irrespective of whether they are a general level claim or high level claim.
- **Claim Criteria** are specific requirements regarding the food or its composition that must be met before a claim can be made. This regulatory parameter also encompasses food eligibility criteria at the food level, that is, whether certain food categories should be excluded from making nutrition, health and related claims. The Policy Guideline indicates that FSANZ should consider alcohol and baby food categories as potential exclusions.

There are two types of ‘claim criteria’:

- *Qualifying criteria* relate to the nutritional component of the claimed food that is the subject of the claim and must be met before the claims can be made; and
- *Disqualifying criteria* relate to the nutritional composition of the food, in relation to risk increasing nutrients.

For example, in relation to a general level health claim which includes a reference to ‘high fibre’ the qualifying criteria will directly relate to the amount of the fibre present in the food while the disqualifying criteria will relate to risk increasing nutrients in the food such as the amount of saturated fat, sodium, or total sugars.

- Unlike claims criteria, which apply specifically to the composition of the food (and eligibility of the food to make a claim), wording conditions apply specifically to the representation of the claim. These conditions could relate to essential elements of the claim or additional mandatory statements required to clarify the context of the claim.

#### *1.5.1 Further Development on the Regulatory Model for Claims*

Since the Initial Assessment, FSANZ has further developed thinking around the use of the regulatory parameters outlined above. These regulatory parameters can be thought of as ‘filters’, which effectively ‘sift’ claims so that they emerge as bona fide nutrition, health and related claims. Whether or not a claim can be made on a food depends on whether the claim and food, to which it will be applied, pass through all the regulatory filters. The filters work in combination with claim definitions which are devised to capture representations, statements, graphics, designs etc. that may either explicitly or implicitly describe the presence or absence of a property of a food (i.e. nutrition content claim) or the relationship between a food or property of a food and a health effect (i.e. health claim).

FSANZ proposes the prerequisite conditions for nutrition and health claims be that they:

- be substantiated according to the substantiation framework;
- make reference to a specific component of the food<sup>3</sup>; and
- make reference to a specific health effect (other than nutrition content claims).

Claim criteria applying to nutrition content claims, general level health claims and high level claims are discussed in Chapter 2, Chapter 3 and Chapter 5 of this attachment respectively. Wording conditions are discussed in Chapter 4.

### 1.5.2 Application of the Regulatory Model

Figure 5.3 provides an overview of how claim definitions and the regulatory parameters of pre-requisite conditions, claim criteria and wording conditions work together to regulate nutrition, health and related claims.

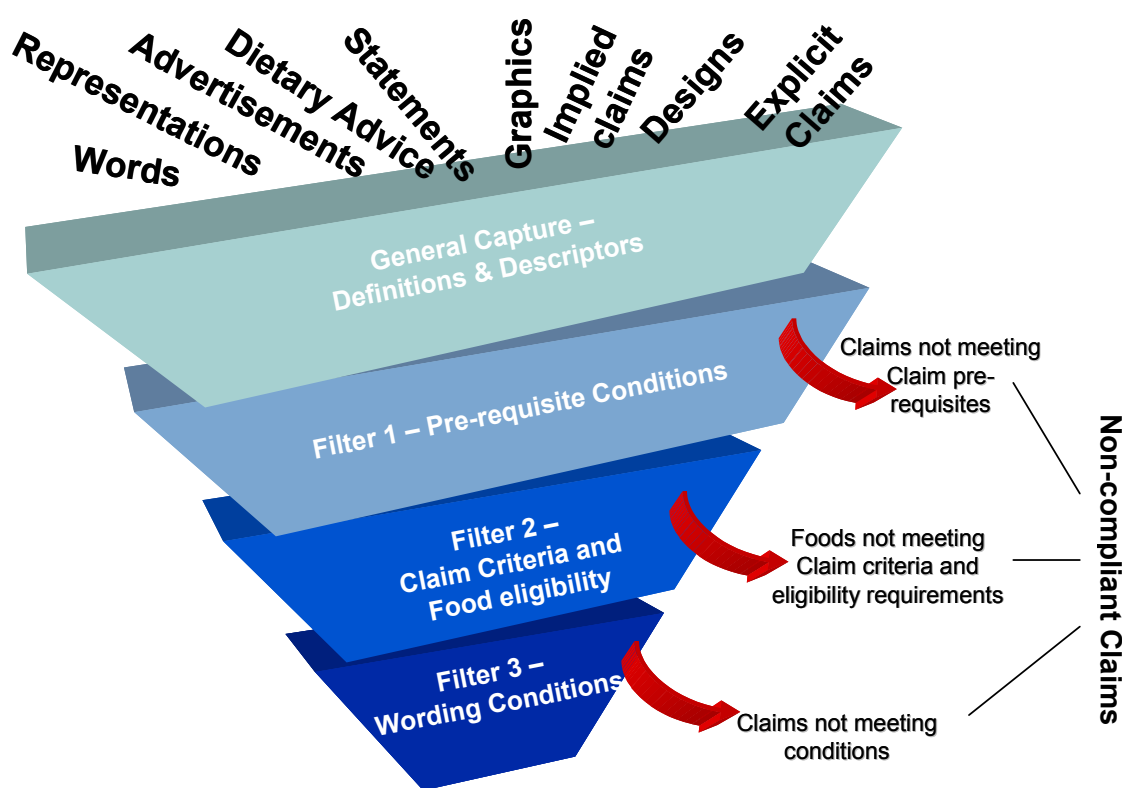
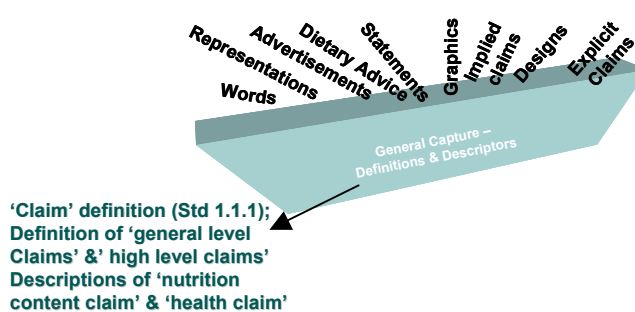


Figure 5.3: Application of the Regulatory Model

<sup>3</sup> Exemptions to this prerequisite condition applies where the substantiation of the health effect is based on the whole food rather than individual components. Refer to Attachment 6: Part 2, Chapter 8 which discusses the regulation of general level health claims in relation to whole foods.

Firstly the regulation will have a broad capture of all claims through the application of the definition of ‘claim’ under Standard 1.1.1. The definition of ‘claim’ is very broad, encompassing any voluntary representations made in relation to a food.

This covers words or other artwork on food labels or conveyed through mediums such as advertisements<sup>4</sup>. It covers verbal representations in relation to food. In order to support the prerequisite process, it is proposed to change the definition of ‘claim’ in Standard 1.1.1 to ensure it captures all potential claims, whether presented explicitly or implicitly.

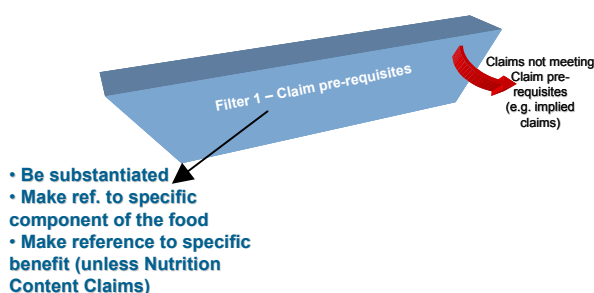


The term ‘claim’ provides a basic threshold for the categories of claims in the Claims Classification Framework. For example, in order for something to constitute a general level claim or high level claim, it must first be captured by the definition of ‘claim’.

FSANZ considers that the definition of ‘claim’ in the *Australia New Zealand Food Standards Code* (the Code) provides a basis for defining the categories of claims. The definition of ‘claim’, which makes reference to ‘representation’ and ‘words or reference in relation to a food’ also captures entities such as graphics, brand names, keywords and various statements that may be construed as ‘implied’ claims.

The definitions around ‘general level claim’, ‘high level claims’, ‘health claim’ and ‘nutrition content claim’ will determine the types of claims, both explicit and implicit, that will be captured in the regulatory framework for nutrition, health and related claims. Claims that will not be captured are those claims that do not indicate the presence or absence of a property of food or claims that do not describe or indicate the relationship between food or a specific component of food and a health effect, as per the definitions for ‘nutrition content claim’ and ‘health claim’ respectively. Examples of such claims are *this food is organic*, *halal food* or *farm fresh*. These types of claims are subject to general fair-trading legislation. Furthermore, FSANZ will provide further detail in interpretive user guides through the use of examples in relation to statements, representations, graphics, designs etc. that fall in or out of the scope of Standard 1.2.7.

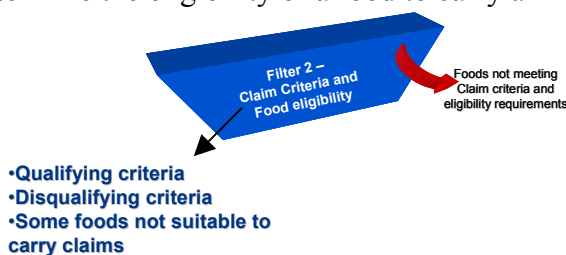
As already mentioned, Draft Standard 1.2.7 includes a general prohibition on the use of nutrition and health claims unless certain conditions are met. These conditions are represented in Figure 5.3 as ‘filters’. The first of these filters is pre-requisite conditions, which are listed in section 1.5.1 above. Note, nutrition content claims do not need to meet these pre-requisites.



<sup>4</sup> Advertising is defined in the Model Food Act as ‘any words, whether written or spoken or any pictorial representation or design, or any other representation by any means at all, used or apparently used to promote, directly or indirectly, the sale of food’

This approach will assist in filtering out ‘implied claims’. It will do this firstly through the broad prohibition on nutrition or health claims (including implied claims) and then only permitting the use of those claims, which include reference to a specific component and health effect (with the exception of nutrition content claims). Thus non-specific claims, including implied claims, will be caught by the general prohibition, and will not be able to meet the pre-requisite conditions – accordingly they will be prohibited. For more detail around FSANZ’s proposed approach for the regulation of implied claims refer to Appendix 5.1.

The second filter relates to permissions that determine the eligibility of a food to carry a claim. This is achieved through the application of qualifying and disqualifying criteria or in prohibiting the use of nutrition, health and related claims on food considered not suitable to carry claims (i.e. ineligible foods). The criteria may vary according to the classification and type of claim made.



Any food not meeting the qualifying criteria; not passing the disqualifying criteria or identified as not suitable to carry a claim, will not be permitted to make a nutrition content claim or health claim.

Attachment 6: Part 1, Chapters 1-19 discusses the criteria that have been determined at Draft Assessment for nutrition content claims and Chapter 3 of this attachment outlines the approach to regulating general level health claims through the use of qualifying and generic disqualifying criteria. Attachment 6: Part 2, Chapter 2 discusses foods that are ineligible to make general level health claims. Chapter 5 of this attachment looks at the criteria that have been determined for high level claims that have been pre-approved by FSANZ thus far.

The final filter relates to wording conditions. Some examples of wording conditions are:

- that the claim has to be made in the context of the total diet;
- that the claim has to state that the specific health effect described in the claim only relates to certain population subgroups; or
- requirements relating to advisory or warning statements being made in conjunction with the claim.



Chapter 4 of this attachment discusses wording conditions for general level health claims. Most of these principles are also applied to high level claims, which are discussed in Chapter 5 of this attachment.

As represented by Figure 5.3 above, the approach to the regulation of nutrition, health and related claims is to have a number of components (or filters) working together to manage certain types of claims and the use of claims on certain types of foods depending on the nutritional profile or suitability of the food to carry a claim.

## 1.6 ‘Step up’ Approach to the Regulation of General Level and High Level Claims

The need for regulation around the types of nutrition content and health claims that food suppliers may wish to use to promote their products follows from consideration of the potential risks to public health and safety insofar as they may mislead and confuse consumers, potentially encouraging consumer choices that may have adverse health impacts.

FSANZ considers a ‘step up’ approach to regulation is appropriate based on the spectrum of claims from nutrition content claims to general level health claims to high level claims. This is founded on the principle that regulatory intervention is warranted where there are greater risks to public health and safety and/or a greater potential for consumers to be misled. While there may be potential health benefits arising from the use of nutrition, health and related claims, in circumstances where these benefits are off-set by an increased risk to the consumer, the level of regulation to which the claim is subject should increase to mitigate the risk. This concept is described in the Policy Guideline in relation to the categorisation of a claim where it is proposed that claims offering a higher ‘degree of promise’<sup>5</sup> to the consumer should be more highly regulated. Figure 5.4 illustrates the ‘step-up’ in the regulation between nutrition content claims and general level health claims and the step up between general level claims and high level claims.

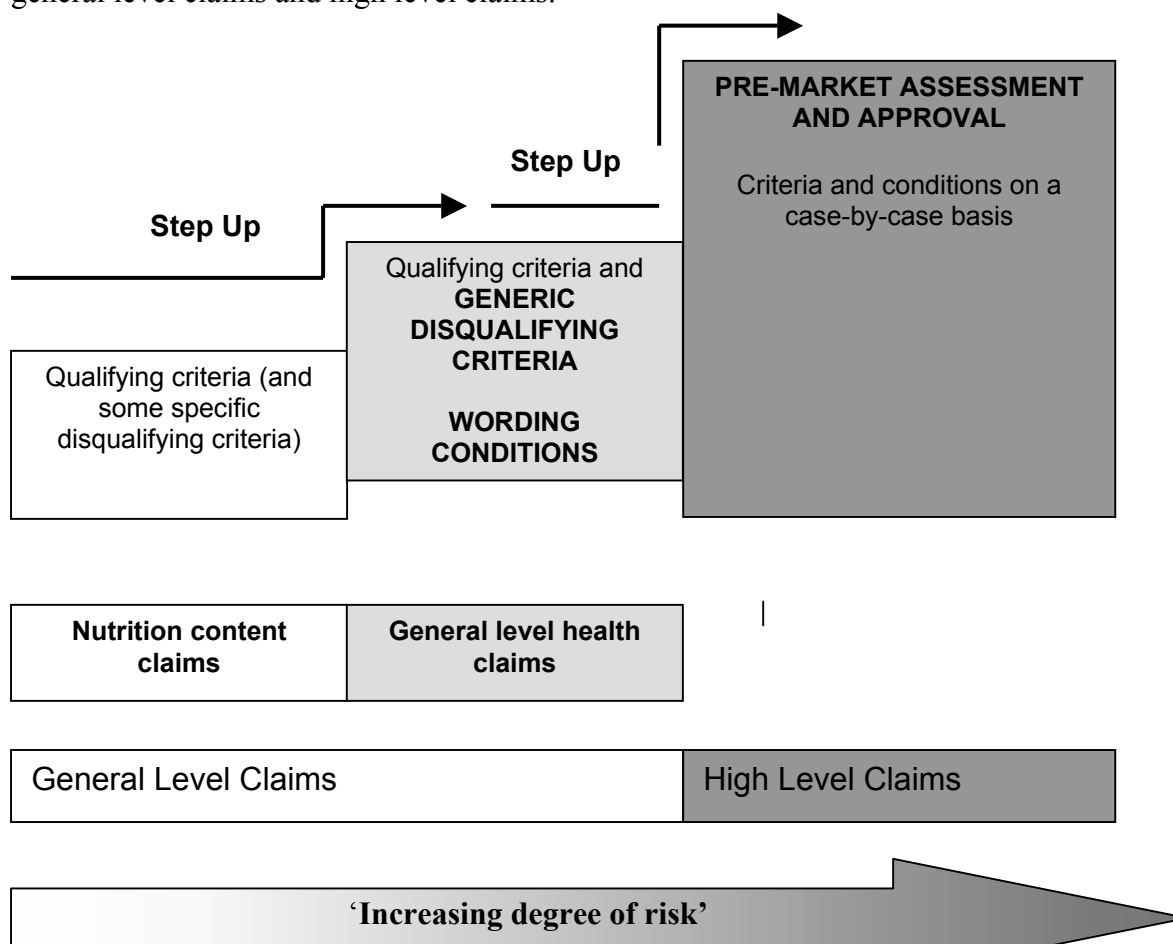


Figure 5.4: ‘Step Up’ approach to Regulation for General Level and High Level Claims

<sup>5</sup> The Policy Guideline states that ‘the categorisation of the claim is based on the degree of promise to the consumer of the claim. That is, the potential benefit to the consumer in consuming that food in preference to other foods, and, commensurately, the degree of risk to the consumer (and public health) in following the advice of the claim.’

### *1.6.1 'Step up' from Nutrition Content Claims to General Level Health Claims*

Within the general level claim classification, FSANZ has described two categories of claims; nutrition content claims and general level health claims. As noted in section 1.3:

**general level claim** means:

- a) a nutrition content claim; or
- b) a health claim that does not, directly or indirectly, refer to a serious disease or biomarker.

These two categories of general level claims are fundamentally different; nutrition content claims relate to the presence or absence of a nutrition related component in a food whereas general level health claims describe the relationship between the consumption of a nutrition related component in a food and a health effect. Due to these differences, FSANZ has considered whether it is appropriate that some aspects of their regulation differ in terms of the stringency of regulation applied. In particular, whether a different approach to specifying criteria and wording conditions is warranted.

FSANZ has determined that greater regulatory control is appropriate around the use of general level health claims through the application of additional food compositional criteria (i.e. generic disqualifying criteria in addition to qualifying criteria) and conditions around the wording of the health claim. The rationale underpinning this approach is discussed in Chapter 3 of this attachment.

Regardless of the differences between nutrition content claims and general level health claims, there will be aspects of the regulatory framework that are consistent between the two types of claims because of their general level classification. These are:

- nutrition content claims and 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
- nutrition content claims and general level health claims will 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, except in cases where the list of pre-approved Nutrient Function Statements is used (refer Attachment 8).

### *1.6.2 'Step up' from General Level Claims to High Level Claims*

The Policy Guideline proposes a 'step up' for the regulation for high level claims. Unlike general level claims, where the supplier is required to substantiate the claim and hold the evidence, high level claims are required to be pre-market assessed and approved by FSANZ. Other regulatory controls around the use of the high level claim such as food compositional criteria or wording conditions will be assessed on a case-by-case basis based on the substantiation of the claim, and may also result in a regulatory approach that creates a 'step up' from general level claims. For instance, qualifying criteria for calcium in respect of a high level claim about calcium and osteoporosis will differ from the requirements for a general level health claim about calcium and strong bones.

FSANZ will pre-approve several high level claims in the new Standard. Chapter 5 of this attachment presents a synopsis of the substantiation reviews commissioned by FSANZ and how the high level claims referring to these diet-disease relationships will be regulated.

## **CHAPTER 2: General Regulatory Approach For Nutrition Content Claims**

### **2.1 Proposed Approach At Draft Assessment**

- There will not be generic disqualifying criteria for nutrition content claims.
- Percentage DI of the claimed nutrient is to be declared in the nutrition information panel when any claim is made in relation to protein, fat, saturated fatty acids, carbohydrate, sugars, sodium or salt and dietary fibre.
- Percentage daily intake (%DI) for energy is to be declared in the nutrition information panel whenever any nutrition content claim is made.
- Nutrition content claims and health claims already regulated by the Code will be included in the new draft Standard, with some amendments to criteria for some claims.
- Analytical methods to substantiate nutrition content claims will not be prescribed, apart from existing methodology for fibre claims.
- FSANZ will not prescribe an exhaustive list of descriptors ('rich in', 'more than', 'fewer' etc) for nutrition content claims but will include a list in a user guide.
- Conditions regarding food for consumption will not be specified in the draft Standard.
- Claims made regarding the property of a food which occurs naturally or intrinsically at a high or low level in a food must be expressed in terms of the category of a food.
- The draft definition of 'reference food' has been simplified from the previous definition in CoPoNC.

### **2.2 Introduction**

The proposed definition for a nutrition content claim is 'a claim about the presence or absence of a property of a food, but does not include an endorsement, dietary information or a cause related marketing statement'. Nutrition content claims include claims about nutrients and about biologically active substances.

Examples of such claims include 'source of omega-3 fatty acids', 'high in fibre', 'reduced in sodium' and 'light/lite'.

The information contained in the following sections relates to generic issues regarding the application of the regulation framework for nutrition content claims. Attachment 6: Part 1 provides a detailed assessment and rationale in relation to criteria and conditions that have been determined for specific types of nutrition content claims.

Although claims about vitamin and mineral content are nutrition content claims, this attachment does not include a review of such claims, as except for a change from a per ‘reference quantity’ basis to a ‘per serve’ basis, they are not being reviewed as part of this Proposal. This decision was made at Initial Assessment because it was considered more prudent to consider the eligibility of vitamin and mineral claims with the permissions for fortification. FSANZ intends to consider this matter further when the new Nutrient Reference Values for vitamins and minerals are official.

Criteria around vitamin and mineral content claims may be considered further, following a FSANZ review of nutrient reference values, which will occur when new values are finalized by Australia’s Commonwealth Department of Health and Ageing, the New Zealand Ministry of Health and the Australian National Health and Medical Research Council. At this time it may be appropriate to re-consider the criteria for vitamin and mineral content claims as well as other content claims such as unsaturated fatty acids.

For discussion on content claims in relation to biologically active substances, see Attachment 6: Part 2, Chapter 3.

### **2.3 Approach to Nutrition Content Claims**

The review of nutrition content claims has been underpinned by the following principles, which were initially developed by FSANZ as part of a former proposal on nutrition content claims<sup>6</sup> and have been further refined in the context of this proposal. They are listed in descending order of priority:

- 1 nutrition content claims should be reviewed in the context of Food Standards Australia New Zealand (FSANZ) objectives and the Policy Guideline on Nutrition, Health and Related Claims;
- 2 nutrition information on food labels, where used, should be developed in the context of national nutrition policies for Australia and New Zealand as a means of safeguarding long-term public health and providing for informed choice;
- 3 labelling information should be accurate, easy to use, unambiguous, and assist in allowing consumers to identify key nutritional aspects of individual food products, comparing these with other products and choosing among relevant food alternatives;
- 4 for suppliers, labelling requirements should not impose unnecessary costs; they should support industry initiatives that promote healthy food choices; and
- 5 the preferred criteria should be consistent with international regulations.

Figure 5.5 provides a decision tree to assist in determining, with consistency, the most suitable regulatory option for individual claims; that is:

- whether no criteria or conditions should be set (in which case the use of these claims is regulated only by fair trading);
- whether qualifying criteria should be determined;
- whether specific disqualifying criteria and/or conditions should be specified (Section 2.4 provides discussion on FSANZ’s proposal not to impose generic disqualifying criteria); and

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<sup>6</sup> This was Proposal P234 – Criteria and Conditions for Making Nutrition Content and Related Claims, which was subsequently subsumed into this current proposal.



- whether specific claims should be prohibited.

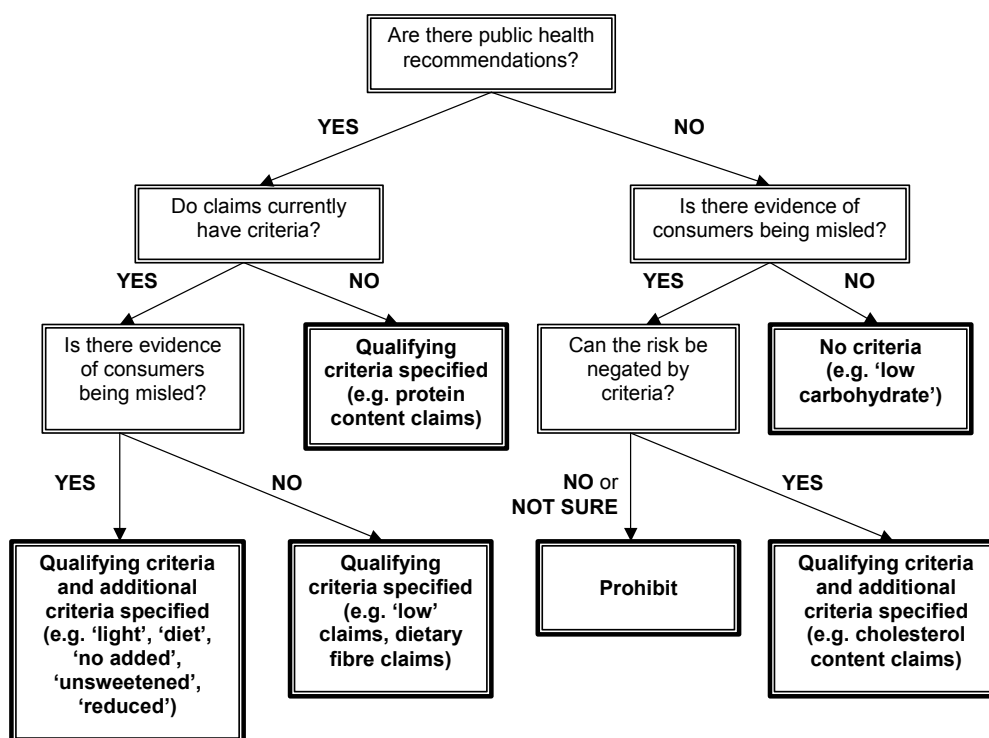


Figure 5.5: Risk Management Options for Nutrition Content Claims

## 2.4 Generic Disqualifying Criteria for Nutrition Content Claims

During the Draft Assessment stage, some public health stakeholders have recommended that generic disqualifying criteria should apply to nutrition content claims. The argument is based on the rationale that nutrition content claims are implied health claims. There is the belief that a halo effect exists whereby a claim leads respondents to view the overall nutrient profile of a product in a more favourable light when compared to no claim at all.

FSANZ did not seek comment on the issue of generic disqualifying criteria from submitters to the Initial Assessment Report. However, a move towards generic disqualifying criteria, even if lenient, is likely to result in the discontinuation of claims on some products that are presently carrying them. As FSANZ's label monitoring study (FSANZ, unpublished) and the University of Wollongong study (Williams, 2003) indicates that 35-42% of products across a range of food categories carry content claims, industry is likely to be negatively impacted by a restriction on the use of such claims. The actual cost to industry would be dependent on the proportion of product affected, which in turn would be subject to the disqualifying criteria imposed.

FSANZ did however seek comment on the application of specific disqualifying criteria to specific claims such as dietary fibre claims and to comparative claims. Submitters' views were varied with industry submitters considering that they are not warranted, while public health and a few industry submitters supported the use of disqualifying criteria for the specified claims.

#### 2.4.1 *Consumer Research that Relates to the Need for Disqualifying Criteria for Nutrition Content Claims*

In recent times, the United States has conducted a small number of experimental studies to examine how consumers interpret nutrient content claims on foods high in other risk increasing nutrients (e.g. a food bearing a 'low salt' claim which is also high in fat). Food shoppers are typically shown mock packages or advertisements with label variations. They are then asked to rate the products on a number of dependent measures such as their attitudes towards the product, their intention to purchase and their perceptions about the healthiness of the product.

Studies by The US Federal Trade Commission (1998); Keller *et al.* (1997); Garretson and Burton (2000); and a large study by the Food and Drug Administration (FDA) in 1998 demonstrate an inconsistency in findings in terms of the halo effect ( the potential for foods with claims to be viewed as healthier overall than foods with no claims). For instance the Federal Trade Commission found no evidence of a halo effect whereas the FDA's findings demonstrated that when a nutrient content claim was present, consumers were more likely to view the product overall as healthier and to state that they were more likely to purchase it. There were, however, limitations in some of the studies, particularly in the case of the Federal Trade Commission because only half the respondents answered the relevant questions and they were not provided with a nutrition information panel.

Garretson and Burton (2000) did not specifically examine the halo effect but, like Keller *et al.* (1997), they found that nutrient content claims, in conjunction with nutrition information panels do not affect product evaluations or purchase intentions. That is, when a nutrition information panel is present, consumers tend to rely on it rather than on the nutrient content claim when making nutrition-related evaluations.

All of the above studies were conducted in the US. Because American consumers are exposed to a different regulatory system for nutrition labelling and nutrition and health claims, the extent to which their research findings can be applied to Australian and New Zealand consumers is unknown. For example, consumers have access to percentage daily value (%DV) information for each nutrient listed on the nutrition facts table, which may assist with interpretation of the information presented.

#### 2.4.2 *Assessment and Rationale*

FSANZ's approach for nutrition content claims is to not apply generic disqualifying criteria, but allow for specific disqualifying criteria in respect of certain nutrient claims where considered necessary. This approach is consistent with minimal effective regulation and based on a risk management approach with the following rationale:

- there is no clear evidence to demonstrate that nutrition content claims are misleading in respect of the food vehicles;
- specific disqualifying criteria can be applied on a case-by-case basis where there is sufficient concern that inappropriate food choice may be made on the basis of a nutrition content claim. For example, polyunsaturated, monounsaturated and omega fatty acid claims are currently permitted on foods provided that specific levels of saturated fat are not exceeded.

In these cases, disqualifying criteria are applied on the basis of an interrelationship between the nutrients in questions where there are direct but opposing impacts on the respective health effect, and thereby, potential for mixed messages and consumer confusion; and

- consumers have diverse needs. In some cases, consumers may only seek information on one nutrient (e.g. sodium). Disqualifying criteria may eliminate certain products from making claims on the basis of nutrients that are not relevant to that person (e.g. sodium claims may not be able to be made because of disqualifying criteria that relate to total sugar content). Similarly, consumers should be able to choose ‘healthier’ options within a food category, even if that food category is not generally seen to be ‘healthy’ per se; and

this approach supports the step up model in the regulation for nutrition and health claims where no generic disqualifying criteria apply to nutrition content claims but do apply to general level health claims.

## **2.5 Units of Measure**

Currently the units of measure used to support qualifying criteria in CoPoNC and Standard 1.2.8 for nutrition content claims in relation to macronutrients and sodium are a mix of the ‘per serve’ and ‘per 100 g’. The qualifying criteria in relation to content claims for risk reducing nutrients such as dietary fibre are based on the ‘per serve’ model, whilst qualifying criteria for content claims relating to risk increasing nutrients such as fat, saturated fat, sugar and salt are based on ‘per 100 g’.

Exceptions apply to certain fatty acids and cholesterol. A disqualifier applies to claims relating to Omega-6, Omega-9, monounsaturated and polyunsaturated fatty acids on a percentage profile for saturated and trans fatty acids. Low cholesterol claims have specific disqualifying criteria, requiring them to meet the conditions for low saturated fatty acid claims in relation to the permitted levels of saturated and trans fatty acids.

The qualifying criteria for general level health claims will be based on the qualifying criteria for content claims. The units of measure for content claims will therefore carry over to general level health claims.

Table 5.3.1 in Appendix 5.3 provides a summary of advantages and disadvantages of per serve and per 100 g units of measure.

FSANZ is recommending the use of the ‘per serve’ measure for general level health claim disqualifying criteria based primarily on the impact on the range of foods that are either included or excluded from making health claims (refer to Appendix 5.3 of this Attachment). For example, a number of foods that are consistent with national nutrition guidelines such as bread and cereals would not meet the proposed general level health claim disqualifying criteria on a ‘per 100 g’ basis. Further rationale supporting the use of the ‘per serve’ model for disqualifying criteria is that it takes account of the way foods are actually eaten. For example, a snack food is generally eaten in small quantities, compared to a main meal food which is eaten in more substantial quantities. However it is acknowledged that the per serve approach for disqualifying criteria advantages small serving sizes and foods eaten in small amounts, and may inappropriately disadvantage larger serving sizes.

Furthermore, Australia and New Zealand do not have standardised serving sizes therefore, in cases where the aim is to achieve a low level of a nutrient (i.e. a claim relating to a reduction of a risk increasing nutrient), the serve sizes can be manipulated to achieve a size which meets the criteria. In the case of health claims relating to risk reducing nutrients, this is not a problem since the disqualifying criteria will always be negative and the qualifier is positive, as such they will balance each other. However, where the qualifier is negative, this balancing mechanism does not exist and could encourage the use of unreasonably small serving sizes in order for the food to qualify for a claim.

FSANZ is therefore proposing to retain the existing unit of measure for qualifying criteria for risk increasing nutrients (e.g. sodium, saturated fat) as ‘per 100 g’. This is supported by the following observations:

- criteria on a ‘per 100 g’ basis produce an equitable outcome for small or large serving sizes;
- no country is using criteria for content claims on a ‘per serve’ basis when the serving sizes are not standardised. ‘Per serve’ criteria are also inconsistent with the Codex approach;
- this will minimise the impact on suppliers who are presently making such claims; and
- throughout the review of nutrition content claims there have been very few submitters who have recommended a change from ‘per 100 g’ to a non-standardised ‘per serve’ basis for risk increasing nutrients.

Table 5.1 below, provides a summary of the recommended units of measure on which criteria for content claims and health claims will be based. FSANZ considers ‘per serve’ to be the most appropriate measure in all cases, except for qualifying criteria for risk increasing nutrients where ‘per 100 g’ is recommended.

**Table 5.1: Basis of unit of measure for qualifying and disqualifying criteria**

	Content Claim		General Level and High Level Health Claims	
	Risk reducing nutrients (e.g. protein, fibre)	Risk increasing nutrients (e.g. sodium, sat fat)	Risk reducing nutrients	Risk increasing nutrients
<b>Qualifying criteria (i.e. how much of claimed nutrient is present)</b>	Per serve	Per 100 g	Conditions for Content claim applies – i.e. per serve	Conditions for Content claim applies – i.e. per 100 g
<b>Disqualifying criteria (i)</b>	Generally don’t apply (ii)	Generally don’t apply (iii)	Per serve (iv)	Per serve (iv)

**Notes:**

- Except for vitamins and minerals where disqualifying criteria are based on ‘claimable foods’ (as per Standard 1.3.2), pending further consideration after publication of the new Nutrient Reference values.
- Where they do apply, disqualifying criteria are a mixture of ‘per 100 g’ and a per cent fatty acid profile (e.g. omega fatty acids).
- The only exception is cholesterol, which has disqualifying criteria in relation to saturated and trans fatty acids on a ‘per 100 g’ basis.
- Disqualifying criteria are based on sodium, saturated fat and the total sugars content of the food vehicle.

FSANZ is proposing to alter the qualifying criteria for vitamins and minerals to ‘per serve’ from ‘per reference value’ for uniformity with other risk reducing nutrients.

## **2.6 Percentage Daily Intake Information**

### *2.6.1 Background*

Daily intake reference values provide information on the total amount of energy, macronutrients and sodium to be consumed daily by an ‘average’ adult, based on an 8700 kJ diet and in accordance with national dietary guidelines. Percentage daily intake (%DI) information therefore expresses the percentage of the daily intake for a particular macronutrient, sodium or energy that will be obtained from consuming one serving of the food. It is intended to assist consumers in understanding the relationship between the nutrient content in a serving of the product and targeted intakes of particular nutrients, and can also be used to make comparisons between products. Percentage DI is a similar concept to percent Recommended Dietary Intake (%RDI), which is used for vitamins and minerals.

Currently there is provision in Standard 1.2.8 to provide %DI information for macronutrients in the nutrition information panel as a voluntary basis in a third column, along with the ‘per serve’ and ‘per 100 g’ data/

From a risk management perspective, %DI information provides a tool to assist consumers in identifying for themselves how ‘healthy’ a food is that is carrying a claim. For instance, foods carrying ‘reduced fat’ claims may have a high energy density. Information on %DI may alert consumers that while the food is ‘reduced’ compared to a reference food, it may nonetheless contribute a significant proportion of the targeted daily energy intake. Percentage daily intake information has particular relevance for ‘reduced’, ‘increased’, ‘light/lite’ and ‘diet’ claims as the contribution of the relevant nutrient or energy is more likely to be placed in the context of a daily diet by the consumer.

There is currently a mandatory requirement in Standard 1.3.2 in relation to micronutrients to either declare the proportion of the Recommended Dietary Intake or the average quantity of the vitamin or mineral for which an Estimated Safe and Adequate Daily Dietary Intake has been prescribed, where claims are made in relation to the presence of vitamins and minerals.

### *2.6.2 Consumer research*

In 1998, ANZFA conducted four focus group sessions in Australia and New Zealand to evaluate consumer reactions to the inclusion of %DI information in the nutrition information panel. The research involved both quantitative and qualitative elements. While the research found that it did not improve decision-making overall, it was used more frequently for both single food judgements and food comparisons when compared to per 100 g and per serve information, and some people ‘strongly liked’ such information because they could immediately relate it to their daily requirements. Respondents were not educated about %DI before undertaking the study; they were however familiar with per 100 g and per serving information because manufacturers were voluntarily using them on food packages. This could therefore have biased respondents in providing better responses to per 100 g and per serving compared to %DI.

From that research a recommendation was made in the report that an education campaign should be undertaken to introduce the concept of %DI to consumers if suppliers chose to adopt the expression, because of the potential for %DI information to assist with consumer choices

### 2.6.3 *Assessment and Rationale*

The Policy Guideline states that a claim should not encourage over-consumption of single foods or ingredients or arouse unwarranted and/or unrealistic expectations of the benefit of an individual. Declaration of %DI for energy and the nutrient that is the subject of the claim should assist in ensuring this principle is adhered to and is consistent with the present approach for vitamin and mineral nutrition content claims where % Recommended Dietary Intake information is required to be declared.

Because nutrition, health and related claims aim to promote the nutritional attributes of a product and in the case of health claims, link them to health outcomes, the requirement to declare %DI information when any nutrition, health and related claim is made, will provide a tool for assessing the overall comparative ‘healthiness’ of food products. Consumers will be able to relate the amount of a nutrient (that is the subject of a claim) and energy in a serving of a food to an average daily intake. In addition, content claims such as comparative claims, and ‘diet’<sup>7</sup> will be potentially less confusing.

The %DI reference values in Standard 1.2.8 are based on an average male/female adult diets and do not necessarily relate to the needs of children. To incorporate reference values for these age groups, where they exist, would be complex, costly and impractical. FSANZ has therefore chosen to use just the one value. Furthermore, as the values are inappropriate for infants and very young children, foods for infants and other particular children’s foods specified by the Code will be exempt from the requirement to declare %DI when nutrition content claims or health claims are made.

### 2.6.4 *Proposed Approach at Draft Assessment*

FSANZ proposes to require %DI information for the claimed nutrient to be declared in the nutrition information panel whenever any nutrition content claim or health claim is made in relation to energy, protein, fat, saturated fatty acids, carbohydrate, sugars, sodium or salt and dietary fibre. The %DI for energy must also be included in the nutrition information panel when any nutrition content claim (including vitamins and minerals), or health claim is made and accompanied by the statement ‘*Percentage daily intakes are [an alternative marker such as an asterisk may be used] based on an average adult diet of 8700 kJ.*

This statement is a lesser requirement than the current situation in Standard 1.2.8, which mandates:

*Percentage Daily Intakes are based on an average adult diet of 8700 kJ. Your daily intakes may be higher or lower depending on your energy needs, (where %DI is supplied on a voluntary basis)*

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<sup>7</sup> The criteria underpinning ‘Diet’ claims equate to ‘low energy’ criteria therefore only the %DI of energy would not to be declared in the nutrition information panel as this is the subject of the claim.

## 2.7 Location of Content Claims in the *Australia New Zealand Food Standards Code*

Nutrition content claims are currently managed in a number of ways. The definition for ‘nutrition claim’ and generic provisions for a small number of content claims are regulated in Standard 1.2.8 of the *Australia New Zealand Food Standards Code* (the Code). Generic provisions for vitamins and minerals are provided in Standard 1.3.2. There are also provisions in the Code for some commodity standards such as those prescribed in Part 2.9 – Special Purpose Foods.

The majority of content claims, in Australia are, however, managed through the *Code of Practice on Nutrient Claims in Food Labels and in Advertisements* (CoPoNC). CoPoNC is not legally enforceable in Australia or New Zealand. In New Zealand, the majority of content claims are regulated under the New Zealand *Fair Trading Act* 1986.

### 2.7.1 Issues Raised by Submitters

Submitters to the Initial Assessment Report were asked for their preferred approach for the placement of generic content claims. Many of the submitters who responded to this question commented generally on the merits of regulating content claims in either a Standard or a Guideline. These comments have been considered as part of FSANZ’s preferred regulatory approach (Option 3) for nutrition, health and related claims in the Draft Assessment Report.

It was noted that for consistency, there should be one Nutrition, Health and Related Claims Standard, which should include pre-requisites for all claims, including content claims. It was recommended that Standards 1.2.8 and 1.3.2, which currently address content claims, be amended to remove reference to claims.

Other submitters commented that where necessary, for example, in Standard 1.3.2, there would need to be either a repetition of the provisions of Standard 1.2.7, or reference to the claims standard to ensure that users were aware of the relevant provisions.

It was also recommended by some submitters that general level claims currently regulated in Standard 1.2.8 should be incorporated into a Guideline, to ensure regulatory consistency, maximum compliance and a single reference point for general level claims.

### 2.7.2 Assessment and Rationale

FSANZ considers that it is important that industry, government, consumers and health professionals be provided with a single reference point in the Code for determining legal requirements in relation to nutrition content claims and health claims. Therefore, FSANZ has recommended that nutrition content claims and health claims already regulated by the *Australia New Zealand Food Standards Code* (with the exception of special purpose foods under Part 2.9 of the Code) will be included in the new Standard. This includes:

- claims in relation to lactose, gluten, polyunsaturated or monounsaturated fatty acid content, omega fatty acid content, low joule and salt, sodium or potassium (currently regulated in Standard 1.2.8); and

- claims about the presence of certain vitamins or minerals (currently regulated in Standard 1.3.2). The permissions for the addition of vitamins and minerals to foods will remain in Standard 1.3.2. This approach is consistent with other standards within Part 1.3 of the Code, which deal with substances added to food, other than labelling requirements.

A number of content claims that are currently managed through CoPoNC have been reviewed and will also be incorporated in the new Standard. The rationale for including these claims in the Standard rather than in a guideline are discussed in the Draft Assessment Report.

## **2.8 Methods of analysis**

### *2.8.1 Background*

Nutrition, health and related claims are voluntary and are used by suppliers to help consumers make healthy, informed food choices and to create a marketing advantage over competitors. The ability of a supplier to make a general level claim or a high level claim may depend on whether a product meets the criteria for certain content claims. Consideration therefore needs to be given to whether the present system for determining the levels of nutrients, energy and biologically active substances will be adequate in the new context of permitting certain health claims.

FSANZ has not generally favoured prescribing acceptable laboratory methods for nutrient analysis because methods are subject to continual improvement. To generally prescribe methods would impose a considerable burden on the regulator, enforcement agencies and the industry to remain up-to-date, which is not commensurate with the risk to consumers. FSANZ expects that laboratory analyses would be appropriate for the food matrix and conducted according to the most up-to-date methods. The choice of an inappropriate method could also be construed as deceptive and contrary to other legislation. Currently claims and nutrient declarations can be based on generally available data, which could be derived from a number of different methods of analysis. Specifying appropriate methods would severely curtail the use of such data, unless the data were exempt from application of prescriptive methods, such as the mandatory nutrition information panel, which then renders the original objective of the prescriptive approach ineffective.

### *2.8.2 Issues Raised by Submitters*

At Initial Assessment FSANZ asked submitters whether there should be prescribed analytical methods for content claims and if so, what approaches or methods were considered appropriate.

The majority of submitters, who were mainly from the food industry and public health agencies, specifically opposed provisions that stipulate analytical methods for content claims. The following reasons were provided for this view:

- the specification of analytical methods would be too inflexible to respond to advances in technology; and
- the most appropriate method of analysis is dependent on the food matrix. The stipulation of test methods might imply that a method is validated for use in all foods, and may consequently lead to incorrect results.



Several submitters did not support the prescription of analytical methods in general, but did recommend the specification of methods for certain nutrients. It was argued that an appropriate limit of detection and/or limit of reporting were required for nutrients such as dietary fibre and its components, gluten, lactose and for claims relating to 'sugar free' and 'fat free'. Others noted that the stipulation of analytical methods would be appropriate where specific guidance is needed; for example, where there is a lack of reliable or internationally validated methods. Submitters in support of prescribed analytical methods in certain circumstances, provided the following reasons:

- dietary fibre is defined by its method of analysis, therefore, for dietary fibre there is no alternative other than to prescribe an analytical method;
- the methods of analysis and associated limits of detection for gluten and lactose determine whether they can be labelled as 'gluten free' or 'lactose free'. In relation to 'gluten free', the current limit of detection of 10 mg/kg is an acceptable level for individuals with Coeliac disease, without suffering ill effects. New methods of analysis with more sensitive levels of detection will mean that many products currently labelled 'gluten free' will no longer be able to make this claim, resulting in fewer choices;
- realistic conditions and criteria and detailed methodologies are needed for 'free' claims. Levels should be set where there is no difference physiologically, clinically and nutritionally between these limits and zero, as is currently the case with 'sugar free' and 'fat free' claims in CoPoNC. Having maximum residual limits for 'free' claims is consistent with international food standards and FSANZ's objectives; and
- standardised methods for 'free' claims would reduce the inconsistency of results between laboratories and subsequently ease the complexity for suppliers and enforcers.

A smaller number of submitters, representing all stakeholder groups, supported the prescription of analytical methods, as they believed it would ensure consistency and minimise confusion and misinterpretation by the food industry. It was also felt that it would minimise the likelihood of consumers being misled. A suggestion was made to review the analytical methods periodically to allow for advances in technology.

In terms of approaches, some of these submitters preferred a prescriptive approach for analytical methods to be placed within a Standard on the basis that this would be in line with other specifications for methodology such as the sampling plan for mercury in fish and microbiological analysis. It was suggested that the Standard specify that the latest edition of the Association of Analytical Chemists International be used. It was also suggested that the Standard specify which analytes/compounds should be determined/included, the levels of accuracy and the limits of detection. Finally, several other submitters preferred that specifications for analytical methods be listed in a Guideline, user guide or code of conduct to allow for flexibility and to minimise the level of prescription. It was also recommended that the methodology take into account the type of food matrix and the nutrition claim, in order to assist industry compliance.

In terms of the use of accredited laboratories, a number of submitters favoured an approach that would require that testing be undertaken by National Association of Testing Authorities, Australia or International Accreditation New Zealand accredited laboratories, either with or without prescribed analytical methods.

However, it was also noted by a small number of submitters that this approach would be a significant cost to industry and would not be easily monitored or enforced. It was commented that National Association of Testing Authorities, Australia registration is not a registration of appropriate methodologies for certain tests, but rather an assurance of the quality of the work conducted. This submitter recommended that National Association of Testing Authorities, Australia accredited labs should only be used with prescribed analytical methodology rather than for verification of nutrition content claims. By comparison, a similar number of submitters rejected the idea that National Association of Testing Authorities, Australia or International Accreditation New Zealand accredited laboratories were necessary. It was noted that National Association of Testing Authorities, Australia registration only extends to specific analyses carried out at the registered laboratory and not necessarily all analyses. Additionally, it was stated that many enforcement agencies and larger companies have in-house laboratories for testing purposes that may not be accredited by National Association of Testing Authorities, Australia. It was further noted that National Association of Testing Authorities, Australia registration is not applicable to overseas laboratories.

### *2.8.3 Assessment and Rationale*

At Draft Assessment, FSANZ is recommending that analytical methods not be prescribed for content claims, other than maintaining the current analytical requirements for dietary fibre which forms the basis of its definition. In general, prescribing analytical methods for nutrients is inconsistent with the requirements of Part 1.2 of the Code. Additional problems with specifying analytical methods have been identified in Section 2.8.1 above.

It is also not appropriate to specify analytical methods for ‘gluten free’ and ‘lactose free’ claims, which are based on the criteria of ‘no detectable’ gluten or lactose, as methods of analysis are becoming increasingly sensitive and therefore, any ‘prescribed’ method of analysis will soon become obsolete. If gluten or lactose is detected using a more sensitive test, any claims could be considered inconsistent with fair trading laws despite complying with the requirements specified in the Code or a Guideline.

FSANZ does not consider that content claims should necessarily be verified by laboratories that are accredited by Australia’s National Association of Testing Authorities (NATA) or by International Accreditation New Zealand (IANZ). Implementation of this approach would impose an additional cost burden on those companies that conduct their own testing but do not have NATA or IANZ accreditation.

## **2.9 Synonyms**

Widespread use of synonyms (or alternative terminology) may result in claims being misleading and not understood because of the belief that there are differences among the terms. At Initial Assessment, FSANZ therefore proposed including a list of alternative terms for each type of content claim. Synonyms that are currently being used or are permitted in overseas countries are:

- Free: ‘zero’, ‘no’, ‘without’, ‘free of’
- Low: ‘little’, ‘few’ (for calories/joules), ‘contains a small amount of’, ‘low source of’
- Reduced: ‘less’, ‘lower’, ‘fewer’
- Increased: ‘more’, ‘more than’, ‘higher’
- No added: ‘without added’, ‘no – added’

- Source: ‘contains’, ‘with’, ‘supplies’, ‘giving’, ‘✓’
- High: ‘good source’, ‘rich’
- Very high: ‘excellent source of’

### 2.9.1 *Issues Raised by Submitters*

At Initial Assessment FSANZ asked if the above synonyms were considered to be similar in meaning to the corresponding content claims. FSANZ also asked whether the list should be considered ‘exhaustive’, and therefore stipulated in a Standard, or ‘illustrative’, and therefore provided in a guideline document as examples for suppliers to use.

The majority of submitters agreed that the listed synonyms were similar in meaning to the types of content claims listed. Some industry submitters suggested that this would depend on the context of the claim. A smaller number of submitters (mainly from the public health sector) disagreed that the listed synonyms were similar in meaning to the types of content claims listed, for one or more of the claims.

Some of these submitters made recommendations regarding the synonyms that were suggested in the Initial Assessment Report, such as:

- ‘free from’ should be added as a synonym for ‘free’ claims;
- ‘increased’ and ‘enriched’ should be added as synonyms for ‘high’ claims;
- the ‘✓’ symbol is inappropriate to indicate ‘source’ claims as this could open the potential for the use of other symbols;
- ‘rich’ is more synonymous with ‘very high’ rather than ‘high’;
- ‘lite’ should be added as a synonym for ‘low’ claims;
- synonyms for ‘reduced’ and ‘increased’ are likely to cause confusion and should not be permitted; and
- the synonyms ‘lower’ and ‘fewer’ for ‘reduced’ are not appropriate as they may be confused with the ‘low’ claim.

Some submitters, representing government and public health sectors, recommended that consumer research is required to understand how the terms are interpreted.

It was also recommended that if not defined, ‘very high’ or ‘excellent’ should not be used for claims where the content of the nutrient is greater than the definition of ‘high’.

The majority of submitters, who were mainly from industry, recommended that the list of synonyms should be illustrative only, however a number of submitters, mainly from government and the public health sectors, favoured an ‘exhaustive’ list and/or that the list be included in a standard. Reasons provided by some of these submitters for favouring a list in a standard were that this would:

- limit the number of synonyms used;
- ensure that those used convey the correct meaning;
- reduce the possibility of ambiguity and misleading claims;
- provide greater clarity for consumers and industry;
- help ensure compliance; and
- improve consumer understanding of the terminology.

Supporting arguments for an illustrative list were that:

- it would allow for creativity and flexibility on nutrition messages;
- it would be difficult for a list to be ‘exhaustive’;
- new phonetic ways to spell could quickly outdate a list; and
- an exhaustive list is inappropriate for low risk claims.

### 2.9.2 *Assessment and Rationale*

Whilst an exhaustive list of synonyms for content claims would limit the number of descriptor terms that could be used, FSANZ considers that such an approach would be unduly prescriptive and not commensurate with the level of risk associated with content claims. Furthermore, it would be difficult to ensure that all appropriate terms and descriptors are captured and maintained in the Standard. For these reasons, FSANZ considers that an exhaustive list of synonyms for content claims is not appropriate.

Nonetheless, it is considered that some guidance is needed in relation to the use of alternative descriptor terms for content claims, particularly as consumer research has shown that there are more descriptor terms being used in nutrition content claims than those currently specified in regulation (Williams, 2003). On this basis, FSANZ is recommending that an illustrative list of synonyms for content claims be given in a User Guide.

FSANZ has developed a suggested list of synonyms for each type of content claim based on consideration of terms that are most appropriate and meaningful, for which there are applicable criteria, and having regard to submitters’ comments at Initial Assessment. It is proposed that this list will be included in a user guide and may be further expanded during the development of the new Standard.

- Free: ‘zero’, ‘no’, ‘without’, ‘free of’
- Low: ‘little’, ‘few’ (for calories/joules), ‘contains a small amount of’, ‘low source of’
- Reduced: ‘less’, ‘fewer’, ‘light/lite’
- Increased: ‘more’, ‘more than’
- No added: ‘without added’, ‘no – added’
- Source: ‘contains’, ‘with’, ‘supplies’, ‘giving’
- High: ‘good source’, ‘rich’

It is considered that terms such as ‘lower’ and ‘higher’ should not be synonymous with ‘reduced’ and ‘increased’ claims, respectively, given the potential for these terms to be confused with ‘low’ and ‘high’ claims. The terms ‘light/lite’ have also been added to the list of synonyms for ‘reduced’ claims, based on FSANZ’s recommendation at Draft Assessment that ‘light/lite’ claims that refer to a nutrient or energy must meet the criteria and conditions for the corresponding ‘reduced’ claim.

## 2.10 **Conditions Regarding Food for Consumption**

Australia’s CoPoNC provides conditions under which content claims may be made. These stipulate that the conditions apply to the food in the form in which it is intended to be consumed.

Thus, if the claim depends for its accuracy on the method of preparation by the consumer, the label must include information that allows the consumer to prepare the food in such a way that the prepared product meets the claim. Also when directions are given for mixing the food with other ingredients, such that the final product does not comply with the claim made for the food, the label must draw attention to the fact that the final product will not meet the claim.

### *2.10.1 Issues Raised by Submitters*

At Initial Assessment, FSANZ asked whether submitters agreed with CoPoNC's conditions regarding food for consumption, and if not, to provide a rationale for why they are not appropriate.

Almost all of the respondents to this question agreed with CoPoNC's conditions regarding food for consumption, mainly because it must be clear to consumers which preparation method the claim applies to.

A small number of submitters disagreed with the conditions regarding food for consumption, for the following reasons:

- consumers do not always prepare food in the same way (as intended by the supplier) and therefore labelling needs to be much clearer in these cases; and
- meat is prepared in a variety of ways including trimming of fat, cooking methods and addition of ingredients and it is more informative and less confusing for consumers if nutritional information about the raw meat is provided.

### *2.10.2 Assessment and Rationale*

Given the recommendation that claims be regulated in a standard FSANZ considers that it is not appropriate to specify conditions under which content claims can be made, as to do so would be inconsistent with the requirements in the Code which apply to food 'as sold', rather than food 'as consumed'. This is based on the rationale that it is difficult to predict how a consumer will choose to consume a particular food even if instructions for preparation of the food are given. Also, it could be misleading to make a content claim on a food based on its suggested method of preparation, when consumers may choose to prepare foods in many ways, including substituting different ingredients.

Under clause 11 of Standard 1.2.8, where a food is intended to be prepared or consumed with at least one other food, a supplier may include an additional column in the nutrition information panel specifying descriptions and quantities of the foods in question, together with the average energy content of the food and average quantities of nutrients and biologically active substances. Consistent with this optional approach for nutrient declaration, a supplier may also provide additional information relating a claim to the food when prepared with other foods providing that, at a minimum, the claim refers to the 'raw' ingredients.

## 2.11 Foods Naturally or Inherently High or Low in a Nutrient

Under CoPoNC, claims made in respect of nutrients which occur at a naturally or inherently high or low level in a food must be expressed in terms that make it clear the claim refers to the whole class of similar foods and not only to the particular brand of food on which the claim appears (for example, 'Bread – a low fat food' is permissible but 'low fat bread' is not as the latter may imply that the particular bread is low in fat compared with other breads). The *New Zealand Food Regulations 1984* provided specific provisions for claims in respect of foods inherently high or low in a particular nutrient or in energy (Regulation 13B). The approach is similar to CoPoNC in that such claims can only be made in respect of a class of food and not specified brands of food. Whilst the *New Zealand Food Regulations 1984* are now repealed they have been included in this discussion as they are still used by New Zealand industry for guidance as a voluntary code of practice.

At Initial Assessment, FSANZ asked whether submitters agreed with CoPoNC and *New Zealand Food Regulations 1984* conditions for foods naturally or inherently high or low in a nutrient and if not, why they were not appropriate.

### 2.11.1 Issues Raised by Submitters

There were a number of submitters from all sectors who agreed with the CoPoNC and *New Zealand Food Regulations 1984* conditions for food naturally or inherently high or low in a nutrient.

Other submitters, mainly from industry, indicated that they did not agree with all of, or aspects of the CoPoNC and *New Zealand Food Regulations 1984* conditions for food naturally or inherently high or low in a nutrient. Their reasons for this included that:

- technology and processing has meant that some foods do not always have the same nutritional composition, e.g. there are many varieties of breads;
- there may be problems with interpretation of 'whole class of similar foods' as there are so many varieties within one class of food that could differ in nutritional value;
- the conditions are not reflective of the current food supply and would limit innovation and development;
- restricting claims like this would not protect consumers;
- conditions are not deemed necessary - claims should be able to relate to a specific food; and
- Nutrition information panels allow consumers to compare packaged products and with education, they should become knowledgeable regarding content claims in basic foods.

It was also queried whether the terms 'bread – low fat food' and 'low fat bread' have different meanings for consumers.

Several industry submitters suggested that although the general principle for these conditions is still valid, changes in technology and marketing practices mean that the requirements should be explained more fully or clearly. They added that this could be done more effectively in a guideline. Some public health submitters suggested that guidelines could be created to assist with identifying whether or not foods should make a statement that the food is naturally or inherently high or low in a nutrient.

### 2.11.2 *Assessment and Rationale*

FSANZ considers that the principles in CoPoNC should be retained, that is, claims made in respect of nutrients which occur at a naturally or intrinsically high or low level in a food must be expressed in terms of the category of a food and not the individual brand of food. This approach is justified on the basis of preventing misleading and deceptive claims. The proposal was also supported by the majority of submitters. This principle has been incorporated in the drafting of the Standard, although it has been expanded to capture not only nutrients but also any other component of the food that is captured under the definition of ‘property of a food’.

FSANZ also notes submitters’ comments in terms of clarifying the term ‘whole class of similar foods’. The draft Standard refers to the term ‘category of food’. For example, a claim in relation to lycopene in tomatoes must state that ‘tomatoes contain lycopene’, not ‘X brand tomatoes contain lycopene’. Further clarification regarding this condition will be provided in an interpretative User Guide to Standard 1.2.7.

## **2.12 Normal Counterpart or Reference Foods**

‘Normal counterpart’ or ‘reference foods’, against which a food may be compared in making a content claim, is defined under CoPoNC as falling into one of three categories:

- the ‘weighted average’ food of that type based on an industry norm for the particular type of food; this category is not appropriate where the composition of ‘normal’ foods of that type on the market varies over a wide range;
- the ‘regular’ product which has been produced for a significant period by the supplier making the claim; and
- a food of the type in question whose composition is determined by reference to published food composition tables.

Under CoPoNC the reference food must be of the same type as the food with which the comparison is made (except in the case of comparative claims between different foods), or as near to the same type as possible. When the basis for selecting the reference food may not be obvious to the consumer, the comparison statement must include an explanation of the choice of the particular reference food.

The former New Zealand *Food Regulations 1984* used the term ‘normal counterpart’, however this term was not defined.

### 2.12.1 *Issues Raised by Submitters*

At Initial Assessment, FSANZ asked submitters whether they agreed with CoPoNC requirements for ‘normal counterpart’ or ‘reference foods’, and if not, why they were not appropriate.

Most of the submitters that responded to these questions generally agreed with CoPoNC requirements for ‘normal counterpart’ or ‘reference foods’.

However some submitters, all from industry, were not supportive of the first requirement (the ‘weighted average’ food of that type based on an industry norm for the particular type of food) because:

- it may be difficult to ascertain the weighted average across every brand on the market;
- the term ‘weighted average’ is too encompassing and would require inclusion of every food in that food group;
- a representative ‘weighted average’ may differ by the foods chosen;
- it requires knowledge of individual sales volumes and implies figures are available for every single brand on the market in Australia and New Zealand; and
- it is a moving target as sales may vary.

Some of these submitters suggested that the reference to ‘weighted average’ be deleted from this requirement.

A small number of submitters did not support the second requirement (the ‘regular’ product which has been produced for a significant period by the supplier making the claim). These submitters suggested omitting the term ‘significant period’ to allow comparative claims to be made between two different versions of a product (regular and ‘reduced’) that are launched at the same time.

Some public health submitters suggested that when a comparative claim is made and the same company making the claim also supplies the ‘regular’ product, then it should only be the ‘regular’ product that can be the reference food.

There was no specific opposition to the third requirement, however some public health submitters suggested that a User Guide specify which food composition tables were appropriate to use.

A number of submitters questioned what happens in situations when a ‘normal counterpart’ or ‘reference food’ does not exist.

### *2.12.2 Assessment and Rationale*

FSANZ acknowledges that the determination of the ‘weighted average’ of a food type, as defined in CoPoNC, is too complex and it has therefore not been considered in the draft definition of ‘reference food’ in the Standard. Similarly, the second CoPoNC requirement that the ‘regular’ product must be produced for a ‘significant period’ has been omitted as this requirement is not considered necessary.

Consequently, the draft definition of ‘reference food’ has now been simplified and incorporates two elements:

it must be a regular product in the same category of food as that food in relation to which a claim is being made. For example if a claim was made about a reduced fat cheese the ‘regular’ product could be full fat cheese; and  
it must be equivalent to the food in relation to which the claim is being made. The term ‘equivalence’ refers to the same ‘type’ of food – for example bread is compared to bread, milk is compared to milk etc.



As the term ‘category of food’ has not been defined, there is a requirement that the reference food be ‘equivalent’ to the claimed food to prevent misleading comparisons, such as bread being compared to a muffin within a category such as ‘bakery products’.

## **CHAPTER 3: Criteria for General Level Health Claims**

### **3.1 Proposed Approach At Draft Assessment**

- Qualifying criteria for general level health claims for nutrients and energy will be based on content claim criteria. Claims in relation to risk decreasing nutrients (such as vitamins and minerals, protein, omega-3 fatty acids and fibre) will need to meet the minimum criteria in relation to nutrition content claims.
- Claims in relation to risk increasing nutrients (such as fat, saturated fat, sodium, total sugars and energy) will be required to meet as a minimum the relevant ‘low’ content claim criteria.
- Food meeting ‘reduced’ criteria only will not be permitted to make general level health claims
- Generic disqualifying criteria will be applied to nearly all general level health claims, with some exceptions.
- The disqualifying criteria require the food to be composed of less than or equal to:
  - Sodium – 325 mg/serve
  - Saturated fat – 4 g/serve
  - Total sugars – 16 g/serve
- Specific disqualifying criteria will apply to meals and main dish products. The disqualifying criteria require the food to be composed of less than or equal to:
  - Sodium – 775 mg/serve
  - Saturated fat – 7 g/serve
  - Total sugars – 31 g/serve
- Foods carrying health claims relating to biologically active substances must meet the generic disqualifying criteria. In addition, 10% (on a per serve basis) of the amount of the substance that provides the claimed health effect needs to be present in the food.
- Where saturated fat, sugars or sodium is the subject of the claim the disqualifying criteria in relation to that nutrient will not apply.
- Infant foods and foods carrying lactose and gluten claims will be exempt from generic disqualifying criteria.
- Specific categories of foods (alcoholic beverages and infant formula) will not be eligible to bear general level health claims.
- At this stage generic disqualifying criteria will not apply to vitamins and minerals, but existing provisions in relation to claimable foods apply

## 3.2 Background

Attachment 6: Part 1 discusses the criteria and conditions that apply to nutrition content claims. In addition to considering the approaches taken for these claims, the need for regulatory parameters which align to the FSANZ Act section 10 objectives have been taken into account in relation to developing an approach for general level health claims. These include the protection of public health and safety; providing adequate information to consumers to enable informed choice; and the prevention of misleading and deceptive conduct. In addition, FSANZ has considered the importance of minimum effective regulation that:

- reduces the likelihood of misleading and non-compliant claims;
- supports consumers' ability to make informed decisions about nutritional benefits of claimed foods;
- promotes the innovation of products that takes account of national nutrition policies;
- provides consistency, certainty and clarity for industry and for enforcement agencies;
- is consistent where appropriate with international regulations; and
- has regard to the Policy Guideline which states among other principles that *consideration should be given during the FSANZ development process for including the criteria for making each level of claim and any parameters (e.g. qualifying and disqualifying criteria or exclusions for certain categories of foods such as alcohol and baby food) should be specifically stated in the standard.*

In its assessment, FSANZ has drawn on stakeholder views regarding the regulation of general level health claims, consumer research and approaches to regulation in other countries.

## 3.3 Relevant Issues Raised in Submissions

At Initial Assessment FSANZ sought advice on whether the criteria and conditions that apply to nutrition content claims could establish the minimum criteria and conditions for general level health claims. The majority of submitters, representing all stakeholder groups, generally agreed that this provided a useful starting point in terms of developing regulation for general level health claims. Some of these submitters highlighted that the content claim criteria should be seen as minimum criteria only and the establishment of additional disqualifying criteria and/or conditions for general level health claims is necessary.

Some submitters representing public health interests noted the need to establish disqualifying criteria in relation to other nutritional aspects of the claimed foods (i.e. risk increasing nutrients). Some submitters also noted that criteria and conditions needed to vary according to food group categories, in order to achieve the best range of healthy foods eligible to make claims.

The Policy Guideline states that a claim can be made providing it is *socially responsible* and does not promote *irresponsible food consumption patterns*. Some submitters related the use of criteria and conditions to ensuring this pre-requisite is met. Some submitters also indicated that it is not socially responsible to market non-core foods with general level health claims to children and it is irresponsible to put any health claim on foods that are high in fat, saturated fat, added sugar, or salt or non-core foods high in energy density. Submissions representing public health interests also recommended, with the exception of whole foods (fruits, vegetables, milk, meat, nuts etc), that claims should not be permitted on foods marketed to vulnerable groups such as infants and children.

One Government submitter indicated the establishment of criteria and conditions for general level claims is appropriate to ensure no misleading statements are made. Other submitters said that criteria and conditions based on content claims criteria ensures that there is consistency in the application of criteria across the general level claims spectrum. One industry submitter stated that having the same minimum requirements would minimise complexity in relation to compliance.

Submitters mostly representing industry opposed the approach that criteria and conditions that apply to nutrition content claims should be used to establish minimum criteria and conditions for other general level claims. Some submitters considered that criteria and conditions should be assessed on a case-by-case basis whilst others commented there is no need for criteria and conditions that take into account other compositional attributes. The only requirement should be that the claim is fully substantiated and can deliver the benefit, this is irrespective of the nutritional make-up of the food.

Other submitters noted that despite being present in amounts lower than those that qualify for a nutrition content claim, it is possible that a small amount of a nutrient could be beneficial. If there is sufficient evidence to support this, then there should not be criteria in place to prevent a claim being made in relation to that product.

### **3.4 Consumer Research**

#### *3.4.1 FSANZ Research*

One of the aims of the FSANZ's (2005b) quantitative research on consumers' perceptions and use of nutrition, health and related claims was to evaluate the impact that various types of nutrition and health claims could have on consumers' perceptions of a product's health benefits and their likely intent to purchase it.

Comparison of the results of consumers' attitudes and behaviour towards products carrying general level health claims and the nutrition content claim is important to assist in determining whether the level of regulation should differ between the two categories of claim. In the research respondents were asked a set of questions about four versions of the same bread product that carried different types of omega claims and one with no claim. Respondents were asked to select from a list of health benefits, which ones they would receive from eating each bread product:

- respondents were more likely to consider that the bread with the general level health claim<sup>8</sup> (37%), would reduce the risk of heart disease compared to the bread with a nutrition content claim<sup>9</sup> (32%);
- likewise, more respondents felt (37%), that the bread with the general level health claim would 'assist in heart health' compared to the nutrition content claim (31%); and
- whilst these results are small, they do present a statistically significant difference.

Statistically more respondents ascribed greater health benefits to the bread with a general level health claim when compared to the bread with a nutrition content claim.

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<sup>8</sup> General level health claim: *'High in omega. A diet high in omega helps maintain healthy veins and arteries'*

<sup>9</sup> nutrition content claim: *'High in Omega'*

The research also indicated that nutrition and health claims have an impact on consumers' intention to purchase a product. Twenty six per cent of respondents indicated that they would purchase the bread without a claim compared to 41% for the nutrition content claim and 48% for the general level health claim.

Aligning these findings to the principle that regulatory intervention is warranted where there are greater risks to public health and safety and/or potential for consumers to be misled, the results provide some evidence to support the need for a 'step up' in the regulation when moving from content claims to general level health claims on the continuum of claims.

### 3.4.2 *International Research*

A comprehensive review of international research on consumer understanding and use of health claims by Williams (2005) identified that consumers derive a 'halo' effect from health claims. Williams reported that health claims do increase consumers' expectations about the healthiness of a product and produce more positive attitudes towards its nutritional value, and they are more likely to purchase it. Williams' review also identified that the presence of health claims limits consumer consideration of information elsewhere on the pack, such as, in the nutrition information panel. However, the recent FSANZ consumer research (2005b) indicates that 80% of respondents would use the nutrition information panel to verify the fat content of a product with a fibre claim. There are no clear answers and consumers do not behave as one group. The over-arching factors of contradictory and inconclusive results and likely differences between consumers in different countries were noted in the Williams (2005) review.

FSANZ's consideration of studies in the United States has found contradictory and inconclusive results with regard to a 'halo' effect occurring with health claims. The Federal Trade Commission (FTC, 1998) found no effect but the study was limited because only about half of the respondents answered the relevant questions and they were not provided with a nutrition information panel because they were viewing claims in advertisements. In contrast, Roe et al (1999) found that consumers were more likely to attribute inappropriate health benefits to products in close-ended questions when a health claim (and to a slightly lesser extent a content claim) was present on a food label, suggesting that the claims create a halo effect. The positive impressions conveyed by either the content or health claim appeared to therefore generalise to other possible health benefits of the product, not just those explicitly identified in the message. The health claim also caused respondents to state that they were more likely to purchase a product compared to the same product without a claim.

A number of other experimental studies, some of which have manipulated both nutrition panel information and health claims, indicate that when the nutrition information panel is available, a health claim does not affect perceptions of product healthfulness, suggesting that consumers will mostly rely on the panel information rather than claims when making nutrition related evaluations (Ford *et al.*, 1996; Mitra *et al.*, 1999; Garretson and Burton, 2000; and Kozup *et al.*, 2003). Such studies are, however, conducted in laboratory type situations and they apply in the United States where nutrition related regulations are different to Australia and New Zealand.

The inconsistent findings between studies may be a result of a number of interacting factors, such as consumers' prior knowledge and demographics (Roe *et al.*, 1999; Levy, 1995); the type of claim (Burton *et al.*, 2000; Levy *et al.*, 1997) and the type of product carrying the claim (Levy *et al.*, 1997).

Overall then, it cannot be said with certainty that a ‘halo’ effect exists when products carry health claims. Some of the research does raise the possibility of this occurring, but issues such as differences between consumers and the regulatory framework in each country also need to be taken into account when comparing such research to the situation in Australia and New Zealand.

### **3.5 Relevant International Approaches**

International approaches to the use of qualifying and disqualifying criteria for claims that are equivalent to general level health claims have also been considered by FSANZ.

- The Codex Guidelines for use of Nutrition and Health Claims (Codex Alimentarius Commission, 2004) recommend that health claims (equivalent to general level health claims) should be permitted provided the following conditions are met:
  - health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrient or constituents in amounts that increase the risk of disease or an adverse health related condition. Health claims should not be made that encourage or condone excessive consumption of the food or disparages good healthy dietary practice.
  - if the claimed benefit is attributed to a constituent in the food, for which a Nutrient Reference value is established, the food in question should be:
    - i. a source of or high in the constituent in the case where increased consumption is recommended; or
    - ii. low in, reduced in, or free of the constituent in the case where reduced consumption is recommended.
- Whilst Canada has set some qualifying criteria for biological role claims (equivalent to general level health claims) for protein and vitamins and minerals, no qualifying criteria have been set for biological roles claims made in relation to energy or other nutrients. The only conditions placed on these claims is that the energy or nutrient value must be declared as appropriate in the Nutrition Facts Table if the food is required to bear a label (Canadian Food Inspection Agency, 2003). Canada do not specify disqualifying criteria around the use of biological role claims.
- In the United States, qualifying or disqualifying criteria are not mandated for structure/function claims (equivalent to general level health claims) on conventional foods.
- The European Union proposal on nutrition and health claims on foods (2003/0165) states that the Commission shall establish specific nutrient profiles which food or certain categories of foods must respect in order to bear nutrition or health claims. The nutrient profiles are to be established, in particular, by reference to the amounts of the following nutrients present in the food:
  - fat, saturated fatty acids, trans-fatty acids
  - sugars

- salt/sodium.

The nutrient profiles will be based on scientific knowledge about diet and nutrition, and their relationship to health.

### **3.6 Assessment and Rationale for the Regulatory Framework for General Level Health Claims**

FSANZ is recommending at Draft Assessment a regulatory framework for general level health claims comprising:

1. Qualifying criteria, to regulate the food component that is the subject of the claim; and
2. Regulatory parameters that take into account the nutritional composition of the claimed food in relation to risk-increasing nutrients.

Risk-increasing nutrients are those nutrients where limited consumption is recommended by dietary and healthy eating guidelines (NHMRC 2003 and Ministry of Health 2005); such as fat, saturated fat, sodium and sugar (and risk reducing nutrients are those with more positive attributes in respect of health effects, such as vitamins, most minerals and fibre).

Some submitters, mostly representing industry, have opposed the establishment of a regulatory framework for general level health claims that goes beyond substantiation requirements. However FSANZ considers that the advantages to industry of having an approach which potentially allows all foods to bear general level health claims provided the claim can be substantiated, where there is no discrimination between foods on the basis of nutritional composition is outweighed by the disadvantages.

The disadvantages of not having a framework that addresses qualifying criteria and the nutritional composition of the claimed food relate to there being:

- a greater potential for consumer confusion in the absence of standardisation of claims. For example the claim '*A diet high in calcium is good for strong bones*' could be placed on a food that only has a little calcium and also on a food that is high in calcium;
- less protection of public health if the regulation does not take into account the composition of the whole food. This relates to the need to minimise the risk of consumers being misled into assuming that the nutritional profile of the food is favourable when in fact it may not be. The onus would then be on consumers to make a total assessment of the food instead of the regulation addressing this pre-market. If consumer judgement is impeded by a 'halo effect' due to the claim (that is, consumers rating a product higher on other health attributes not mentioned in the claim), the high order principles of the Policy Guideline are potentially undermined, particularly the following:
  - 'give priority to protecting and improving the health of the population'; and
  - 'support government, community and industry initiatives that promote healthy food choices by the population';

- less industry imperative to develop products that support national nutritional policies and reference values. This may be counter to the intention of the Policy Guideline by allowing foods with nutritional profiles that are not consistent with national nutrition guidelines to be marketed with health claims; and
- a greater reliance on the substantiation framework to ‘manage’ all aspects of making general level health claims which it is not designed to do. The substantiation framework does not take into account issues relating to consumer interpretation of claims and the interplay between the claimed nutrient in a food and the nutritional profile of the whole food.

Regulatory parameters that take into account the nutritional composition of the claimed food in relation to risk-increasing nutrients are consistent with the concept of more stringent requirements with increasing risk (promise) of a claim. That is, a ‘step up’ in the regulation should occur for general level health claims that refer to a relationship between a food and a health effect, when compared to a simple content claim.

### *3.6.1 Specific Rationale for Recommending Qualifying Criteria for General Level Health Claims*

FSANZ has recommended that qualifying criteria be applied to general level health claims. The use of qualifying criteria provides a standardised approach to the regulation of general level health claims. It ensures that the product must have a minimum or maximum amount of the food component that is the subject of the claim before a claim can be made, which serves to prevent potentially misleading claims.

Furthermore, the qualifying criteria for nutrition content claims will be used as the basis for establishing qualifying criteria for general level health claims. This approach is:

- consistent with Codex Guidelines for the Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2004);
- provides consistency in the application of qualifying criteria across the general level claim spectrum; and is
- consistent with the Policy Guideline which states that FSANZ should consider the application of qualifying criteria as a regulatory control regarding the use of claims.

In order to make a general level health claim in relation to a nutrient where increased consumption is recommended (i.e. risk reducing nutrients such as vitamins and minerals, protein, omega-3, 6 and 9 fatty acids, poly/monounsaturated fatty acids and fibre), it will be necessary to meet the minimum requirements set for nutrition content claims in relation to the nutrient.

General level health claims that relate to nutrients where decreased consumption is recommended (i.e. risk increasing nutrients such as, fat, saturated fat, sodium, total sugars and energy) will be required to meet the relevant ‘low’ content claim criteria. It is envisaged the approach for specifying ‘low’ criteria will promote the innovation of products that are more consistent with national nutrition guidelines.

Foods only meeting 'reduced' content claims criteria will not be eligible to make general level health claims. Whilst it may be considered appropriate to identify 'healthier' alternatives in some food categories through the use of 'reduced' content claims as a means to provide wider consumer choice (e.g. 'reduced fat' potato crisps), FSANZ does not consider it appropriate for foods to qualify to bear general level health claims when only meeting 'reduced' criteria. 'Reduced' is a different genre of claim to 'low'. It is a comparative claim and relates to a 25% or more reduction of a risk increasing nutrient; however the food itself could still be relatively high in that risk increasing nutrient. Consumption of the food may mean a consumer is less likely to be able to follow the nutrition and dietary guidelines relating to moderation of intake, for example:

- 'Choose foods low in salt'; 'limit saturated fat intake and moderate total fat intake' and 'consume only moderate amounts of sugars and foods containing sugars' (NHMRC, 2003); and
- 'Prepare foods or choose pre-prepared foods, drinks and snacks:
  - with minimal added fat, especially saturated fat,
  - that are low in salt; if using salt, choose iodised salt;
  - with little added sugar; limit your intake of high sugar foods' (Ministry of Health, 2003).

A general level claims Matrix at Appendix 5.2 indicates the specific criteria that apply to nutrition content claims and general level health claims.

#### 3.6.1.1 Qualifying Criteria for general level health claims in relation to biologically active substances

FSANZ has also determined an approach to establishing qualifying criteria for general level health claims in relation to biologically active substances. Refer to Attachment 6: Part 2, Chapter 3 for the full discussion on assessment and rationale. The qualifying criterion is:

- 10% (on a per serve basis) of the amount of the substance that provides the claimed health effect needs to be present in the food to allow a general level health claim to be made.

#### *3.6.2 Approaches in Establishing Regulatory Parameters Around Risk Increasing Nutrients*

FSANZ is recommending at Draft Assessment that the regulatory framework for general level health claims (and high level claims, refer to Chapter 5) include regulatory parameters that take into account the nutritional composition of the claimed food in relation to risk-increasing nutrients, which supports the protection of public health. FSANZ has considered two approaches for these regulatory parameters in the form of either:

- *Disclosure Statements*, which are additional labelling requirements. For instance, criteria in relation to risk increasing nutrients are established and if the levels permitted by the criteria are exceeded, this triggers the requirement for additional labelling to draw consumers' attention to the level of the risk increasing nutrient(s) in the food.



- *Disqualifying criteria*, which must be met before a claim can be made. For instance, criteria in relation to risk increasing nutrients are established and if the levels permitted by the criteria are exceeded, then a general level health claim is not permitted to be made in relation to that food product.

### 3.6.2.1 Disclosure Statements

In comparison to disqualifying criteria, disclosure statements are generally considered to be less restrictive for industry as the criteria underpinning them do not prevent products from making general level health claims, but trigger additional labelling requirements. As a result, more information in relation to the food is provided on the label, which needs to be interpreted and used correctly by consumers in their decision-making.

For example, a cheddar cheese meets the qualifying criteria for making the general level health claim: *This food is a good source of calcium. A healthy diet high in calcium from a variety of foods helps build strong bones.* However, the cheddar cheese is also high in saturated fat and sodium (risk-increasing nutrients). If the regulatory decision was to require a disclosure statement, an overt statement such as *see nutrition information for saturated fat and sodium content* could be triggered because of the high saturated fat and sodium content. In this case the statement would be required to be positioned near the claim.

The intent of the disclosure statement is to direct consumers to the nutrition information panel to check the nutritional profile of the whole food, for example, the saturated fat and sodium content of the cheddar cheese. Therefore, in addition to the nutritional benefits of the food being conveyed by the claim, it is also being suggested through the use of the disclosure statement that consumers also consider other, less desirable, nutritional aspects of the food. The consumer can then weigh up the benefit of eating the cheddar cheese in relation to its potential to assist in maintaining strong bones against any potential health concerns in relation to consuming a food that is high in saturated fat and sodium.

### 3.6.2.2 Limitations of Disclosure Statements

The use of disclosure statements was investigated in FSANZ's quantitative consumer research (FSANZ, 2005b). The research focused on the use of disclosure statements to identify differences in perceived health benefit between a product with a source of fibre claim and the same product with a claim and an additional disclosure statement of *see nutrition information for fat content*. The research demonstrated that with the disclosure statement, 85% of respondents indicated they would look at the nutrition information panel compared to 79% for the product without the disclosure statement. This result indicates that disclosure statements may be useful in prompting consumers to search for further information on the label in relation to risk increasing nutrients. However, when asked what the disclosure statement meant, a third (34%) said it prompted them to look for information on fat elsewhere on the package, though a third (33%) also believed the manufacturer was legally required to put the statement on the packet. Only one in five (20%) felt that the 'food must be high in fat' whilst 34% indicated that the 'manufacturer is trying to highlight fat favourably' and 17% indicated that the food must be low in fat.

This finding highlights the need for consumer education around the intent of disclosure statements (i.e. to highlight that there are high levels of risk increasing nutrients in the product) and to encourage consumers to check nutrition information about nutrients other than the claimed nutrient. This will assist in mitigating the risk of consumers assuming that the disclosure statement indicates that the product contains favourable or lower levels of risk increasing nutrients.

The FSANZ quantitative research (FSANZ, 2005b) also investigated whether respondents demonstrated an ability to interpret the nutrition information panel in relation to fat once they were prompted to check it through the use of a disclosure statement. A little over half the respondents were able to correctly determine that the product example was a medium fat food. The addition of a 'guide to assessing fat' positioned near the nutrition information panel, which indicated on a per 100 g basis the levels of fat considered to be low, medium and high, did not significantly improve this result (1% improvement).

The results of the FSANZ quantitative research (2005b) only investigated the use of disclosure statements that highlighted one risk-increasing nutrient. The reality is that products may contain several risk increasing nutrients of which the consumer would need to take into account when making a product choice. Other FSANZ research (FSANZ, 2003) has highlighted that consumers do demonstrate an ability to correctly interpret information about single nutrients in the current nutrition information panel format but when comparing to similar products tend to concentrate on one nutrient at a time. For example, consumers may focus on only choosing a 'lower fat' product, even when their final product choice is only 0.1 g lower in fat (an insignificant difference) compared to an alternative product that is 18% lower in sugar (FSANZ 2003).

The effectiveness of disclosure statements has been tested in a number of studies in the United States. A Federal Trade Commission study found that statements that disclose an absolute amount of a risk increasing nutrient (e.g. saturated fat per serving: 7 g) or an absolute and relative amount (e.g. saturated fat per serving: 7 g; % of maximum daily value: 35%) did not improve consumers' understanding of the amount of risk increasing nutrient in the food. They in fact had the reverse effect in terms of their ability to communicate effectively, as they were perceived as positive health information (Federal Trade Commission, 1998). A strong verbal warning, such as 'X is high in saturated fat' was, however, successful in alerting consumers to the high level of the risk increasing nutrient, although it was more successful for one of the tested products (a cheese) compared to the other (a soup). Furthermore, a recent study by the FDA found that qualifying statements about the strength of science relating to a health claim did not 'reliably convey the intended level of scientific support for a health claim' and that people in the study 'attributed more certainty (rather than less certainty) to claim with disclaimers than those without disclaimers (Derby and Levy 2005). Further consumer research on the limitations of disclosure statements are discussed in the context of nutrition content claims in Attachment 4.

### 3.6.2.3 Disqualifying Criteria

Disqualifying criteria are generally considered more restrictive for industry than disclosure statements, as some foods are prevented from making claims because they exceed certain levels specified for risk increasing nutrients. However, under this approach there is less onus on the consumer to interpret and use other labelling information to determine whether the food is generally a healthy food choice (i.e. lower in risk increasing nutrients).

Essentially, if the regulatory decision is to apply disqualifying criteria, this decision has been made for the consumer because only those foods that do not exceed the levels set for risk increasing nutrients can make health claims. This therefore reduces the potential risk arising from the ‘halo effect’ of health claims on foods.

### 3.6.3 *Rationale for Recommending Generic Disqualifying Criteria for General Level Health Claims*

Addition of disqualifying criteria to the regulatory framework means the focus of the regulation is on the whole food, not just the claimed nutrient, effectively preventing foods that have high levels of risk increasing nutrients from making claims. This therefore supports the protection of public health and ensures that claims be *consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition and health promotion* as stated in the Policy Guideline.

This approach also supports consumers in choosing foods as part of a diet that is consistent with nutrition and dietary guidelines. As disqualifying criteria will be based on nutrients of public health concern, and are designed to exclude foods that may contribute to intake of nutrients that are inconsistent with dietary intake recommendations, there is less onus on consumers to interpret other labelling elements such as disclosure statements and the nutrition information panel in order to determine whether the claimed food (which may only be making claims in relation to one or two components of the food) is a good/healthy food choice in the overall diet. FSANZ’s (2003) consumer research highlighted that when consumers are choosing between two similar products on a ‘healthy food’ basis, consumers do not demonstrate an ability to distinguish the significance of difference in levels of nutrients and tend to only concentrate on one nutrient at a time. The inclusion of disqualifying criteria, which relate to several nutrients, mitigates the risk of consumers not using or not being able to interpret other labelling elements effectively. Such an approach may also reduce the necessity for, or extent of, consumer education around the use of health claims.

This approach also promotes the development of products to meet both qualifying and disqualifying criteria and therefore provides an industry incentive to develop products that support national nutrition policies.

In addition, disqualifying criteria together with qualifying criteria provide requirements to assist industry with compliance and enforcement agencies with guidelines for enforcement. This is consistent with the Policy Guideline, which states that the regulation should *allow for effective monitoring and appropriate enforcement*.

The use of disqualifying criteria for general level health claims also is consistent with the Codex Guidelines for use of Nutrition and Health Claims (2004), which state that claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility. In addition, some submitters have indicated their support for the establishment of disqualifying criteria for general level health claims. Public health submitters in particular have indicated that it is irresponsible to put any health claims on foods that contain high levels of risk increasing nutrients and noted the Policy Guideline states that claims should not promote irresponsible food consumption patterns.

### 3.6.3.1 Rationale for not recommending disqualifying criteria based on food categories

Some submitters have suggested that, rather than having generically applicable disqualifying criteria, specific disqualifying criteria based on food categories are necessary in order to take into account the nutritional composition of different foods. It was considered that this would achieve the best range of healthy food choices. Indeed, various endorsement programs such as the National Heart Foundation ‘Pick the Tick’ program and the GI Symbol Program have established category specific criteria based on core composition and the way foods are used. It was suggested in The National Heart Foundation’s submission that category specific criteria are particularly relevant for the ‘Pick the Tick’ program because food categories vary in their nutritional attributes and in their potential for changing nutritional profiles.

Whilst FSANZ acknowledges that food category specific criteria do have a number advantages as outlined above, FSANZ’s assessment is that such a framework would be difficult to develop and complex to implement. Determining the scope of particular food groups to set specific disqualifying criteria would be a detailed task in order to cover all possible foods, and would require a level of arbitrary decision making. There would also be the need to conduct regular reviews of food categories to ascertain:

- whether newly developed products are adequately captured within a food category; and
- whether specific criteria for a food category would need to be amended as product formulations change.

This approach is more resource intensive than setting generic disqualifying criteria that applies across the board. In their submission, the National Heart Foundation acknowledges that developing and reviewing category specific criteria is resource intensive and that the review of criteria is an ongoing process in light of the ever-changing market place. From an international perspective, neither Canada, the United States, nor the United Kingdom have developed category specific criteria in relation to the regulation of health claims.

### *3.6.4 Derivation of Generic Disqualifying Criteria*

The following section provides a summary in relation to the steps taken by FSANZ for the development of generic disqualifying criteria. Appendix 5.3 provides a detailed analysis and rationale in relation to the development of generic disqualifying criteria.

Three risk increasing nutrients are the subject of the general level health claims (and high level health claims, refer to Chapter 5) generic disqualifying criteria:

- sodium;
- saturated fat; and
- total sugars.

The use of added sugars as a basis for a disqualifying criterion was considered in place of total sugars. However, total sugars were considered the most appropriate nutrient group, given that both total and added sugars both contribute to energy intake, and are digested, absorbed and processed by the body through the same mechanism. (It is noted that different sugar-containing foods may be absorbed at differing rates (i.e. have different glycaemic effect), depending on a number of factors). Practical considerations around the limited availability of data relating to added sugar content for analysis were also considered.

The approach followed to determine disqualifying criteria was to:

- select appropriate daily intake recommendations for each nutrient;
- convert to nutrient amounts ‘per eating occasion’; and
- express per a selected unit measure.

These steps are further explained below.

#### 3.6.4.1 Daily intake recommendations for nutrients subject to disqualifying criteria

Intake recommendations for each nutrient were selected from current information in the Dietary Guidelines for Australian Adults (NHMRC, 2003), the New Zealand Food and Nutrition Guidelines (Ministry of Health, 2003) and the draft Nutrient Reference Values (NHMRC and Ministry of Health, 2005). Proposed intake values were also assessed against dietary intakes reported in the Australian National Nutrition Survey 1995 (McLennan and Podger, 1998) to ensure realistic population targets were selected.

The intake recommendations are:

Sodium:	2,300 mg/day (US Upper Level of Intake)
Saturated Fat:	12% total energy intake (8,700 kJ/day) = 28g per day (New Zealand Dietary Guidelines)
Total sugars:	20% total energy intake (8,700 kJ/day) = 109g per day (Australian Dietary Guidelines)

#### 3.6.4.2 Nutrient amounts for nutrients that are subject to disqualifying criteria

Research previously undertaken by the United Kingdom government in development of their *Rules of Thumb* and *Guideline Daily Amounts* concepts (Rayner *et al* 2003) was drawn on for conversion of the nutrient intake values (per day) to ‘a per eating occasion’ basis. These United Kingdom concepts provide guidance as to what constitutes a ‘lot’ (25%) and ‘a little’ (3%) of a daily intake of certain risk nutrients provided by an individual food. The disqualifying values for sodium, saturated fat and total sugars were set at the midpoint between ‘a lot’ and ‘a little’, i.e. midway between 3% and 25% of the daily intake amount, equal to 14%. This percentage translates to 7 serves of foods per day and was benchmarked against the number of foods recommended per day in the Australian *Guide to Healthy Eating* that would contribute the disqualifying nutrient of interest. It was considered that 7 serves of ‘healthy food guide’ foods in the daily diet contribute to overall consumption of the nutrient of interest. The figure of 7 serves of food seems to be a reasonable average amount to be used as the basis of the calculations.

Calculations yielded the following rounded disqualifying amounts to be applied to individual foods, equivalent to 14% of the selected intake recommendations for each nutrient of interest:

- sodium – 325 mg;
- saturated fat – 4 g; and
- total sugars – 16 g.

### 3.6.4.3 Unit measure for disqualifying criteria

Two approaches were considered: per 100 g; or per serve. In testing various possible unit measures against product types, a per serve approach had advantages over a per 100 g approach because a per serve measure is the only approach that takes account of the way foods are eaten. For example, a snack food may be eaten as a small quantity compared to a main meal food that is eaten in more substantial quantities. Foods sold as complete ‘meals’ also require special consideration in respect of disqualifying criteria as they constitute a number of serves. A literature review conducted by Rayner *et al* (2004) also indicated that a per serve measure is probably the most common measure used internationally for nutrient profiling, although per 100 g is also commonly used. The context of the review encompassed both the regulatory environment and development of nutritional guidelines for consumers. In addition, per serve nutritional information is already required as a component of the nutrition information panel, and therefore calculation of the nutrient content for sodium, saturated fat and total sugars does not represent an additional burden to suppliers. Therefore, a per serve basis was chosen for application of the disqualifying criteria.

It is noted that serving sizes for foods in Australia and New Zealand are determined by the supplier. This provides a supplier the discretion to alter their food’s serve size, in particular the option of reducing their serve size to satisfy the risk increasing nutrient disqualifying criteria. This possibility is self-limiting in relation to risk decreasing nutrient general level health claims (and high level health claims, refer to Chapter 5), since by reducing the food’s serve size a supplier would also reduce their likelihood of meeting the minimum qualifying criteria for claiming the nutrient of interest. However, in the case of general level claims relating to risk increasing nutrients, suppliers could benefit from reducing their food’s serve size and thus reducing both the amount of disqualifying nutrients and the nutrient of interest. For this reason FSANZ will monitor closely the application of serve size nutritional criteria in relation to general level health claims (and high level health claims, refer to Chapter 5). A review of this issue will be placed on FSANZ’s future work plan, and should the outcome deem it necessary, work to standardise serve sizes will be initiated. It is noted that standardised serve sizes are already in use in the United States and Canada. Fair trading laws will provide an additional safeguard against blatant manipulation of serve sizes by suppliers in order to meet the disqualifying criteria.

### *3.6.5 Final Generic Disqualifying Criteria*

The disqualifying criteria for general level health claims to be proposed by FSANZ at draft assessment requires the food bearing the claim to be:

- sodium – less than or equal to 325 mg/serve;
- saturated fat – less than or equal to 4 g/serve; and
- total sugars – less than or equal to 16 g/serve

### *3.6.6 Consideration of energy content as a potential criterion*

Energy content per serve was also considered as a possible alternate criterion to total sugars on the basis that protein, sugars and fats contribute to energy content and that over consumption of energy relative to energy expenditure is a determining factor for the current prevalence of overweight and obesity.

It was concluded that use of energy as a disqualifying criterion would discriminate against some nutritious protein-containing foods but favour foods for which carbohydrates were the predominant energy source. For example, establishing a sufficiently low criterion to exclude soft drink and confectionery also results in the exclusion of many primary foods including meat, fish, nuts and eggs. It was concluded that use of total sugars as a disqualifier nutrient provided more refinement to the range of foods that may to carry general level health claims.

### 3.6.7 Exemptions to the generic approach

Some foods will be exempt from the generic disqualifying criteria. These include foods carrying lactose and gluten claims and infant foods. These are described and discussed in Attachment 6: Part 2, Chapter 1.

At this stage vitamins and minerals will not be required to meet generic disqualifying criteria (refer to Attachment 6, Part 2, Chapter 1).

Alcohol and infant formula will not be allowed to carry health claims. Refer to Attachment 6: Part 2, Chapter 2.

Specific disqualifying criteria will be applied to meals and main dish products as discussed in Attachment 6: Part 2, Chapter 10.

## **CHAPTER 4: Conditions Around Wording of Health Claims**

### **4.1 Summary of Proposed Approach At Draft Assessment**

- Wording conditions for health claims are specified – the claim must state the property of the food and the specific health effect in relation to that property. Health claims must also be made in the context of a healthy diet consisting of a variety of foods.
- Wording conditions will be placed around health claims where the evidence suggests that the specific health effect cannot be attributed to the general population.
- The wording of the health claim in its entirety must be presented so that all the elements of the claim are in the one place.
- Percentage daily intake (%DI) for energy is to be declared in the nutrition information panel whenever any health claim is made.
- %DI of the claimed nutrient is to be declared in the nutrition information panel when any claim is made in relation to protein, fat, saturated fatty acids, carbohydrate, sugars, sodium or salt and dietary fibre.
- Specific wording and labelling conditions for general level claims regarding biologically active substances are proposed.

## 4.2 General Wording Conditions

General wording conditions relate to wording requirements that are applicable to all claims, with the exception of nutrition content claims<sup>10</sup>. General wording conditions are that the claim has to state the property of the food, the specific benefit and that claim is to be worded in the context of the total diet. The following sections are written in the context of general level health claims. However, the principles discussed here also relate to the wording conditions that will be applied to high level claims on a case-by-case basis when high level claims are pre-approved. See Chapter 5 on criteria and conditions relating to high level claims that are being pre-approved by FSANZ.

## 4.3 ‘Property of the Food’ and Specific Benefit

Some wording conditions, which are proposed to be mandatory elements of health claims, have already been determined through the development of pre-requisites conditions (discussed previously in Chapter 1), a strategy designed to minimise the use of implied claims. These are that the claim must:

- make reference to a specific component of the food; and
- other than nutrition content claims, make reference to a specific health effect.

These pre-requisites are justified on the grounds of providing consumers with adequate information to make an informed choice and to prevent misleading or deceptive claims. The second pre-requisite is also supported by the Policy Guideline which states that *claims must communicate a specific rather than broad benefit*.

Rather than referring to the terminology used in the policy guideline (i.e. ‘specific benefit’) Standard 1.2.7 will refer to the ‘specific health effect’ as this will align with the definition of ‘health effect’ that is included in the standard. The specific health effect communicated by the general level health claim must be scientifically substantiated in terms of the diet-health relationship and the evidence must be held by the claimant.

FSANZ has determined that the qualifying criteria for general level health claims will be based on the qualifying criteria for nutrition content claims. Therefore it is appropriate to require that the specific component of the food be expressed in terms of a nutrition content claim, for example ‘low in saturated fat,’ ‘low in sugar’; ‘good source of vitamin C’. Therefore this links the wording requirement to the corresponding qualifying criteria for the nutrition content claim.

### 4.3.1 Proposed Approach at Draft Assessment

The Standard will require that claims must communicate the specific component and specific health effect however the terminology used in the drafting will be consistent with current definitions. Therefore the claim will be required to state:

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<sup>10</sup> Nutrition Content Claims only have to state the ‘property of the food’ and meet any compositional criteria that are used for defining terms e.g. ‘low fat’ or ‘high fibre’ etc



- the property of the food<sup>11</sup>; and
- the specific health effect in relation to that property.

#### 4.4 Total Diet Context

##### 4.4.1 Policy Guideline

The Policy Guideline states that *claims... may only be made in the context of the appropriate total diet (that must be described)*. The policy guideline also provides further rationale as to the inclusion of a requirement relating to the total diet context. It states that *claims about a food or component can describe a health benefit for the population but must not:*

- *encourage over-consumption of single foods or ingredients;*
- *state or imply that a healthy diet is reliant on the inclusion of a single food arouse unwarranted and/or unrealistic expectations of the benefit to the individual.*

##### 4.4.2 Consumer Research

FSANZ's (2005a) qualitative consumer research explored the inclusion of the total diet context as a requirement in relation to the wording of claims. Most participants felt there was a need to include the diet context in claims and that if such words were not included it would imply that *all one had to do was consume that product to obtain the benefit* (FSANZ, 2005a).

The research also explored what the concepts of 'healthy diet', 'balanced diet' and 'total diet' meant to participants. Each of these terms was incorporated into examples of claims.

The term 'healthy diet' was most preferred by participants, and everyone appeared to have a similar shared understanding of what it meant such as:

- only good foods
- good food and plenty of exercise
- only vegetables – 'rabbit food'.

The term 'total diet' was the least preferred by participants because it was considered to be too vague or abstract and was most open to wide range of interpretation. The qualitative research also reported that some participants felt that the combined term 'healthy, balanced diet' was more meaningful, although it was acknowledged that this would need to be tested quantitatively.

Other research internationally has also explored these wording issues. 'As part of a healthy diet' was viewed by some participants in the United Kingdom as being fundamental to the claim but was irrelevant to other participants (Food Standards Agency, 2002).

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<sup>11</sup> Under current drafting of the draft Standard 1.2.7, 'property of the food' means –  
 energy, a nutrient, or a biologically active substance, or -  
 a component; or  
 an ingredient; or  
 any other feature or constituent of the food that is associated with a health effect, including glycaemic index or glycaemic load.

In Canada, participants did not pay as much attention to the ‘healthy diet’ although some people wondered to what extent a claim was void if people did not follow a healthy diet (Health Canada, 2000).

#### 4.4.3 *Relevant International Approaches*

International regulations highlight the necessity of ensuring that claims are expressed in terms of the total diet context and have worked this concept into regulation in various ways, including:

- Codex defines reduction of disease risk claims, as claims that relate to the consumption of a food or food constituent in the context of the total diet, to reduce risk of developing a disease.
- Canada regulates certain diet related health claims (equivalent to high level claims) on foods where sound scientific evidence has established a relationship between certain elements of healthy diets and reduction of risk of certain disease. A diet related health claim is a statement that describes the characteristics of a diet that may reduce the risk of developing a diet related disease or condition and the properties of a food that make it suitable part of the diet. The regulations prescribe the wording of these claims, which are all in the context of a ‘healthy diet’. For example ‘*a healthy diet low in saturated and trans fats may reduce the risk of heart disease. (Naming the food) is free of saturated and trans fats.*’
- In the USA, risk reduction claims (equivalent to high level claims) must include information regarding the value that intake or reduced intake, as part of a total dietary pattern, may have on a disease or a health related condition. The claim must enable the public to understand the information provided and the significance of information in the context of a total daily diet.
- Regulation in the European Union only permit health claims where there is also a statement indicating the importance of a balanced diet and a healthy lifestyle.

#### 4.4.4 *Assessment and Rationale*

FSANZ has interpreted the reference in the Policy Guideline to the *context of the appropriate total diet (that must be described)* as indicating that the claim should communicate that the specific health effect is achieved from consuming a healthy diet that has adequate amounts of the claimed nutrient (or property of the food) from a variety of foods, so that consumers do not perceive that the claimed food alone will provide the specific health effect. Further, the substantiation requirements for general level health claims are based on the diet-health relationship, therefore it is important to emphasise this relationship in the claim.

For example, if a supplier made a claim about strong bones and teeth (specific health effect) and calcium (property of the food related to the specific health effect), the claim could be worded in the following way to convey the total diet context:

*A healthy diet consisting of a variety of foods rich in calcium helps to achieve strong bones and teeth. ‘XX’ Milk is a good source of calcium*

It is also important to consider the type of food bearing the claim and the claimed health effect in relation this wording condition. For instance, it may not be appropriate for the claim to be considered in the context of a ‘healthy diet involving the consumption of a variety of foods’ where:

- the food bearing the claim is for a specific population group where the diet of this group does not normally consist of a variety of foods, for instance the transitional nature of infant dietary requirements; or
- the property of the food that is the subject of the claim is not widely available in the food supply. For instance, unlike conventional macro and micro nutrients, some biologically active substances may not be naturally occurring in a variety of foods, or biologically active substances developed by the food industry may only be added to certain products due to food vehicle suitability or as a measure to build functional food branding. Further information on the regulation of claims in relation to biologically active substances is discussed in Attachment 6: Part 2, Chapter 3; or
- the claim relates to a dietary interaction such as *A good source of vitamin C. Vitamin C increases the absorption of iron from the diet. Iron contributes to normal blood formation.* Consumption of Vitamin C is only going to assist in the absorption of iron from the diet, if foods containing iron are consumed. Further information on dietary interaction claims are discussed in Attachment 6: Part 2, Chapter 4.

FSANZ considers that the drafting of the wording condition should take these circumstances into account and require that the claims be considered in context of a healthy diet consisting of a variety of foods but that this be phrased as appropriate to the type of food bearing the claim and the specific health effect claimed.

For instance, including age appropriate statements may satisfy the healthy diet context requirement where claims are made in relation to infant foods. e.g.....*when consumed as part of a healthy diet appropriate for infants [or children under two years].*

To satisfy the requirement where the property of the food is not widely available in the food supply, rather than making the healthy diet context as part of the claim and relating it to the specific health effect, it may be more appropriate to uncouple this wording condition from the claim itself and a statement in conjunction with the claim be made indicating the *importance of maintaining a healthy diet from a variety of foods.*

Finally, in the case of dietary interaction claims, it may be appropriate for the statement to be modified to include, *as part of a healthy diet involving the consumption of a variety of foods, including iron rich foods such as red meat [etc].*

FSANZ considers it necessary to draw out this issue in the interpretive user guide documents.

FSANZ has also received some comments from stakeholders as to whether the word *nutritious* should precede the wording *variety of foods* in accordance with words used in national nutrition guidelines. However, as the phrase *variety of foods* is presented within the context of a *healthy diet*, FSANZ considers that *nutritious foods* is implied and, use of the word *nutritious* could be optional rather than mandatory in the interests of not being overly prescriptive.

#### 4.4.5 *Proposed Approach at Draft Assessment*

FSANZ proposes that Standard 1.2.7 require that claims be made in the total diet context. As there is evidence to suggest that the term ‘total diet’ is not well understood by consumers, the drafting of the Standard should relate to a ‘varied and healthy diet’ context to ensure suppliers use this terminology instead of ‘total diet’. While FSANZ considers it necessary that the claim be phrased so that a healthy diet means consuming a variety of foods, this should be appropriate to the type of food bearing the claim and the specific health effect claimed.

Guidance in terms of meeting this wording requirement will also be outlined in an interpretive user guide.

### 4.5 **Additional Wording Conditions**

Additional wording conditions are those that may apply only to certain types of claims depending on the specific health effect claimed or the food that bears the claim. Additional wording conditions are discussed in the following sections and refer to claims that relate to specific population subgroups and advisory and warning statements that must be made in conjunction with the claim.

### 4.6 **Claims Relating to Specific Population Sub-groups**

#### 4.6.1 *Policy Guideline*

The Policy Guideline provides guidance in relation to the wording of claims where the claimed benefit relates to a specific population subgroup only. It states that *claims about a food or component can describe a health benefit for the population but must not:*

- *imply or state a universal or guaranteed benefit for all individuals except where permitted by the Australia New Zealand Food Standards Code;*
- *imply or state a health benefit for the population unless the population subgroup is stated.*

#### 4.6.2 *Assessment and Rationale*

Using the hypothetical example (in section 4.4.4) about calcium and strong bones, if the evidence supported that the consumption of a calcium rich diet provided the benefit of strong bones and teeth to children and adolescents only, this must be communicated as part of the claim. Therefore the claim would be worded as follows:

*A healthy diet consisting of a variety of foods rich in calcium helps to achieve strong bones and teeth in children and adolescents. ‘XX’ Milk is a good source of calcium.*

NB: There may also be situations where advisory statements are required where the claims food is not appropriate for certain population subgroups such as infants or pregnant or lactating women. See discussion on advisory and warning statements at Section 4.7.

#### 4.6.3 *Proposed Approach at Draft Assessment*

FSANZ proposes that Standard 1.2.7 includes a wording condition that requires the specific population subgroup to be included as part of the claim where the evidence supports that the specific health effect cannot be attributed to the general population but to specific population subgroups only.

### **4.7 Advisory or Warning Statements**

#### 4.7.1 *Policy Guideline*

In certain circumstances an advisory or warning statement may be required where a claim is made or where certain foods bear the claim. The policy guideline states that, *where advisory or warning statements in relation to the claim are required, they must appear in close proximity to the claim in the same communication medium.*

#### 4.7.2 *Assessment and Rationale*

In this situation, the advisory or warning statement could be physically linked to the health claim (such as two sentences that follow each other) or closely situated near the health claim such as directly underneath the wording of the health claim. This situation differs from advisory and warning statements regulated under Standard 1.2.3 – Mandatory Advisory Statements and Declaration, which has broader application. Standard 1.2.3 does not prescribe where on the label these warning and advisory statements should be positioned because they relate to general disclosure obligations and are not linked to where a claim in relation to a specific property of the food is being promoted for consumption.

#### 4.7.3 *Proposed Approach at Draft Assessment*

Standard 1.2.7 will include provisions where certain advisory or warning statements are required. As these requirements will only be triggered when a claim is made it is more appropriate that the provision will exist in Standard 1.2.7 as opposed to Standard 1.2.3, which has broader application.

### **4.8 Split Claims**

#### 4.8.1 *Background*

FSANZ considers as general conditions that claims must state:

- the property of the food;
- the specific health effect claimed in relation to the property of the food; and
- how the specific health effect is achieved as part of a healthy diet consisting of a variety of foods, as appropriate to the type of food and specific health effect claimed.

These are essential elements of the claim that must always be presented together in order to comply with the wording conditions of the standard. Furthermore, there may also be additional wording conditions (on a case-by case basis) required to communicate that the specific benefit only relates to certain population subgroups and/or to provide warning or advice messages.

These conditions may also be considered as essential elements for the formation of a fully compliant claim or statements that need to be made in conjunction with the claim.

However, if all these elements are presented together, the claim itself together with additional warning or advisory statements may mean the total message becomes long and wordy. This raises the question of how useful and comprehensible such a format would be to consumers. It also raises the issue of whether this results in a reduced flexibility for suppliers' use of claims to promote products that meet all nutrition composition criteria. FSANZ therefore must consider whether 'split claims' is an appropriate mechanism to counteract these potential shortcomings of the requirements.

#### 4.8.2 Policy Guideline

The Policy Guideline makes reference to split claims, indicating that where claims are separated into sections, *the first part of the claim must direct the reader to further information provided elsewhere in the same communication medium.*

#### 4.8.3 Consultation with Industry

At a recent meeting with members of the Australian Food and Grocery Council, industry representatives voiced their concerns regarding the formation of claims and the proposal that all essential elements need to be presented together in order to satisfy the requirements. They indicated that in the majority of cases, those suppliers wishing to promote products through the use of health claims would position the claim on the front panel of a packet so that the claimed benefit is highly visible to the consumer. However, they advised that space on the front panel, particularly in smaller packages and where multiple languages are used, is limited.

Industry emphasised the importance that claims be succinct, user friendly and flexible. Mindful of these principles, industry would like the ability to split claims so that the message on the front of the package is 'short and punchy', for example the statement 'good for bones', whilst the remaining elements of the claim may be presented on another part of the packet such as the back panel.

These sentiments are supported by one study in the USA, which reported that food suppliers found the mandated labelling requirements to be onerous and the lengthy and complex wording not attractive to consumers, resulting in a poor uptake of the use of health claims by suppliers two years after the Nutrition Labelling and Education Act of 1990 was introduced (Petruccelli, 1996).

#### 4.8.4 Consumer Research

Several studies have examined the effect of various devices on communication effectiveness, such as shorter rather than longer claims and split claims. There appears to be evidence to suggest that shorter claims are preferred and are more effective than longer claims (Levy, 1995; Levy *et al.*, 1997; National Consumer Council, 1997; Paul *et al.*, 1999). The Food and Drug Administration's qualitative research found that consumers favoured shorter product-specific health messages and its experimental data found some small effects to show that shorter claims were better than longer ones (Levy, 1995; Levy *et al.* 1997). The Quaker Oats Company also demonstrated that a shorter claim is not misleading and can communicate the disease relationship more effectively than a longer Food and Drug Administration claim (Paul *et al.*, 1999).

Finally a qualitative study in the United Kingdom revealed that consumers found the longer, more complex claims confusing and therefore did not trust them (National Consumer Council, 1997).

Opinion about split claims was mixed in Canada's qualitative study (Health Canada, 2000). Some people believed it was necessary to have the whole claim in one part of the label in order to ensure the totality of information (Levy *et al*, 1997). Others however, felt it would be too much information in one place and therefore splitting the claim would be more effective in making the crucial part easily discernible. Splitting messages between the front and back label made little difference in the Food and Drug Administration's experimental study (Levy *et al*, 1997).

#### 4.8.5 *Relevant International Approaches*

Some international regulations address the issue of split claims. In both Canada and the USA, the high level claim equivalents are required to have all elements of the claim displayed in one place on the label. Regulation in Canada goes further by stating that all words within the claim should have equal prominence and have no part highlighted.

In relation to the equivalent of general level health claims in Canada and the USA, the regulations are not as explicit. In Canada there doesn't appear to be any conditions prohibiting the use of split claims. However biological role claims do not have to be made in the context of the total diet. Therefore, the examples of claims provided in the regulations may not be considered as long and wordy, for instance, *Protein helps build and repair body tissues* and *Vitamin A aids in normal bone and tooth development*. A similar situation in the USA exists for structure function claims.

#### 4.8.6 *Assessment and Rationale*

It is important that the objective of educating consumers about healthier food choices and the benefits of maintaining a healthy diet are maintained through the use of health claims on foods. This enables consumers to make informed choices and relate the information to their own health status or health concerns. This context may be lost if the essential elements of the claim were permitted to be separated. However, FSANZ acknowledges that the regulation needs to strike a balance between ensuring that the full context of the claim is provided but that the information is meaningful to consumers and that industry can utilise the framework effectively.

Whilst FSANZ considers that the essential elements of the claim should always be stated together, the following options allow suppliers to provide information in a location on the package that is separate to the claim in its entirety.

General level health claims must communicate all essential elements together and display these in one place on the label. However there is the option to state:

- a) the property of the food; or
- b) the property of the food and the specific health effect,

on the front of the package so long as there is a statement (message device) in conjunction with either a) or b) that directs the consumer to the general level health claim which must be stated in its entirety elsewhere on the package of food.

This option allows suppliers to have ‘short punchy’ claim elements on the front on the package such as:

- *Good Source of Calcium; or*
- *Rich in calcium for strong bones and teeth.*

These claim elements would be accompanied by an additional statement to direct the consumer to the health claim in its entirety, such as *see back of pack*.

In this case, the back of the package would have the entire general level health claim with all essential claim elements:

*A healthy diet consisting of a variety of foods rich in calcium helps to achieve strong bones and teeth. ‘XX’ Milk is a good source of calcium.*

The same principle in relation to split claims for general level health claims is also applicable to high level claims.

#### 4.8.6.1 Positioning of the additional statement

FSANZ considers that the additional statement that directs the consumer to the claim in its entirety would need to be positioned near the claim element in order for it to be noticed by the consumer. The use of additional statements to direct consumers to other information on the label were investigated as part of FSANZ’s (2005a) qualitative research on nutrition, health and related claims. These types of additional statements were referred to in the study as ‘message devices’. Whilst the wording of the message devices used in the research was not the same as the type discussed here, there are some general outcomes of the study that can be applied broadly to the use of such additional statements on labels.

In relation to the positioning of message devices, the research showed that participants preferred that both the claim and message device be situated on the front of the package and that they be linked in an obvious way (FSANZ 2005a). The research suggests that message devices become ineffective when positioned on the front but distant from a claim because consumers take longer to find and link the two pieces of information (FSANZ 2005a). However, the length of the statement when combining the claim and message device also needs to be considered. The research indicates the impact of the message device is eroded when the combined statement is too long and wordy and therefore may be missed by consumers (FSANZ 2005a). Close but separate positioning with common graphics, colour and font style seems to be quite effective (FSANZ 2005a).

The research also indicated that the message device was more readily observed when it was placed in a position that follows the natural direction that the consumer’s eye travels during product assessment (FSANZ 2005a). To be noticed, the study suggests that messages devices be potentially positioned below or in parallel with the claim and not above the brand name of the product (because all the participants began reading the label at the brand name and worked downwards) (FSANZ 2005a).



#### 4.8.7 *Proposed Approach at Draft Assessment*

Standard 1.2.7 will allow suppliers the option to have shorter statements of the front of packages, so long as the general level health claim or high level claim in its entirety and any warning and advisory statements that are required to be made in conjunction with the health claim are stated elsewhere on the package. Consumers should be directed to the health claim and any warning and advisory statements through an additional statement that is made in conjunction with the shorter statement.

As the wording of the additional statement used to direct consumers to the health claim in its entirety will not be prescribed, the user guide that will be developed to facilitate the interpretation of the Standard will provide suitable examples of additional statements.

#### **4.9 Percentage Daily Intake**

As previously discussed in Chapter 2, Section 2.6 of this attachment, FSANZ proposes to require %DI information for the claimed property to be declared in the nutrition information panel whenever any nutrition content or health claim is made in relation to a property for which there is a reference value in the Code (i.e. energy, protein, fat, saturated fatty acids, carbohydrate, sugars, sodium, (and salt) and dietary fibre). Percentage Recommended Dietary Intake information or the average quantity of the vitamin or mineral for which an Estimated Safe and Adequate Daily Dietary Intake has already been prescribed under Standard 1.3.2, where nutrition content or health claims are made in relation to vitamins and minerals.

The %DI for energy must also be included in the nutrition information panel when any claim is made. The statement '*Percentage daily intakes are [...or an alternate marker such as asterisk] based on an average adult diet of 8700 kJ*' must also be included in the nutrition information panel.

#### **4.10 Wording Conditions For Nutrition Content Claims And General Level Health Claims In Relation To Biologically Active Substances**

FSANZ has determined some specific wording and labelling conditions for nutrition content claims and general level health claims in relation to biologically active substances, which are summarised below. Refer to Attachment 6: Part 2, Chapter 3 for the full discussion on assessment and rationale.

- As for content claims, claims that imply that a food is a 'good source' or comparison statements are not permitted for general level health claims based on biologically active substances.
- General level health claims made in respect of biologically active substances which occur naturally in food must be expressed in terms which make it clear that the claim refers to the whole class of similar foods, and not only to the particular brand of food on which the claim appears.

- General level health claims for biologically active substances must state the amount of the substance that provides the claimed health effect in the context of a healthy diet including a variety of foods. In this context, consideration needs to be given to the amount of the biologically active substance that needs to be supplied in a serve of the food before a general level health claim about the relationship is used in the labelling of a specific food.

## CHAPTER 5: Regulatory Framework For High Level Claims

### 5.1 Proposed Approach At Draft Assessment

- Qualifying criteria, determined through the substantiation process and disqualifying criteria, determined on a case-by-case basis, will be used to determine which foods are eligible to bear high level claims.
- The same wording conditions as prescribed for general level health claims will also apply to high level claims. The wording of the claim will not be prescribed but the actual elements of the claim that must be included will be outlined in the draft Standard.
- Percentage daily intake (%DI) information will be required as for general level claims.
- Six high level claims have been pre-approved for inclusion in the draft Standard:
  1. Calcium, Vitamin D and osteoporosis
  2. Calcium and bone mineral density
  3. Sodium and blood pressure
  4. Folic acid and foetal neural tube defects
  5. Saturated fatty acids, trans fatty acids and serum LDL cholesterol.
  6. saturated fatty acids and serum LDL cholesterol
- The criteria and conditions that apply to the pre-approved high level claim for folic acid and foetal neural tube defect will also apply to the equivalent general level health claim.

High level claims will be pre-approved by FSANZ following the substantiation of specific diet-disease relationships, which will be derived from thorough reviews of the available evidence on the particular diet-related disease in question. The regulatory parameters outlined in Section 5.2 will be applied to the substantiated relationships, as described below.

### 5.2 Regulation of High Level Claims

#### 5.2.1 Food Compositional Criteria for High Level Claims

The same regulatory principles that apply to general level health claims in relation to food compositional requirements will be taken into account when establishing criteria for high level claims. The application of criteria provides a standardised approach to the types of foods that will be eligible to bear pre-approved high level claims. Therefore, FSANZ will determine the need for:

1. *Qualifying criteria*, to regulate the food component that is subject of the claim. This will be determined through the substantiation process; and
2. *Disqualifying criteria*, to regulate the nutritional composition of the claims food in relation to risk in creating nutrients. Where applicable, FSANZ will apply the generic disqualifying criteria that apply to general level health claims as these fulfil the objective of ensuring that foods bearing health claims are consistent with national nutrition guidelines. However, on a case-by-case basis, FSANZ may determine that additional or different disqualifying criteria are required.

FSANZ may also determine that other restrictions on the use of a high level claim in addition to the regulatory controls offered by food compositional criteria is appropriate. For instance, the high level claim relating to folic acid and foetal neural tube defects will not be permitted on foods that are not recommended for consumption by pregnant women regardless of these foods meeting compositional criteria.

### 5.2.2 *Wording Conditions*

Where possible FSANZ has applied the same regulatory principles as those outlined for general level health claims in Chapter 4 for determining the wording conditions for each high level claim. That is, the claim must state:

- the property of the food;
- the specific health effect in relation to the property of the food; and
- the specific health effect must be considered in the context of a healthy diet involving the consumption of a wide variety of foods, as appropriate to the type of food and the specific health effect claimed.

These are considered to be essential elements of the claim that must be communicated together and displayed in one place on a label.

FSANZ considers that in the interest of providing minimum effective regulation prescribed wording of high level claims is unnecessary. However, guided by the regulatory principles around wording outlined in Chapter 4, Standard 1.2.7 will reflect each element specific to the pre-approved diet disease relationship. Table 5.2b outlines these specific wording conditions.

Other regulatory principles around wording that need to be taken into account for each pre-approved diet disease relationship include:

- Where the substantiated specific health effect relates to certain population subgroups only, this must be stated as part of the claim. This is also considered as an essential element of the claim that must be communicated with those essential elements outlined above, and displayed in the one place on the label.
- Where necessary, advisory or warning statements that are triggered when making certain claims or when certain claims are placed on particular foods, must appear in conjunction with the claim.
- Suppliers will be able to ‘split’ claims so long as the following condition is observed. Either the:

- a) property of the food; or
- b) property of the food and the specific health effect related to the property of the food;

may be stated on the front of the package so long as there is an additional statement made in conjunction with either a) or b) that directs the consumer to the high level claim which must be stated in its entirety (i.e. all essential elements including those already stated on the front of the pack) elsewhere on the package of food. Any associated warning or advisory statements would also be made in conjunction with the claim in its entirety.

### 5.2.3 *Other Labelling Requirements*

FSANZ proposes to require %DI information for the claimed nutrient to be declared in the nutrition information panel whenever any high level claim is made in relation to a property for which there is a reference value in the Code (i.e. energy, protein, fat, saturated fatty acids, carbohydrate, sugars, sodium (and salt) and dietary fibre).

Where high level claims are made in relation to vitamins and minerals there is a requirement to state in the nutrition information panel the percent Recommended Dietary Intake information or the average quantity of the vitamin or mineral for which an Estimated Safe and Adequate Daily Dietary Intake is required.

The %DI for energy must also be included in the nutrition information panel when any high level claim is made. The statement '[Percentage daily intakes are] based on an average adult diet of 8700 kJ' must also be included in the nutrition information panel. Refer to Chapter 2, Section 2.6.

## 5.3 **Pre-approved High Level Claims**

FSANZ has commissioned a series of reviews of diet-disease relationships that form the basis of high level claims that are proposed to be approved. These reviews were prepared by experienced Australian and New Zealand scientists using the streamlined approach set out in the revised draft Substantiation Framework (refer to Attachment 8), and draw on reviews that formed the basis of labelling claims approved by Canada. They were peer-reviewed by the Scientific Advisory Group.

The four reviews that have been finalised are:

1. Calcium and osteoporosis or bone mineral density
2. Sodium and hypertension
3. Folic acid and foetal neural tube defects.
4. Saturated fatty acids, trans fatty acids and serum LDL cholesterol

From these reviews six diet-health relationships have been substantiated which are summarised in Table 5.2a below. Table 5.2b then outlines how those regulatory parameters described in Section 5.2 have been applied to the substantiated relationships. Table 5.2b also indicates the compositional criteria for each pre-approved diet disease relationship discussed in the following sections.

Attachment 10 provides summaries of the findings of the reviews including the circumstances under which the relationships were substantiated. The [full reviews](#) are available on the FSANZ website.

Each of the substantiated relationships has been accepted on the basis of a convincing level of evidence. The claim elements (i.e. dietary factor/ health effect) may, in some cases, differ slightly from the substantiated relationship in order to allow some flexibility for industry to use claims that are potentially more meaningful and/or acceptable to consumers. For example, where a relationship may be based on ‘LDL and total cholesterol’, the claim may simply refer to ‘blood cholesterol’. Likewise FSANZ has also determined that the term ‘blood pressure’ is an appropriate alternative to ‘hypertension’.

### 5.3.1 Food Compositional Criteria

As outlined previously, qualifying criteria relating to each claim has been determined through the substantiation process. No additional disqualifying criteria have been identified for claims based on the relationship between folic acid and neural tube defects; sodium and blood pressure; saturated fatty acids and LDL cholesterol or saturated and trans fatty acids and LDL cholesterol. Thus the generic disqualifying criteria will apply in these cases.

For claims relating to calcium, the requirement will be that the food meets the requirement of a ‘claimable food’ pending the review of the Nutrient Reference Values. This approach is consistent with the requirements for making general level health claims in relation to vitamins and minerals.

**Table 5.2a: Substantiated relationships and proposed claim elements.**

<b>Substantiated relationship</b>	<b>Dietary factor(s)</b>	<b>Health effect</b>	<b>Target group</b>
<p><b>1. Calcium, vitamin D and osteoporosis</b></p> <p>Increased dietary intake of calcium, vitamin D status, and risk of the frail elderly, particularly women, developing osteoporosis (expressed either as bone mineral density or as fracture incidence).</p>	<p>High calcium intakes and adequate vitamin D status</p>	<p>Reduced risk of osteoporosis, expressed as enhanced bone mineral density and/or reduced risk of osteoporotic fracture</p>	<p>Women and men aged 65 years and over</p>
<p><b>2. Calcium and bone mineral density</b></p> <p>Increased dietary intake of calcium and enhanced bone mineral density, particularly in women.</p>	<p>Diets high in calcium</p>	<p>Enhanced bone mineral density</p>	<p>General population, particularly women</p>

<b>Substantiated relationship</b>	<b>Dietary factor(s)</b>	<b>Health effect</b>	<b>Target group</b>
<p><b>3. Sodium and blood pressure</b></p> <p>Reduction in dietary intake of sodium and reduction in blood pressure.</p>	Diets largely free of salt or low in sodium	<p>May help maintain normal blood pressure</p> <p>May help reduce blood pressure</p>	General adult population
<p><b>4. Folic acid and foetal neural tube defects</b></p> <p>Relationship between intake of folic acid in the peri-conceptual period and risk of development of neural tube defects in the foetus.</p>	High folate intake at least one month before and 3 months after conception	May reduce the risk of foetal neural tube defects	Women of child bearing age
<p><b>5. Saturated fatty acids and serum LDL cholesterol</b></p> <p>Relationship between reduction in dietary intake of saturated fatty acids and reduction in blood levels of low-density lipoprotein (LDL)-cholesterol.</p>	Diets low in saturated fatty acids	<p>May help reduce blood LDL cholesterol levels</p> <p>May help reduce serum LDL cholesterol levels</p> <p>May help reduce total blood cholesterol levels</p> <p>May help reduce total serum cholesterol levels</p> <p>May help reduce blood cholesterol levels</p> <p>May help reduce serum cholesterol levels</p>	General population
<p><b>6. Saturated fatty acids, trans fatty acids and serum LDL cholesterol*</b></p> <p>Derived from relationship 5. above and a relationship between reduction in dietary intake of trans unsaturated fatty acids and reduction in blood levels of low-density lipoprotein (LDL)-cholesterol.</p>	Diets low in saturated fatty acids and unsaturated trans fatty acids.	<p>May help reduce blood LDL cholesterol levels.</p> <p>May help reduce serum LDL cholesterol levels.</p> <p>May help reduce total blood cholesterol levels.</p> <p>May help reduce total serum cholesterol levels.</p> <p>May help reduce blood cholesterol levels.</p> <p>May help reduce serum cholesterol levels.</p>	General population

\* Note: On the basis of the relationships between saturated fatty acid and LDL-cholesterol, and trans fatty acids and LDL cholesterol, FSANZ provides approval for claims made on the basis of saturated fatty acids and LDL-cholesterol, or saturated fatty acids and trans unsaturated fatty acids and LDL-cholesterol however, claims in relation to trans unsaturated fatty acids alone and LDL-cholesterol have not been approved. This is because it is not clear whether the effect of trans fatty acids on LDL cholesterol is biologically meaningful at low levels of intake, which is likely to be the case in Australia and New Zealand.

**Table 5.2b: Application of the Regulatory Framework to diet disease relationships**

	Restriction on Use of Claim	Food Compositional Criteria	Wording Conditions in the Standard				Additional information on lifestyle factors (in guideline document) <sup>12</sup>	EXAMPLE CLAIM	
			Property of Food	Specific Health Effect	'Healthy Diet' Context	Population Subgroup			Advisory Statements/ other labelling
<b>Calcium, Vitamin D and Osteoporosis</b>	N/A	<p><u>Qualifying Criteria:</u> The food contains no less than 300 mg calcium/serve</p> <p><u>Must be a 'claimable food'.</u> NB. Subject to Nutrient Reference Values' review</p>	<p>Calcium to be stated as the property of the food and expressed in terms of a content claim (i.e. 'High in Calcium', 'good source of calcium' etc).</p> <p>Vitamin D can also be stated as a property of the food (in addition to calcium above) if the food meets requirements of clause 6 or 7 of Std 1.3.2. <i>NB. this is not a qualifier to make the claim – there is no minimum level of Vitamin D required to be in the food before making this high level claim</i></p>	'reduced risk of osteoporosis' OR 'enhanced bone mineral density' OR 'reduced risk of osteoporotic fracture'	A healthy diet with a high intake of calcium from a variety of foods and that provides for adequate Vitamin D status	Women and men aged 65 years and over	%RDI Calcium in nutrition information panel % DI Energy in nutrition information panel	N/A	<i>A healthy diet consisting of a variety of foods high in calcium and that provides for adequate vitamin D status may [reduce the risk of osteoporosis] in women and men aged 65 years and over. [Food] is high in calcium.</i>

<sup>12</sup> Additional information on lifestyle factors can be included as part of the claim where the evidence compiled for the substantiated diet disease relationship also references lifestyle factors, however this is not a wording requirement. FSANZ will provide more detail in a Userguide.

	Restriction on Use of Claim	Food Compositional Criteria	Wording Conditions in the Standard					Additional information on lifestyle factors (in guideline document) <sup>12</sup>	EXAMPLE CLAIM
			Property of Food	Specific Health Effect	'Healthy Diet' Context	Population Subgroup	Advisory Statements/ other labelling		
<b>Calcium and Enhanced Bone Density</b>	N/A	<p><u>Qualifying Criteria:</u> The food contains no less than 200 mg calcium/serve</p> <p><u>Must be a claimable food.</u> NB. Subject to Nutrition Reference Values review</p>	Calcium to be stated as the property of the food and expressed in terms of a content claim (i.e. 'High in Calcium', 'good source of calcium' etc).	'enhanced bone mineral density'	A healthy diet with a high calcium intake from a variety of foods	General population particularly women	%RDI Calcium in nutrition information panel % DI Energy in nutrition information panel	The importance of weight bearing exercise	<i>A healthy diet high in calcium from a variety of foods assists in improving bone density, which has particular importance in women. [Food] is a good source of calcium.</i>
<b>Sodium and Blood Pressure</b>	N/A	<p><u>Qualifying Criteria:</u> The food contains no more than 120 mg of sodium per 100 g of food, or 120 mg per 100 mL of liquid food</p> <p><u>Disqualifying Criteria:</u> No more than 4 g/serve of Saturated Fat and 16 g/serve of Total Sugars</p>	'Low in Sodium' or 'Low in salt' (this terminology links to qualifying criteria)  'Sodium/salt free' OR 'Free of sodium/salt' can be stated as the property of the food if the food has nil sodium/salt.	'maintenance of normal blood pressure' OR 'reduced blood pressure'	A healthy diet consisting of a variety of foods low in sodium/salt	General adult population	%DI Sodium in nutrition information panel % DI Energy in nutrition information panel  Potassium content must be indicated in the nutrition information panel (links to content claim requirement for 'low sodium claim')	The importance of maintaining a healthy body weight.	[Food] is sodium free. A healthy varied diet including foods low in sodium assists adults in reducing blood pressure.



	Restriction on Use of Claim	Food Compositional Criteria	Wording Conditions in the Standard					Additional information on lifestyle factors (in guideline document) <sup>12</sup>	EXAMPLE CLAIM
			Property of Food	Specific Health Effect	'Healthy Diet' Context	Population Subgroup	Advisory Statements/ other labelling		
<b>Folic Acid and Neural Tube Defect</b>	Claim is not permitted on foods that are recommended to be avoided during pregnancy	<p><u>Qualifying Criteria:</u> The food contains no less than 65 µg folate and/or folic acid per serve</p> <p><u>Disqualifying Criteria:</u> No more than - 4 g/serve of Saturated Fat; 325 mg/serve of Sodium; and 16 g/serve of Total Sugars</p>	Folate to be stated as the property of the food and expressed in terms of a content claim. (e.g. 'Good source of etc)	'increased maternal folate consumption in at least the month before and 3 months following conception may reduce the risk of foetal neural tube defects'	'recommendation that women consume at least 680 micrograms of dietary folate equivalents per day at least 1 month before and 3 months after conception'	Women of child bearing age	%RDI folate in nutrition information panel % DI Energy in nutrition information panel	N/A	<i>This [food] is high in folates. Consumption of at least 680 micrograms of folates a day at least 1 month before and 3 months after conception may reduce the risk of foetal neural tube defects.</i>
<b>Saturated fatty acids and LDL Cholesterol</b>	N/A	<p><u>Qualifying Criteria</u> The food contains no more saturated and trans fatty acids than (a) 0.75g per 100 ml for liquid food; and (b) 1.5g per 100 g for solid food</p> <p><u>Disqualifying Criteria</u> No more than - ; 325 mg/serve of Sodium and 16 g/serve of Total Sugars</p>	'Low in saturated fatty acids' (this terminology links to qualifying criteria)	May help reduce [blood LDL cholesterol] OR [serum LDL cholesterol] OR [total blood cholesterol] OR [total serum cholesterol] OR [blood cholesterol] OR [serum cholesterol] levels	A healthy diet consisting of a variety of foods low in saturated fatty acids	General population	%DI saturated fatty acids in nutrition information panel % DI Energy in nutrition information panel 'Energy needs' statement included	N/A	<i>A healthy diet consisting of a variety of foods low in saturated fatty acids may help reduce total serum cholesterol levels. This [food] is low in saturated fatty acids.</i>

	Restriction on Use of Claim	Food Compositional Criteria	Wording Conditions in the Standard					Additional information on lifestyle factors (in guideline document) <sup>12</sup>	EXAMPLE CLAIM
			Property of Food	Specific Health Effect	'Healthy Diet' Context	Population Subgroup	Advisory Statements/ other labelling		
<b>Saturated &amp; trans fatty acids and LDL Cholesterol</b>	N/A	<u>Qualifying Criteria</u> The food contains no more saturated and trans fatty acids than (a) 0.75g per 100 ml for liquid food; and (b) 1.5g per 100 g for solid food <u>Disqualifying Criteria</u> No more than - ; 325 mg/serve of Sodium and 16 g/serve of Total Sugars	'Low in saturated and trans fatty acids' (this terminology links to qualifying criteria)	May help reduce [blood LDL cholesterol] OR [serum LDL cholesterol] OR [total blood cholesterol] OR [total serum cholesterol] OR [blood cholesterol] OR [serum cholesterol] levels	A healthy diet consisting of a variety of foods low in saturated fatty acids and trans fatty acids	General population	%DI saturated fatty acids in nutrition information panel % DI Energy in nutrition information panel 'Energy needs' statement included	N/A	<i>This [food] is low in saturated and trans fatty acids. Total blood cholesterol may be reduced when consuming a healthy diet consisting a variety of foods low in saturated and trans fatty acids.</i>

## 5.4 General Level Health Claims Relating to Maternal Folic Acid Consumption and Normal Foetal Development

### 5.4.1 Background

At a recent meeting of the Standard Development Advisory Committee (30<sup>th</sup> September 2005) the issue of how to appropriately regulate claims that indirectly refer to the diet-disease relationship of maternal folic acid consumption and foetal neural tube defects was discussed. For example, the claim:

*This [food] is high in folate. As part of a healthy diet consisting of a variety of foods, folate assists in normal foetal development during pregnancy,*

would not normally be classified as a high level claim because it does not reference a serious disease or condition, and therefore would not normally be subject to the specific criteria and conditions that relate to the pre-approved high level claim. However, in referring to *normal foetal development during pregnancy* and alike, it can be argued that the claim is based on the diet-disease relationship by referring to the absence of neural tube defects through the consumption adequate amounts of folate.

### 5.4.2 Assessment and Rationale

FSANZ recognises that suppliers may choose not to use the pre-approved high level claim, because the reference to the serious disease or condition may attribute negative connotations to the product. This was given as one of the primary reasons regarding the slow uptake of the permitted pilot health claim regarding maternal folate consumption and a reduced risk of foetal neural tube defects on products and associated advertising. However, FSANZ considers that general level health claims relating to maternal folic acid consumption and normal foetal development should be regulated in the same way as the pre-approved high level claim, given the evidence substantiating both types of claims would be identical.

In addition, several aspects of the folic acid and foetal neural tube defect diet-disease relationship highlight the critical need for FSANZ to regulate the general level health claim in the same way as the pre-approved high level claim.

- The diet-disease relationship relates to a specific population sub-group that could be particularly vulnerable to the information conveyed by the general level health claim.
- A level of 680 µg dietary folate equivalents is the minimum daily protective amount to achieve the health effect. Therefore, general level health claims that communicate the health effect in a positive way should only be on foods that meet the high level claim qualifying criteria. This criterion takes into account a reasonable number of serves of food that can be consumed on a daily basis to reach the required daily level.
- the diet-disease relationship relates to a very specific period in which the consumption of folic acid will achieve the health effect, that is, one month prior to conception and three months after conception. This is unlike the other diet-disease relationships reviewed, which more often relate to permanent changes in the diet. This is important information that should be communicated by the general level health claim.

### 5.4.3 Proposed Approach at Draft Assessment

In the context of the issue raised at the meeting of the Standards Development Advisory Group for Nutrition, Health and Related Claims, members generally supported the approach to apply the high level claim qualifying criteria to the regulation of the general level health claims that relate to maternal folate consumption and normal foetal development. However, discussion was limited to this aspect.

Following assessment of this issue, FSANZ proposes that any food compositional criteria or any other restrictions around use, wording conditions and other labelling requirements that apply to the pre-approved high level claim for folic acid and foetal neural tube defect will also apply to the equivalent general level health claim.

## CHAPTER 6: Related Claims - Endorsements

### 6.1 Summary of Recommendations

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

### 6.2 Policy Guidance

The Policy Guideline defines ‘endorsement program’ as *in the commercial sense – an advertising testimonial: an instance of public endorsement of a product for advertising purposes.*

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

Although the Policy Guideline recommendations regarding endorsements have been followed to some extent, there has been some deviation from them based on the FSANZ consumer research and submitters’ comments in response to the Initial Assessment Report. This has been further discussed in the rationale outlined below.

### 6.3 Relevant Issues Raised in Submissions

At the time of consulting on the Initial Assessment Report, specific approaches to the regulation of endorsements had not been raised, therefore responses received focus on broad issues/options only.

Key themes that emerged in the submissions included:

- That endorsements need to demonstrate that they have a positive effect on food choices, independent of other nutrition, health and related claims.
- There needs to be clarity around the definition of ‘endorsement’ and some examples of ways to define endorsements needed to be provided. Clarity was also sought on when an ‘endorsement’ becomes a claim and how they would fit within the new regulations. Clarity was seen as essential in order to ensure industry and consumer confidence in the system.
- It was suggested that an ‘endorsement’ be subject to the same regulatory requirements as other claims, that is, they be considered a general level claim if the logo (trademark), purpose and principles underpinning the programme do not reference a serious disease or a biomarker and a high level claim if it does reference a serious disease or a biomarker. Another submitter recommended that endorsements that consist of a logo or Certification Trademark be classified as general level claims and those that include the name of a disease in the endorsement be classified as high level claims.
- In terms of what constitutes an ‘endorsement’, questions were raised about whether advice from health professionals, celebrities, nutrition and health organisations were included. It was noted that dietary advice could be considered to be outside the claims framework, to be a general level claim, or a high level claim depending on the context it is presented within.
- Concerns were expressed about excessive administrative constraints on reputable programs which may cause delays in implementing necessary changes and thereby have a negative effect on public health – this not only related to labelling but also to education materials.
- At present there are endorsements and logos in the market place that have been approved as Certification Trademarks and some that have not. There was some concern around those that are not underpinned by a reputable health organisation and the potential for those to mislead consumers. The regulation of such ‘endorsements’ was firmly supported.
- The issue of Certification Trademarks was raised with the National Heart Foundation ‘tick’ provided as an example. It was noted that the rules underpinning Certification Trademarks are assessed by the Australian Competition and Consumers Commission, Intellectual Property Australia, and the Intellectual Property Office of New Zealand. It was noted that the process for obtaining approval of a certification programme is very rigorous, involving submission of all rules and schedules for review, a period of ‘advertising’ of the proposed rules and/or changes to them for external comment and a final assessment prior to approval being granted.
- It was suggested that given that the underlying purpose of the new provisions for nutrition, health and related claims is to protect consumers from misleading and deceptive claims, the fact that Certification Trademarks have been approved by Australian Commission, Intellectual Property Australia and the Intellectual Property Office of New Zealand and that the Certification Trademarks ‘owner’ has been found to be a suitable certifying body should provide sufficient ‘quality assurance’ and obviate the need for any further ‘approval’ by FSANZ.

Further to this, it was proposed that Certification Trademarks should be the means by which reputable endorsement programmes are distinguished from those with the potential to mislead consumers.

- From an industry perspective, some submitters thought that the regulation of endorsements would create a level playing field and create market opportunities where profits would outweigh costs. Other submitters felt that there would be increased costs associated with legal, administrative and substantiation issues associated with duplication of administration together with compliance and enforcement.
- It was noted that the major impact would be in relation to cost and timing when current endorsements were considered high level claims and thus require pre-approval.
- Other positive aspects of regulating endorsements were that it would: ensure that consumers were informed about the purpose of the endorsement; there would be a beneficial impact on product development/nutrition composition in terms of reducing risk of disease; increased consumer choice of healthier foods; a competitive food industry; support for government health promotion messages and economic support for nutrition research.
- There were mixed views as to whether the National Heart Foundation ‘tick’ program should be considered a general level or high level claim. Together with this, the difficulty of trying to categorise endorsements was noted because of the ambiguity associated with the messages associated with the endorsement.
- It was noted by one submitter that the control of endorsements was vital to the success of the standard especially given the Heart Foundation have clearly been able to contravene the prohibition, creating an unfair playing field for other suppliers.
- A number of submitters recommended that there should be a ‘grandfathering’ clause relating to endorsements that are in current use.
- In terms of the impact on enforcement agencies, regulation of endorsements was thought to provide greater clarity but possibly the need for greater resources to enable ongoing monitoring of endorsements.

#### **6.4 FSA NZ Consumer Research**

A key objective of the quantitative research carried out by FSA NZ (2005b) was to investigate the influence of endorsements on respondents’ perceptions in relation to the health benefits of the product. Respondents were shown four variations of a tinned salmon product in random order, each with a different type of claim:

- product with non-specific endorsement – National Heart Foundation Tick only;
- product non-specific general level claim – Tick removed and claim added: ‘this food is part of a healthy diet’;

- product with a specific general level claim – Tick removed and claim added ‘a diet low in saturated fat is beneficial for a healthy heart. This product is low in saturated fat’;
- product with high level claim – Tick removed and claim added ‘A diet low in saturated fat helps reduce the risk of heart disease. This product is low in saturated fat’.

A total of 518 respondents completed the module on endorsements.

Respondents were questioned about the credibility of claims and what information on the food label they used to verify the claims. Questions were also asked about the influence of the claims on perceived health benefit in relation to the population group who might benefit and the nature of the benefit, the effectiveness of the benefit and influence on intent to purchase.

It is important to note that there may be an influence of the particular endorsement used in this research. The National Heart Foundation Tick has considerable acceptance and inherent credibility in Australia and New Zealand and it is possible that the findings may not be replicable if the endorsement was less well known.

The results indicate that respondents are significantly more likely to consider a product with a non-specific endorsement to be credible (i.e. trust what it says completely) (77%), when compared to a product with a non-specific general level claim (62%), a product with a specific general level claim (62%) or a product with a high level claim (54%). The results also indicated there was no consistent difference in overall perception of effectiveness in communicating health information between the endorsement, a non-specific general level claim, a specific general level claim or a related high level claim.

When examining results from a question relating to the perceived benefits, it was found that the National Heart Foundation endorsement was perceived to be similar to both a high level claim (in that 51% understood it to relate to a reduced risk of heart disease; 50% also understood this for the high level claim) and a specific general level claim (in that 53% understood that it assisted in heart health; 47% also understood this for the specific general level claim). Because the endorsement lacked specificity, consumers assigned many meanings to it. From a regulatory point of view, the results suggest that the non-specific endorsement cannot be classified easily in the Claims Classification Framework.

The lack of claim specificity may contribute to the finding that more consumers thought the products with the non-specific endorsement (65%) and the non-specific general level claim (63%) would benefit ‘all types of people’ compared to the specific general level claim (58%) and specific high level claim (57%). Similarly the proportion of consumers who thought eating the product would lead to a better diet overall was higher for the products with non-specific general level claims (58%) and non-specific endorsement (44%) compared to products with the specific claims (general level claim 37% and high level claim 36%).

The research also addressed the impact of endorsements on the consumer’s intent to purchase. It found that a non-specific endorsement did not have a greater impact on intent to purchase than the other types of claims.

More respondents perceived the non-specific endorsement claim as having a ‘very strong effect on health’ (13%) compared to the other types of claims but the difference was only significant for the non-specific general level claims (9%).

## 6.5 Definitions

FSANZ proposes the following definitions.

*That **endorsement** means a design used, or intended to be used, to distinguish food certified by an endorsing organisation in relation to its nutrition or health features from other foods not so certified, and includes a certification trade mark, but does not include –*

- a) a design that distinguishes food in relation to ethical, religious or environmental features including vegetarian, halal, kosher or organic designs; or*
- b) a design that includes a reference to a serious disease other than as part of the name of the endorsing organisation.*

*That **endorsing organisation** means an independent, non-profit or not-for-profit organisation formed for nutrition, health, community or government purposes, the name of which may include a serious disease, but does not include an organisation established by suppliers or their representatives.*

## 6.6 Assessment and Rationale

The proposed approach has taken account of many factors including the recommendations of the Policy Guideline, stakeholder comments, results of the FSANZ consumer research and international practice.

Various models for the regulation of endorsements have been explored and while the Policy Guideline recommended that ‘*endorsement programs that state or imply a nutrition, health or related claim must comply with the principles and requirements of the relevant claim category. They will require a statement to explain why the endorsement has been granted (e.g. meets the nutrient criteria required by the endorsement program)*’, FSANZ has decided to:

1. treat current endorsements independently of future endorsements;
2. apply only certain elements of the Claims Classification Framework to the regulation of future endorsements rather than broadly applying the Claims Classification Framework as for nutrition and health claims;
3. not mandate the inclusion of a statement explaining why the endorsement has been granted on labels.

Specifically, the rationale for the recommendations outlined below is based on the following arguments:

### 6.6.1 Current Endorsements

- Applying the requirements of the Claims Classification Framework to all current endorsements would result in many current endorsements:



- becoming illegal; or
- having to modify their criteria considerably (and thereby rule out many foods that currently carry the endorsement); and
- having to add a number of wording elements such as reference to the component of food and specific health benefit and the total diet context.

This approach was considered to have greater cost than benefit from the perspective of the endorsing agency, consumers and food suppliers. There are a number of endorsement programs that are currently well established and are considered to have an important role in educating consumers and in promoting public health. Therefore, it would be undesirable to impose the regulatory measures as discussed. This approach will enable such endorsements to continue unchanged;

- Many current programs are run by credible health/medical or community/government organisations that have public health as their central objective, and given this important role, FSANZ should be able to entrust them in delivering effective health messages to consumers that are not misleading; and
- By approving current endorsement programs through a principle based system (as opposed to applying the numerical criteria that sits within the Claims Classification Framework), FSANZ avoids the difficulties associated with developing one system of regulation that fits the purpose, target group and criteria of all current programs but provides some assurance that the nutrition criteria sitting behind the endorsement are consistent with national nutrition policy principles.

#### 6.6.2 *Future Endorsements*

- Applying the requirements of the Claims Classification Framework to future endorsements also has disadvantages in that:
  - it is extremely difficult to categorise endorsements in terms of whether they fall within the general level claim or high level claim category. This point was made by submitters to the Initial Assessment Report and is supported by the results of the FSANZ quantitative research which demonstrates that respondents perceived the National Heart Foundation tick to be similar to both a general level claim and a high level claim;
  - there are a number of wording requirements associated with the Claims Classification Framework, including the need to make specific reference to the component of the food, the specific health benefit and present the claim/endorsement within the total diet context. By mandating such elements, the benefits of using a logo to communicate a message, would be diminished. This approach could also pose problems in relation to placement of the endorsements on small packages;
  - organisations that have a serious disease or condition in their name, are at a distinct disadvantage if they want to use a logo that includes their name, as an endorsement;
  - it is considered inappropriate that endorsements relating to a serious disease or condition associated with gluten or lactose should be required to comply with the nutrition disqualifying criteria in the Claims Classification Framework given that:

1. the purpose of the endorsement is focused on directing people with a specific food intolerance to appropriate foods; and
  2. the range of foods available to this group of the population is already significantly restricted.
- By treating future endorsement programs as recommended by FSANZ:
    - organisations that include a reference to a serious disease or condition in their name, will be able to use their logo in the form of an endorsement without having to meet the requirements for making a high level claim. This is considered fair given that such organisations have the protection and promotion of public health as their primary focus and have an important role in educating consumers. The fact that their name includes a reference to a serious disease should not mean that an endorsement from such an organisation ought to be regulated differently from endorsements provided by similar organisations where their name does not reference a serious disease or condition;
    - there will be no question in terms of how to categorise endorsements. No endorsement will need to meet the requirements of making a high level claim;
    - there will be some consistency in terms of how endorsements will be regulated compared to nutrition and health claims in that:
      - the general level health claim substantiation requirements need to be met; and
      - where applicable, the same qualifying and/or disqualifying criteria will need to be met;
    - foods complying with the general level health claim disqualifying criteria ensures promotion of foods consistent with nutrition policies;
    - the benefits associated with using an endorsement (including that they can become well recognised symbols from a trustworthy organisation for nutrition education) can be realised;
    - endorsements will not be required to include an additional statement on the food label explaining why the endorsement has been granted given that certain requirements of the Claims Classification Framework need to be met, including nutrition criteria and/or disqualifying criteria. It was considered to be too burdensome and ineffectual for small packages. It will be suggested in a user guide that this information be incorporated in education materials associated with the endorsement.

## 6.7 Proposed Approach at Draft Assessment

That the management of endorsements will be based on a **two phase system focusing on current endorsement programs; and future endorsement programs** as follows:

### 6.7.1 *Current programs*

Endorsements that are currently in existence will need to be pre-approved by FSANZ to continue unchanged. To be pre-approved, they will need to:

- fit within the definition of endorsement as outlined above; and
- the nutrition criteria that the endorsement program applies to products will need to be consistent with Australia/New Zealand nutrition policy principles.

Pre-approved endorsements will be listed in the Standard as being exempt from the requirements of the Standard. FSANZ has identified several current endorsement programs that may meet the criteria and conditions for pre-approval (refer to Appendix 5.4).

Any current endorsement program that is not pre-approved by FSANZ will have to be regulated as a nutrition or health claim and therefore meet the relevant requirements of the Claims Classification Framework, depending on the nature of the claim made. See Figure 5.6 below for a diagrammatic representation of the regulation of current endorsements.

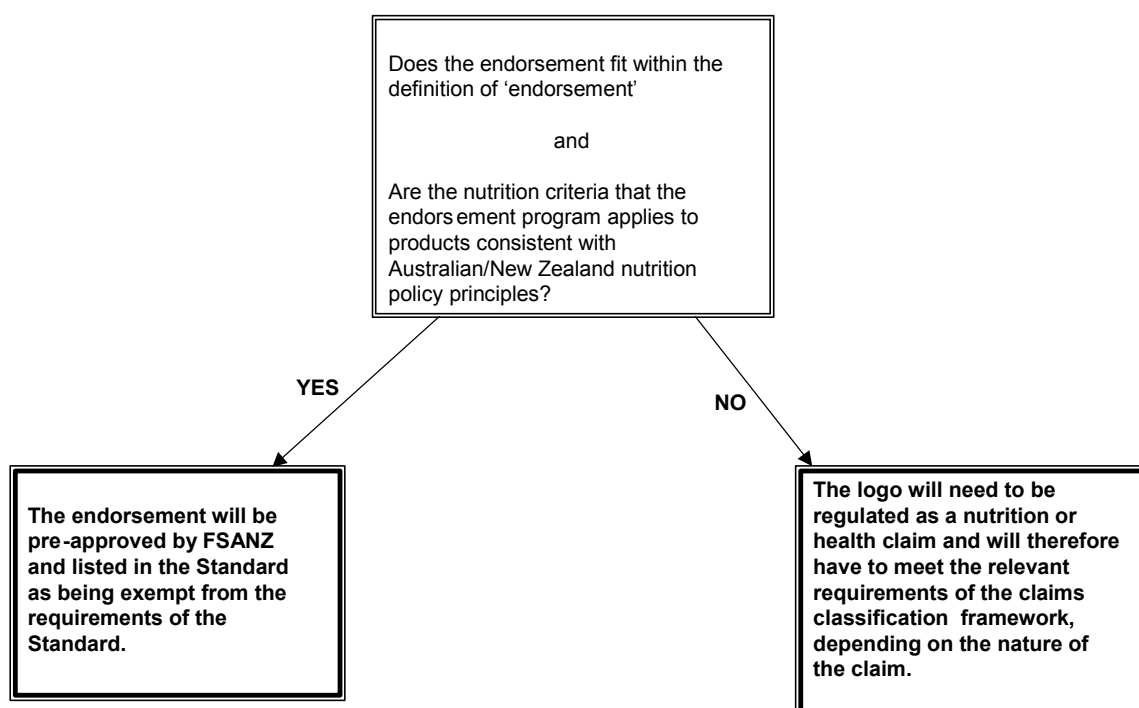


Figure 5.6: Regulatory Framework for current endorsements

Appendix 5.4 outlines the current endorsement programs that have been recommended for pre-approval to date, with an accompanying rationale to indicate the basis for pre-approval.

### 6.7.2 Future Endorsement Programs

Like current endorsements, future endorsements will need to fit within the definition of ‘endorsement’ as specified.

In addition to this:

1. If the endorsement **does not reference a serious disease**:

- a. the endorsement will need to meet the general level health claim substantiation framework;
  - b. the food carrying the endorsement will need to meet the general level health claim disqualifying criteria; and
  - c. the food carrying the endorsement will need to meet relevant qualifying criteria if the endorsement specifically relates to a property of the food.
2. If the endorsement **does reference a serious disease where it is in the name of the organisation and the serious disease or condition is not associated with gluten or lactose**:
- a. the endorsement will need to meet the general level health claim substantiation framework;
  - b. the food carrying the endorsement will need to meet the general level health claim disqualifying criteria; and
  - c. the food carrying the endorsement will need to meet relevant qualifying criteria if the endorsement specifically relates to a property of the food.
3. If the endorsement does reference a serious disease **where it is in the name of an organisation that relates to a serious disease or condition associated with gluten or lactose**:
- a. the endorsement will need to meet the general level health claim substantiation requirements; and
  - b. the food carrying the endorsement will need to meet any related qualifying criteria as specified in the Code – for example, gluten free criteria.

The regulation of future endorsement is represented diagrammatically below in Figure 5.7.

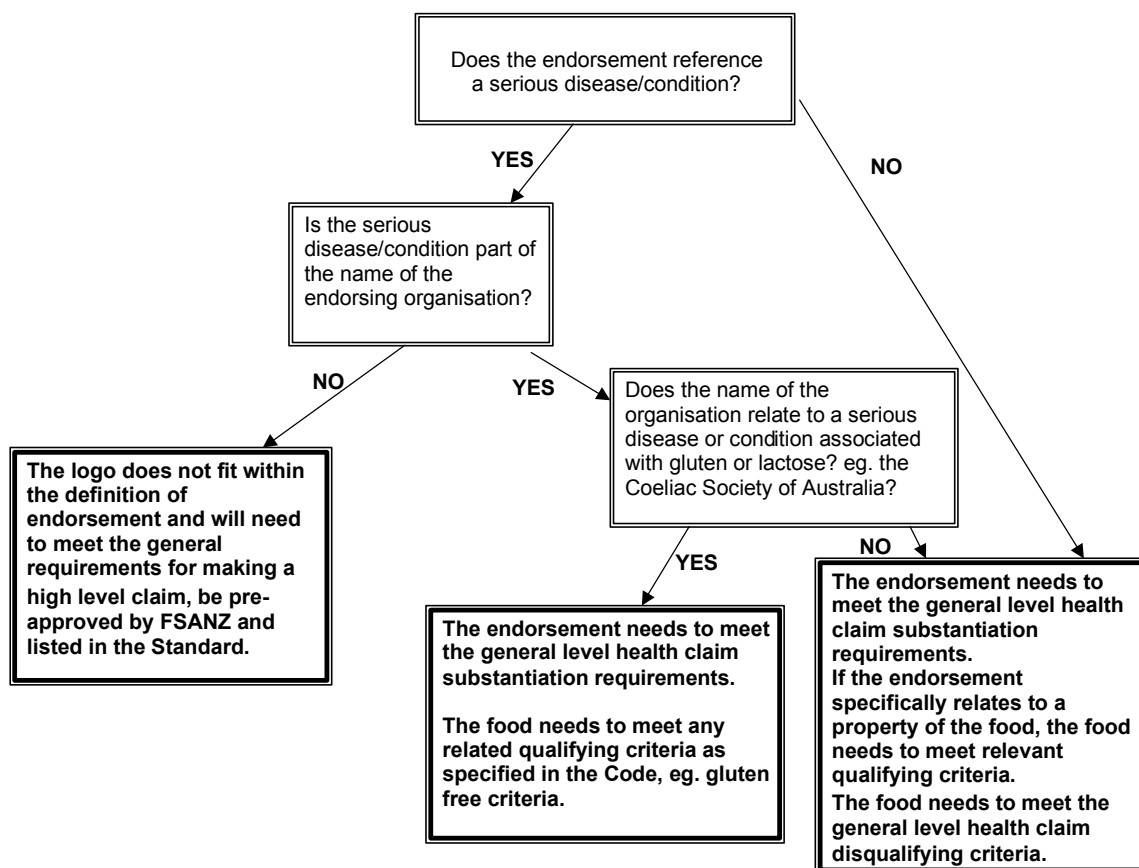


Figure 5.7: Regulatory Framework for Future Endorsements<sup>13</sup>

If the endorsement incorporates a nutrition or health claim, then the same conditions apply as outlined above. If an endorsement is accompanied by a claim that is not technically part of the endorsement, the claim will need to comply with the relevant requirements of the Claims Classification Framework, depending on whether it is a nutrition claim, a general level health claim, or a high level claim. This can be seen below in Figure 5.8

<sup>13</sup> Based on the premise that the endorsement fits within the definition of ‘endorsement’

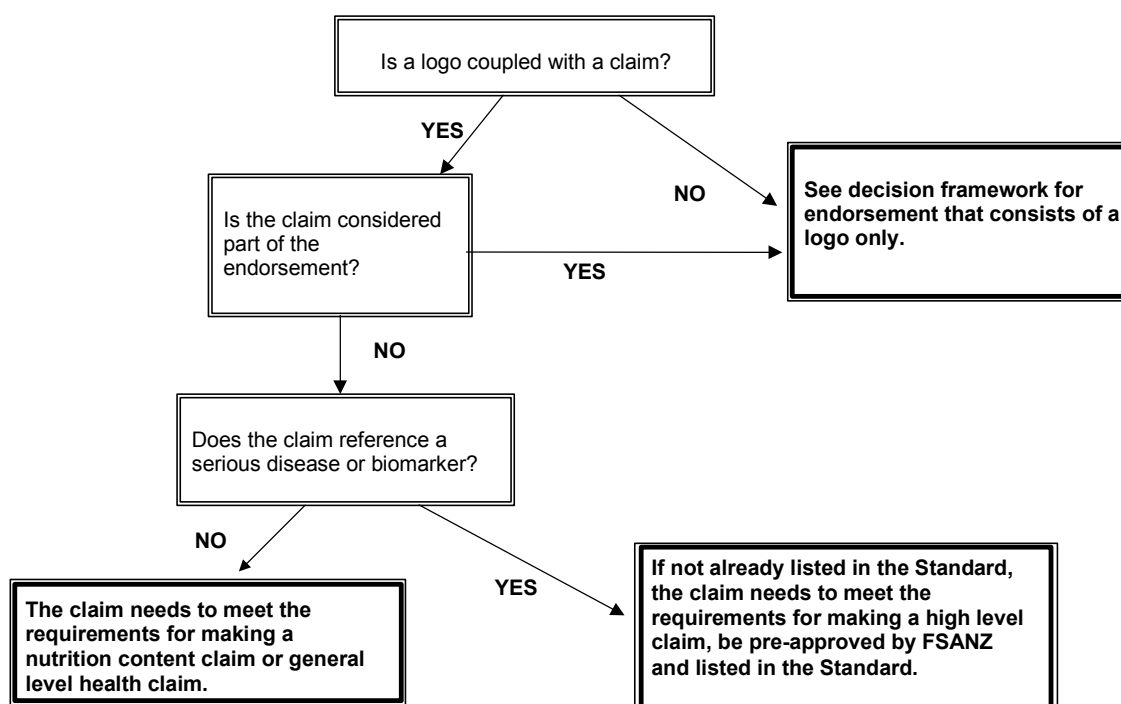


Figure 5.8: Regulatory Framework for Future Endorsement Coupled with a Claim<sup>14</sup>

If a logo references a serious disease that is not in the name of an organisation, it is technically not an ‘endorsement’, as the definition of endorsement excludes *a design that includes a reference to a serious disease other than in the name of the endorsing organisation*. In this case, the logo will need to meet the general requirements for making a high level claim.

#### 6.7.2.1 Education materials relating to future endorsements

When producing education materials about an endorsement, the endorsing agency will be permitted to reference the serious disease that is the subject of their organisation. However suppliers using the endorsement will not be allowed to reference a serious disease unless it is the subject of a pre-approved claim already listed in the Standard.

<sup>14</sup> Based on the premise that the endorsement fits within the definition of ‘endorsement’

## CHAPTER 7: Related Claims - Cause Related Marketing

### 7.1 Summary of Proposed Recommendation

There will be a mandatory requirement that a disclaiming statement be used in conjunction with a cause-related marketing statement on food labels and in advertising.
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### 7.2 Policy Guideline

Cause-related marketing is where a supplier donates a proportion of money from the sale of a product to an organisation. An example of a Cause-related marketing statement is *Proceeds from the sale of this product will be donated to the Royal Society for Osteoporosis*<sup>15</sup>.

The Policy Guideline suggests that a disclaiming statement is required to ensure that Cause-related marketing statements are not perceived as health claims and therefore not caught by the regulatory frameworks for general level claims and high level claims.

### 7.3 Relevant Issues Raised in Submissions

Submitters believed that cause-related marketing statements may have the following impacts:

- consumers might interpret a cause-related marketing statement as a health claim or an endorsement.
- opportunities are provided for industry to support organisations which results in benefits for all stakeholders;
- a significant negative economic impact would occur if cause-related marketing were restricted or the definition includes individual sponsorship arrangements (e.g. nationally and internationally recognised athletes);
- regulation of cause-related marketing would provide a level playing field for health agencies.

A number of submitters were not aware of any evidence on how consumers interpret cause-related marketing, so many suggested the need for consumer research.

Some public health submitters opposed cause-related marketing statements on food packages and proposed a number of conditions that should apply to cause-related marketing strategies. Other public health agencies believed that they should not be disadvantaged by restrictions and that any regulation should apply equally to organ related and disease related charities. Several submitters who represented nutrition and health interests believed that cause-related marketing statements should be regulated under the claims framework when there is a risk of misinterpretation or when a health charity is involved. Various disclaimers were proposed by mainly health related agencies.

Industry supported cause-related marketing and generally supported the use of a disclaimer, but they did not want the wording to be mandatory (although guidance could be provided in a user-guide). It was pointed out that any misrepresentations would either result in the cause-related marketing statement being classified as a nutrition, health or related claim or would be enforced by fair trading law.

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<sup>15</sup> This example was used in research commissioned by FSANZ (2005a).

## 7.4 Assessment and Rationale

### 7.4.1 Mandatory Requirement for a Disclaiming Statement

FSANZ's (2005a) qualitative research indicated that cause-related marketing statements were not perceived as health claims. When examining two sets of nutrient related claims (calcium and omega-6), cause-related marketing statements were consistently ranked low (or bottom) in the list of claims in terms of consumers expecting the product carrying the statement to provide a health benefit..

FSANZ's (2005b) quantitative consumer research investigated perceived health benefits communicated by the cause-related marketing statement *Proceeds from this product will go to the Royal Society for Diabetes*. Contrary to the qualitative research, respondents believed that a product with a cause-related marketing statement was more beneficial to health than a product without a cause-related marketing statement. Respondents were significantly more likely to feel that the baked beans with the cause-related marketing statement provided:

- a reduced risk of diabetes (33% compared to 9%)
- a diet lower in sugars (21% compared to 13%); and
- a low Glycaemic Index (21% compared to 16%).

This result provides evidence to support the recommendation provided by the Policy Guideline regarding the use of a disclaiming statement in conjunction with a cause-related marketing statement. FSANZ considers that the outcome of the consumer research and the recommendation of the Policy Guideline to be sufficient justification to include this as a mandatory requirement in the Standard.

### 7.4.2 Disclaiming Statement

FSANZ has also explored the issue of the wording of the disclaiming statement, which was raised at Initial Assessment. There were a number of examples of disclaiming statements provided by submitters, ranging from the very obvious (to suppliers and regulators) but not very helpful to or informative to consumers such as, *this is not a health claim* to other statements that were long, wordy and may not be scientifically correct and could be potentially misleading to consumers such as, *The [organisation linked to the cause] does not endorse this food product and it will not help in the reduction of risk of disease nor in the enhancement of health*.

Due to this disparity of examples provided at Initial Assessment, FSANZ considers this to be demonstrative of the polarity of disclaimers that may appear in conjunction with the cause-related marketing statements once the regulations comes into force and may cause considerable confusion amongst consumers. However, to prescribe wording for the disclaimer would be a requirement more stringent than that currently required for advisory statements where there are health and safety considerations.

As such, the provision in the Standard which triggers the mandatory requirement for a disclaiming statement to be used in conjunction with the cause-related marketing statement will include sufficient information to indicate the type of information that should be conveyed by the disclaimer, in order to limit consumer confusion.



FSANZ has determined that a statement to the effect that the product company makes no claims in relation to the food/product being beneficial for managing the serious disease referenced in the cause-related marketing statement, must be made in conjunction with the cause-related marketing statement.

#### 7.4.3 *Definition of 'cause-related marketing statement'*

The assessment of submissions at initial assessment also highlighted the need to define 'cause-related marketing statements' to differentiate such statements from endorsements and health claims, which are subject to different regulatory parameters such as the claims classifications framework and substantiation requirements. This definition will ensure that suppliers appreciate what constitutes a cause-related marketing statement on food labels or in advertising and that in these instances a disclaiming statement is also required to be included on the label or in advertising.

As demonstrated by the quantitative consumer research, consumers may ascribe health benefits to a food where a cause-related marketing statement is used, however this is most likely confined to where the name of the organisation that is the subject of the cause-related marketing statement makes reference to a disease or health outcome. Stakeholders also raised the issue that a significant negative economic impact may occur if cause-related marketing were restricted or the definition includes individual sponsorship arrangements.

Therefore, in the context of the regulatory framework for nutrition, health and related claims, the definition of 'cause-related marketing statement' will be narrow so that it only captures organisations where the name of the organisation references a serious disease rather than other types of organisations or individuals. FSANZ proposes the following definition:

***Cause related marketing** means a statement that the sale of the food will contribute to fundraising for an organisation, the name of which refers to a serious disease.*

#### 7.5 **Proposed Approach at Draft Assessment**

FSANZ has identified the following recommendations at Draft Assessment in relation to cause-related marketing statements.

- There will be a mandatory requirement that a disclaiming statement be used in conjunction with a cause-related marketing statement on food labels and in advertising.
- The wording of the disclaimer will not be prescribed although the Standard will indicate the information that must be conveyed by the disclaimer.
- A definition of 'cause-related marketing' will be included in the standard to differentiate such statements from endorsements and nutrition and health claims.

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## Implied Claims

### Background

Whilst the Policy Guideline addresses ‘implication’ in relation to a number of specific aspects of claims (e.g. reliance on single food, target population, guaranteed benefit) it does not specifically address non- or limited text-based claims. Rather, it provides policy principles that all ‘claims’ must meet. FSANZ has therefore adopted a pre-requisite approach that potentially captures both explicit and implicit claims, and subjects the latter to the same requirements for substantiation as explicit claims. In practice, these requirements will be difficult to meet – without the ‘claim’ becoming more explicit.

It is proposed that the Standard for Nutrition and Health Claims will include a general prohibition on the use of nutrition and health claims (including claims derived implicitly through the use of other visual elements such as graphics or key words). The prohibition will need to be drafted in order to avoid capturing inappropriate information, such as, dietary advice. In order to be a ‘nutrition or health claim’, certain conditions will need to be met, such as, only permitting the use of those claims which have been substantiated, and include reference to a specific ‘component’ and associated benefit. The most basic of these conditions are claim prerequisites. If a nutrition or health claim meets these prerequisites, it will then be eligible for further consideration within the context of the standard.

The proposed prerequisites are, that the claim:

- can be substantiated according to the substantiation framework;
- make reference to a specific [component] of the food; and
- make reference to specific benefit (for health claims only).

### Definition of ‘claim’

In order to support the prerequisite process, it is proposed to change the definition of ‘claim’ in Standard 1.1.1 to ensure it captures all potential claims, whether presented explicitly or implicitly.

The current definition of a claim is as presented below.

<b>Term</b>	<b>Current definition in Standard 1.1.1 in the Code</b>
Claim	Means any statement, representation, information, design, words or reference in relation to food, which is not mandatory in this Code.

The definition of a ‘claim’ is very broad, encompassing any voluntary representations made in relation to a food. This covers words or other artwork on food labels, or conveyed through other mediums such as advertisements.<sup>16</sup> It also covers verbal representations in relation to food.

<sup>16</sup> Advertising is defined in the Model Food Act as ‘any words, whether written or spoken, or any pictorial representation or design, or any other representation by any means at all, used or apparently used to promote, directly or indirectly, the sale food’.

The term ‘claim’ provides a basic threshold for the categories of claims in the Claims Classification Framework. For example, in order for something to constitute a general level claim or a high level claim, it must first meet the criteria for being a claim.

FSANZ considers that the current definition of ‘claim’ in the Code provides a basis for defining the categories of claims. The current definition of claim, which makes reference to ‘representation’ and ‘words or reference in relation to a food’ captures entities such as graphics, brand names, keywords and various statements that may be construed as ‘implied’ claims.

However, for the purpose of clarity and to facilitate compliance and enforcement, FSANZ considers it is appropriate to amend the current definition in Standard 1.1.1 to put it beyond doubt that claims may be presented explicitly or implicitly.

FSANZ suggests to amend the current definition for claim in Standard 1.1.1 in the Code, as below, noting that further thought needs to be given to the terminology used, such as ‘implied claims’.

<b>Term</b>	<b>Proposed amended definition for inclusion in Standard 1.1.1</b>
Claim	means any statement, representation, design or information in relation to a food or property of a food which is not mandatory in this Code, and includes an implied claim.

### **Relevant issues raised in submissions**

Submitters’ comments on the issue of ‘implied claims’ indicated a range of views around the establishment of criteria for managing these. Whilst some suggested it would be desirable, it was noted that the development of criteria would be difficult in practice when considering images and TV advertisements and other examples of implied claims.

NZFSA were opposed to FSANZ developing criteria as doing so suggests that FSANZ or the enforcement body can accurately interpret for the consumer, any implications associated with the claim. Other submitters also noted that some implied claims would be addressed through the provisions of State Food Acts and the Trade Practices Act regarding false and misleading conduct.

Some NZ industry submitters recommended a self-regulatory advertising code to address implied claims with a legislative backing such as advertising rules provided for in legislation.

### **Relevant international approaches**

It is noted that internationally this term does not have an agreed definition or consistent use; hence some information is not directly comparable.

Canada suggests certain words should be avoided or ‘used with caution’, such as healthy, nutritious, wholesome, good for you, and there is specific policy around the use of heart symbols and the term ‘heart’. Objection is taken to claims such as ‘heart smart choices’ or ‘heart smart eating’.

The United States position is that claims about a food that suggest a food may be useful in maintaining healthy dietary practices and which are made with an explicit content claim (e.g., healthy, contains 3 grams of fat) are implied claims and are prohibited unless provided for in a regulation in the Food and Drug Administration. However, it is likely that many implied claims fall under structure/function claims, which are unregulated and a health symbol may be used, such as a heart symbol.

Codex does not provide any express provisions or prohibitions for implied claims in either the current Guidelines for use of Nutrition Claims or the Draft Guidelines for use of Nutrition and Health Claims.

Currently in the European Union, there is only a general provision that claims should not mislead the consumer and that the label, presentation and advertisement of a food cannot attribute prevention, treatment and curing properties to a food. Many claims found on the market make reference to general, non-specific benefits and to general wellbeing. It is currently being proposed that such claims may only be made if accompanied by a specific permitted health claim.

### **Consumer research**

FSANZ's qualitative consumer research indicated that pictures and key words appeared to attract attention and convey information pertaining to potential health benefits; participants said this was particularly the case in time-poor and/or distracted situations. Health-conscious participants indicated they were more likely to verify information on potential health benefits by using other label elements such as ingredient lists or nutrition information panels; non health-conscious participants seemed more likely to accept and trust graphical examples.

The subsequent quantitative research followed up on this issue. There were some indications of products with a brand name or graphics communicating potential health benefit more effectively than products with explicit claims in relation to specific sub-groups of the population and/or specific benefits however, when considered overall – findings were not consistent and not statistically significant in relation to implied claims being any more or less effective than explicit claims. Therefore from the broader perspective, the conclusion is drawn that key words and graphics have similar impact to explicit claims. Furthermore, when asked about impact on behaviour, that is, likely purchase of the product(s) there were no significant differences between products with keywords or graphics and products with general level or high-level claims.

### **Assessment and rationale**

Potential 'implied health claims' include those represented through, for example, graphics, key words, brand names and endorsements. The approach outlined above will assist in filtering out such claims. It will do this by putting in place a broad prohibition on nutrition or health claims (including implied claims), and then only permitting the use of those claims, which include reference to a specific [component] and benefit. Thus, non-specific claims, including implied claims, will be caught by the general prohibition, and will not be able to meet the claim prerequisites. Accordingly, they will be prohibited. Endorsements will be permitted through a separate process (refer to Chapter 6).

An alternative approach would be to specifically prohibit ‘implied claims’. However, this is seen as problematic due to the inherent difficulties of defining implied claims as ‘implied claims’ represents a concept rather than a specific and readily defined term, and is used in a variety of ways both domestically and internationally. It also gives rise to the serious problem of determining what a claim implies, and for whom, which is inherently uncertain and subjective, and likely to give rise to insoluble difficulties for enforcement agencies.

### **Proposed Approach at Draft Assessment**

In order to ensure that there can be no argument that implied claims are captured by the Code, FSANZ proposes to amend the current definition for claim in Standard 1.1.1 as follows:

<b>Term</b>	<b>Proposed amended definition for inclusion in Standard 1.1.1</b>
Claim	Means any statement, representation, design or information in relation to a food or property of a food, which is not mandatory in this Code, and includes an implied claim.

In order to ensure that the use of implied claims is minimised, they will be addressed primarily through the health claims standard by claim prerequisite conditions, that is, general requirements that all nutrition and health claims:

- be substantiated according to the substantiation framework
- make reference to a specific component of the food
- other than nutrition content claims, make reference to specific health effect

Substantiation of a claim will be required to relate to either the wording or the image/graphic that implies the highest health effect.



**Matrix of Qualifying and Disqualifying Criteria for General Level Claims**

**Table 5.2.1: Matrix of Qualifying and Disqualifying Criteria for General Level Claims**

Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
1. Nutrients where increased consumption is recommended – 'risk decreasing nutrients'	Protein	<p>A <b>nutrition content claim</b>: the food contains at least 5 g of protein per serve</p> <p>'<b>Good source of protein</b>': the food contains at least 10g of protein per serve</p> <p>'<b>Increased protein</b>':</p> <ul style="list-style-type: none"> <li>(a) a serving of the food contains at least 5 g of protein, before the food is enriched with protein; and</li> <li>(b) the food contains at least 25% more protein as the same quantity of reference food; and</li> </ul> <p>The claim states:</p> <ul style="list-style-type: none"> <li>(a) the identity of the reference food;</li> <li>(b) the difference between the protein content of the food and of the reference food; and</li> </ul> <p>In addition, the claim is presented so that all elements of the claim are in one place</p>	Minimum requirement to meet nutrition content claim criteria.	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b>  <b>Sodium: 325 mg/serve</b>  <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b>  <b>Sodium: 775 mg/serve</b>  <b>Total Sugars: 31 g/serve</b></p>

<sup>17</sup> Criteria may include specific disqualifying criteria in addition to qualifying criteria.

Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
	Dietary Fibre	<p>A <b>nutrition content claim</b>: a serving of the food contains at least 2 g of dietary fibre. For meals/main dishes a serving of the food contains at least 5.5 g of dietary fibre</p> <p><b>'good source of fibre'</b>: a serving of the food contains at least 4 g of dietary fibre. For meals/main dishes a serving of the food contains at least 11 g of dietary fibre</p> <p><b>'Increased fibre'</b>:: a serving of the food contains at least 2 g of dietary fibre, before the food is enriched with dietary fibre. For meals/main dishes a serving of the food contains at least 5.5 g of dietary fibre, before the food is enriched with dietary fibre; and the food contains at least 25% more dietary fibre as the same quantity of reference food; and</p> <p>The claim states:</p> <ul style="list-style-type: none"> <li>the identity of the reference food; and</li> <li>the difference between the dietary fibre content of the food and the reference food.</li> </ul> <p>In addition, the claim is presented so that all elements of the claim are in one place.</p>	Minimum requirement to meet nutrition content claim criteria.	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b>  <b>Sodium: 325 mg/serve</b>  <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b>  <b>Sodium: 775 mg/serve</b>  <b>Total Sugars: 31 g/serve</b></p>
	Omega –3 fatty acid	<p><b>Nutrition Content claim</b></p> <ol style="list-style-type: none"> <li>1. The type of omega fatty acid is specified immediately after the word 'omega'</li> <li>2. The food contains no less than – 200 mg alpha-linolenic acid per serve; or 30 mg total eicosapentaenoic acid and docosahexaenoic acid per serve; and</li> <li>3. Other than for fish or fish products with no added saturated fatty acids, the food contains – as a proportion of the total fatty acids content, no more than 28% saturated fatty acids and trans fatty acids; or no more saturated fatty acids and trans fatty acids than 5 g per 100 g</li> <li>4. The nutrition information panel indicates the source of omega-3 fatty acids, that is, alpha-linolenic acid, docosahexaenoic acid and/or eicosapentaenoic acid.</li> </ol> <p><b>'Good Source'</b>: the food complies with the conditions 1 to 4 above and the food contain no less than 60 mg total eicosapentaenoic acid and docosahexaenoic acid per serve</p>	Meet the requirements 1 to 4 for nutrition content claim	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b>  <b>Sodium: 325 mg/serve</b>  <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b>  <b>Sodium: 775 mg/serve</b>  <b>Total Sugars: 31 g/serve</b></p>

Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
	Omega – 6 fatty acid	<p><b>Nutrition Content Claim</b>            The type of omega fatty acid is specified immediately after the word 'omega' and the food contains, as a proportion of the total fatty acids content: no more than 28% saturated fatty acids and trans fatty acids; and no less than 40% omega-6 fatty acid</p>	Meets content claim requirements	Food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 4 g/serve</b> <b>Sodium: 325 mg/serve</b> <b>Total Sugars: 16 g/serve</b>
	Omega – 9 fatty acid	<p><b>Nutrition Content Claim</b>            The type of omega fatty acid is specified immediately after the word 'omega' and the food contains, as a proportion of the total fatty acids content: no more than 28% saturated fatty acids and trans fatty acids; and no less than 40% omega-9 fatty acid</p>	Meet content claim requirements	Food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 4 g/serve</b> <b>Sodium: 325 mg/serve</b> <b>Total Sugars: 16 g/serve</b>  For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 7 g/serve</b> <b>Sodium: 775 mg/serve</b> <b>Total Sugars: 31 g/serve</b>
	Poly unsaturated fatty acids	<p><b>Nutrition Content Claim</b>            The food contains, as a proportion of the total fatty acids content: no more than 28% saturated fatty acids and trans fatty acids; and no less than 40% polyunsaturated fatty acids</p>	Meet content claim requirements	Food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 4 g/serve</b> <b>Sodium: 325 mg/serve</b> <b>Total Sugars: 16 g/serve</b>  For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 7 g/serve</b> <b>Sodium: 775 mg/serve</b> <b>Total Sugars: 31 g/serve</b>

Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
	Mono unsaturated fatty acids	<p><b>Nutrition Content Claim</b> The food contains, as a proportion of the total fatty acids content, no more than 28% saturated fatty acids and trans fatty acids; and no less than 40% monounsaturated fatty acids</p>	Meet content claim requirements	<p>Food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 4 g/serve</b> <b>Sodium: 325 mg/serve</b> <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 7 g/serve</b> <b>Sodium: 775 mg/serve</b> <b>Total Sugars: 31 g/serve</b></p>
	Vitamins and Minerals <sup>18</sup>	<p>A <b>nutrition content claim</b> about the presence of a vitamin or mineral may only be made on a claimable food and the food must have at least 10% [RDI or ESADDI] per serve <b>'Good Source of'</b> claims: 25% [RDI or ESADDI] per serve</p>	Minimum requirement that the food must be a claimable food and must have at least 10% [RDI or ESADDI] per serve in order to make general level health claims about a vitamin or mineral.	<p>N/A Food will be required to be a 'claimable food' currently specified in Standard 1.3.2. The claimable food requirement acts as disqualifier.</p>

<sup>18</sup> Except for a change from a per 'reference quantity' to a 'per serve' basis, the criteria relating to vitamin and mineral content claims will not be revised during the this assessment process. They will be reviewed subsequently by FSANZ following introduction of the new nutrient reference values.

Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
2. Nutrients where a reduction in consumption is recommended – 'risk increasing nutrients'	Fat	<p><b>'Low (in) fat'</b>: Food contains no more fat than 1.5 g per 100 mL for liquid food; and 3 g per 100 g for solid food</p> <p><b>'Reduced (in) fat'</b>: the food contains at least 25% less fat as the same quantity of reference food; and the claims states: the identity of the reference food; and the difference between the fat content of the food and the reference food. In addition, the claim is presented so that all elements of the claim are in one place.</p> <p><b>'x% fat free'</b>: must meet requirements for 'low fat' claim</p>	Minimum requirement to meet 'low' criteria in order to make general level health claims	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b>  <b>Sodium: 325 mg/serve</b>  <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b>  <b>Sodium: 775 mg/serve</b>  <b>Total Sugars: 31 g/serve</b></p>
	Saturated and <i>trans</i> fatty acids	<p><b>'Low (in) saturated and <i>trans</i> fatty acids'</b>: the food contains no more saturated and <i>trans</i> fatty acids than – (a) 0.75 g per 100 mL for liquid food; and (b) 1.5 g per 100 g for solid food.</p> <p><b>'Reduced (in) saturated and <i>trans</i> fatty acids'</b>: the food contains: at least 25% less saturated and <i>trans</i> fatty acids as the same quantity of reference food; and both saturated and <i>trans</i> fatty acids are reduced relative to the same quantity of reference food.</p> <p>The claims also states: the identity of the reference food; and the difference between the saturated and <i>trans</i> fatty acid content of the food and the reference food. In addition, the claim is presented so that all elements of the claim are in one place</p>	Minimum requirement to meet 'low' criteria in order to make general level health claims	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b>  <b>Sodium: 325 mg/serve</b>  <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b>  <b>Sodium: 775 mg/serve</b>  <b>Total Sugars: 31 g/serve</b></p>

Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
	Saturated fatty acids	<p><b>'Low (in) saturated fatty acids'</b>: the food contains no more saturated and <i>trans</i> fatty acids than – (a) 0.75 g per 100 mL for liquid food; and (b) 1.5 g per 100 g for solid food.</p> <p><b>'Reduced (in) saturated fatty acids'</b>: the food contains at least 25% less saturated fatty acids as the same quantity of reference food; and no more trans fatty acids as the same quantity of reference food; and The claims also states: the identity of the reference food; and the difference between the saturated fatty acid content of the food and the reference food.</p> <p>In addition, the claim is presented so that all elements of the claim are in one place.</p>	Minimum requirement to meet 'low' criteria in order to make general level health claims	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b> <b>Sodium: 325 mg/serve</b> <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b> <b>Sodium: 775 mg/serve</b> <b>Total Sugars: 31 g/serve</b></p>
	Sugar or Sugars	<p><b>'Low (in) sugar(s)'</b>: the food contains no more sugars than 2.5 g per 100 mL for liquid food; or 5 g per 100 g for solid food.</p> <p><b>'Reduced (in) sugar(s)'</b>: the food contains at least 25% less sugars as the same quantity of reference food and the claim states: the identity of the reference food; and the difference between the sugar content of the food and the reference food.</p> <p>In addition, the claim must also be presented so that all elements of the claim are in one place</p> <p><b>'No added sugar(s)'</b>: the food contains no added sugars, honey, malt and malt extracts; and the food contains no added concentrated and/or deionised fruit juice, unless the food is standardized under Standard 2.6.1 or 2.6.2. If the food contains naturally occurring sugars, the claim states the food contains naturally occurring sugars. The claim is presented so that all elements of the claim are in one place.</p> <p><b>'Unsweetened'</b>: in addition to meeting all criteria for 'no added sugar(s)', unsweetened claims cannot be made unless the food contains no added: intense sweeteners; or sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol</p> <p><b>'x% sugar free'</b>: must meet requirements for 'low sugar' claim</p>	Minimum requirement to meet 'low' criteria in order to make general level health claims.	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b> <b>Sodium: 325 mg/serve</b> <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b> <b>Sodium: 775 mg/serve</b> <b>Total Sugars: 31 g/serve</b></p>

Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
	Cholesterol	<p><b>'Low Cholesterol'</b>: the food complies with the conditions for a nutrition content claim in relation to cholesterol free; and the food contains no more than 20 mg cholesterol per 100 g.</p> <p><b>'Reduced'</b>: the food complies with the conditions for a nutrition content claim in relation to cholesterol free and the food contains at least 25% less cholesterol as the same quantity of reference food. The claim also states: the identity of the reference food; and the difference between the cholesterol content of the food and the reference food.</p> <p>The claim is also presented so that all elements of the claim are in the one place.</p> <p><b>'Cholesterol free'</b>: the food complies with the conditions for a nutrition content claim in relation to low saturated fat.</p>	Minimum requirement to meet 'low' criteria in order to make general level health claims.	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b>  <b>Sodium: 325 mg/serve</b>  <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b>  <b>Sodium: 775 mg/serve</b>  <b>Total Sugars: 31 g/serve</b></p>
	Salt /Sodium	<p><b>'Low (in) salt/sodium'</b>: food contains no more sodium than 120 mg sodium per 100 mL for liquid foods and 120 mg per 100 g of solid food. The nutrition information panel must also indicate the potassium content in the food.</p> <p><b>'Reduced salt/sodium'</b>: the food contains at least 25% less sodium as the same quantity reference food and the claims also states: the identity of the reference food; and the difference between the sodium content of the food and the reference food.</p> <p>The claim is also presented so that all elements of the claim are in the one place and the nutrition information panel indicates the potassium content.</p> <p><b>'No added salt/sodium and unsalted'</b>: The food contains no added sodium compound and no added salt. The ingredients of the food contain no added sodium compound and no added salt. The nutrition information panel indicates the potassium content and if the food naturally contains sodium, the claim states that the food contains naturally occurring sodium.</p>	Minimum requirement to meet 'low' criteria in order to make general level health claims	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b>  <b>Sodium: 325 mg/serve</b>  <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b>  <b>Sodium: 775 mg/serve</b>  <b>Total Sugars: 31 g/serve</b></p>

Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
	Energy	<p><b>Low energy:</b> the average energy content of the food is no more than 80 kJ per 100 ml liquid foods; or 170 kJ per 100 g of solid foods. Where a food is to be prepared as directed on the label, the average energy content of the food must be calculated for the food as prepared.</p> <p><b>Reduced energy:</b> the food contains at least 25% less energy as the same quantity of reference food. The claims also states: the identity of the reference food; and the difference between the energy content of the food and the reference food. The claim is also presented so that all elements of the claim are in the one place.</p> <p><b>'Diet'</b> the food complies with the conditions for a general level health claim in relation to sodium, saturated fatty acids and sugars content of the food. The food also: complies with conditions for a nutrition content claim in relation to low energy; or the food contains at least 40% less energy as the same quantity of reference food, and the energy content of the food has been reduced by at least 170 kJ per 100 g for solid food or 80 kJ per 100 mL for liquid food relative to the reference food. If (b) applies that claims states the identity of the reference food and the difference between the energy content of the food and the reference food and the claim is also presented so that all elements of the claim are in the one place.</p>	Minimum requirement to meet 'low' criteria in order to make general level health claims	<p>Food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 4 g/serve</b>  <b>Sodium: 325 mg/serve</b>  <b>Total Sugars: 16 g/serve</b></p> <p>For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients.</p> <p><b>Saturated Fat: 7 g/serve</b>  <b>Sodium: 775 mg/serve</b>  <b>Total Sugars: 31 g/serve</b></p>
	Light/lite	The claims states the characteristic of the food to which the claim relates and if the claim relates to a nutrient, energy or salt the food complies with the conditions for a reduced nutrition content claim in relation to that nutrient, energy or salt. The claim is presented so that all elements of the claim are in the one place.	Not permitted – foods that meet 'reduced' criteria for any nutrient or energy are not eligible to make general level health claims.	N/A



Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
	'Diet'	The food must meet the disqualifying criteria for general level health claims; and the food must meet the conditions for 'low energy' claims or the food must contain at least 40% less energy compared to the same quantity of reference food; and there must be a reduction in energy content of at least 170 kJ per 100 g or 80 kJ per 100 mL; and the claim states the identity of the reference food and the difference between the energy value of the food and the reference food; the claim must be presented so that all elements of the claim are in one place	Meet the 'diet' claim criteria	'Diet' claims already required to meet generic disqualifying criteria
3. Claims in relation to certain food properties or types of foods.	Gluten	All claims state whether it is a gluten free or low gluten claim. <b>'Free'</b> : the food contains: no detectable gluten; and no oats or their products or cereals containing gluten that have been malted, or their products. <b>'Low'</b> : the food contains no more than 20 mg gluten per 100 g of the food	The claim states whether it is a gluten free or low gluten in the claim. Minimum requirement to meet 'low' criteria.	Exempt from disqualifying criteria
	Lactose	All claims state whether it is lactose free or low lactose in the claim. <b>'Free'</b> : the food contains no detectable lactose; and the nutrition information panel indicates the lactose and galactose component. <b>'Low'</b> : the food contains no more than 2 g of lactose per 100 g of the food; and the nutrition information panel indicates the lactose and galactose content	The claim states whether it is a lactose free or low lactose in the claims Minimum requirement to meet 'low' criteria.	Exempt from disqualifying criteria
	GI / GL	<b>Content claim</b> The claim refers to the presence of the substance; and subject to (b), the claim does not include any descriptors in relation to the level of the substance that is present; and the claim may include the numeric value of the glycaemic index or load of the food.	Meet content claim requirements	Food must not exceed the amounts specified for the following risk increasing nutrients. Saturated fatty acids: <b>4 g/serve</b> <b>Sodium: 325 mg/serve</b> <b>Total Sugars: 16 g/serve</b>  For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 7 g/serve</b> <b>Sodium: 775 mg/serve</b> <b>Total Sugars: 31 g/serve</b>

Category	'Property of the Food'	Nutrition content claim criteria <sup>17</sup>	General level health claims criteria	Generic Disqualifying Criteria for General level health claims
	Wholegrain	A <b>nutrition content claim</b> : ≥8 g wholegrain per serve <b>Good source</b> : ≥15g wholegrain per serve	Minimum requirement to meet the nutrition content claim criteria in order to make general level health claims.	Food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 4 g/serve</b> <b>Sodium: 325 mg/serve</b> <b>Total Sugars: 16 g/serve</b>  For meals/main dish products, the food must not exceed the amounts specified for the following risk increasing nutrients. <b>Saturated Fat: 7 g/serve</b> <b>Sodium: 775 mg/serve</b> <b>Total Sugars: 31 g/serve</b>
	Alcohol	Content claims referring to alcohol content or energy content only, are permitted on foods that, if packaged, would be required to include a statement of alcohol content under clause 2 of Standard 2.7.1. <b>'Low alcohol'</b> : must meet Clause 4 of Standard 2.7.1.  Nutrition content claims referring to 'low energy' or 'reduced energy' in a food that, if packaged, would be required to include a statement of alcohol content under clause 2 of Standard 2.7.1 must either meet the <b>'low energy'</b> or <b>'reduced energy'</b> nutrition content claim criteria respectively.  'Light/Lite' claims are only permitted in relation to alcohol content and energy content. The characteristic that makes the food 'light/lite' must be stated adjacent to the claim. For 'light/lite' claims relating to energy, the food must comply with the criteria and conditions for making a 'reduced energy' claim.	Not permitted	N/A
	Infant Formula	Not permitted	Not permitted	N/A
	Infant Foods	Where permitted by Standard 2.9.2	Where permitted by Standard 2.9.2	Exempt from Disqualifying criteria

### Disqualifying Criteria For Health Claims

A variety of nutrients and food components can be selected for application in nutrient profiling of foods. Reduction of fat, particularly saturated fat, sugars and sodium intakes are all priorities for the governments of both Australia and New Zealand and therefore are priority nutrients for development of disqualifying criteria for health claims.

The three risk-increasing nutrients that have been selected as the elements of the health claim disqualifying criteria are:

- sodium;
- saturated fat; and
- total sugars.

This section presents details on the derivation of the proposed disqualifying values for each nutrient criterion. Application of the criteria to a range of foods has been modelled using food composition data and consideration given to the conversion of disqualifying criteria to either a 'per serve', or 'per 100 g' basis.

#### Rationale for Selection of Disqualifying Nutrients

##### *Sodium*

Health rationale: One of the Australian Dietary Guidelines for Adults is '*choose foods low in salt*'. This guideline is based on well accepted scientific evidence that a reduction in dietary sodium intake will decrease the mean population blood pressure and reduce the prevalence of hypertension. Risk of stroke and ischaemic heart disease increase continuously with blood pressure. The New Zealand Ministry of Health (MoH) 'Food and Nutrition Guidelines for Healthy Adults' contain similar advice, to *prepare foods or choose pre-prepared foods, drinks and snacks: that are low in salt....* This advice is underpinned by the same health rationale as for the Australian guidelines.

Intake recommendations: The current Dietary Guidelines for Australian Adults recommend that dietary sodium intake be less than 2300 mg per day for the general adult population (NHMRC 2003). The New Zealand Food and Nutrition Guidelines for Healthy Adults suggest a Recommended Dietary Intake of 920 – 2300 mg (Ministry of Health, 2003). The adoption of the draft joint Nutrient Reference Values for Australia and New Zealand will change the current Recommended Dietary Intake to an Adequate Intake range of 460 – 920 mg per day with a upper level of intake of 2300 mg per day (represents a 'no added salt' diet and intakes often exceed this amount).

**FSANZ has selected a sodium intake of 2,300 mg per day for derivation of this disqualifying criterion.** This is consistent with dietary guidelines of both countries, as well as the proposed Upper Intake Limit.

## *Saturated fat*

Health rationale: One of the Australian Dietary Guidelines is ‘*limit saturated fat intake and moderate total fat intake*’. In relation to health risks associated with saturated fat intake, it is noted that saturated fat is the strongest dietary determinant of plasma low density lipoprotein(LDL) concentration, which is the most strongly established of the diet-influenced risk factors associated with Coronary Heart Disease. It is also noted that (total) fat intake can be a contributor to excess energy intake, in turn contributing to overweight and obesity.

The New Zealand guidelines contain similar advice, stating ‘*prepare foods or choose pre-prepared foods, drinks and snacks with minimal added fat, especially saturated fat*’. Once again, this guidance is underpinned by the same health rationale as the Australian guideline, around plasma LDL cholesterol concentration and coronary heart disease risk.

Intake recommendations: The contribution of saturated fat intake to energy is considered in the individual dietary guidelines for both Australia and New Zealand, and mentioned but not quantified in the draft joint Nutrient Reference Values for Australia and New Zealand. The draft joint Nutrient Reference Values do not provide any explicit recommendations around the intake of saturated fatty acids. However, the paper does state that dietary modelling has shown that if all fat consumed is low in saturated fat (i.e. 20% of fat energy), a 35% fat diet would provide about 7% of total energy as saturated fat. The New Zealand Food and Nutrition Guidelines for Healthy Adults recommends that saturated fat intake amount to no more than 12% of total energy (Ministry of Health, 2003). The Dietary Guidelines for Australian Adults recommend a population intake averaging 10% of total energy as a target (NHMRC, 2003). The 1995 Australian National Nutrition Survey revealed that the saturated fatty acid intake averaged 12.7 % (with a median of 12.5%) of total energy for Australian adults aged 19 years and over (men and women combined). This demonstrates that the figure of 12% from the New Zealand guidelines is well placed in relation to actual population intakes.

FSANZ has selected 12% of total energy intake from saturated fat in the derivation of this disqualifying criterion.

## *Sugars*

Health rationale: Like sodium and saturated fat intakes, reduction of sugars in the diet of Australians and New Zealanders is a priority for both governments, as well as in an international context. The Australian Dietary Guidelines for Adults provides examples of the public health concerns underpinning advice to reduce sugar intakes. The background chapter addressing the guideline ‘*consume only moderate amounts of sugars and foods containing added sugars*’ contains detailed discussion of the issues around reduction of sugars in the diet. There are two principal health factors underpinning the guideline:

- Strong evidence for the role of sugar in the aetiology of dental caries. Dental caries remains a significant public health problem in Australia, as well as other countries.
- Inappropriately high intakes of sugar may displace other nutrients from the diet. It is also noted that high levels of sugars intake contribute to weight gain, overweight and obesity, as does any excess dietary energy.

Intake recommendations: In the conclusion to the background chapter for the Australian guideline, it states that *for most Australians consumption of 15-20% of energy as sugars is not incompatible with a healthy diet, however, consumption of amounts of sugars greater than this could lead to an undesirable decrease in nutrient density of the diet.*

The New Zealand Ministry of Health's guidelines suggest that added sugars should be no more than 15% of total energy, due to the potential problems associated with excess energy and dental caries.<sup>19</sup>

Both total and added sugars have been considered as possible bases for disqualifying criteria (further detail regarding total and added sugars is presented in Annex 1). It is proposed that the disqualifying criteria for sugars focus on total sugars. This decision is based on the fact that total and added sugars both contribute to energy intake, and are digested, absorbed and metabolised by the body through the same mechanism. (It is noted that different sugar-containing foods may be absorbed at differing rates (i.e. have different glycaemic effects), depending on a number of factors). Practical considerations around available data for analysis also contributed to the decision to focus on total sugars. A fuller discussion of issues relating to total and added sugars is found in Annex 1.

It is proposed that the value for the total sugars disqualifying criteria be set in relation to 20% of total energy intake. This is the upper limit of the 15-20% range recommended in the Australian Dietary Guidelines. Results from the 1995 Australian National Nutrition Survey indicate that this parameter is achieved in practice, as for adults aged 19 years and over (men and women combined) the intake of total sugars contributed on average 20.2 % of total energy (with a median of 19.4%), about 40-50% of which was derived from added sugars. Selection of the upper limit of the Australian Dietary Guidelines differs from the New Zealand Ministry of Health food and nutrition guideline for an intake no more than 15%, however this value is for added sugars only.

Therefore, the higher value of 20% daily energy intake encompasses sugars that are both naturally occurring and added. FSANZ has selected 20% of total energy intake from total sugars in the derivation of this disqualifying criterion.

### **Choice of Model for Application of Disqualifying Nutrients**

Nutrient criteria can be applied in a number of ways, including per serve of food and per 100 grams of food. There are advantages and disadvantages for each measure, as set out in Table 5.3.1 below. FSANZ has recommended use of 'per serve of food' as the basis for disqualifying criteria for health claims; and applied the recommended daily values to the 'per serve' model.

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<sup>19</sup> A further discussion around international recommendations for sugar intakes is located in Annex 1.

**Table 5.3.1: Comparison of the advantages (A) and disadvantages (D) of per 100 g measure and per serve units of measure**

#	Model 1 – per 100 g	A/D	Model 2 – per serve	A/D
1.	As most foods are described in food composition tables on a per 100 g basis the nutrient information for this measure is easily available to suppliers.	A	Serving size is calculated as part of the Nutrition Information Panel on food labels so that suppliers wishing to make a claim can use this information without the need for further calculations.	A
2.	Does not take into account the realities of how people eat. A food that is high in a nutrient on a per 100 g basis may actually be eaten in very small amounts, or conversely foods low in nutrients per 100 g may be eaten in a large amount and thus provide a reasonable intake of a nutrients.	D	The use of per serve as a measure recognizes that people eat different foods in different amounts.	A
3.	Discriminates against foods eaten in small amounts.	D	Does not discriminate against foods that are eaten in small quantities.	A
4.	Discriminates for foods high in water. Often foods high in water are very low in nutrients but these foods are also eaten in large amounts at a sitting.	D	Does not discriminate against foods that have a high water content.	A
5.	Provides as standardised approach in the absence of standardised serving sizes.	A	Serving size varies within foods, the serving size of milk is dependent on whether it is used in tea and coffee, on breakfast cereal, or from a glass as a beverage.	D
6.			Suppliers can reduce their serving size in order to fall within the risk increasing nutrient cut-off values. However, doing so reduces the likelihood of the product meeting the risk decreasing nutrient profile requirements.	-
7.			Is the most common measure used internationally for disqualifying and qualifying criteria.	

### **Application of Nutrient Disqualifying Criteria to a ‘per serve’ Model**

In order to apply the proposed nutrient disqualifying criteria to foods, calculations must be carried out to yield a value for the maximum level of each risk-increasing nutrient permitted per serve of a food.

### *Total energy intake*

Calculation of disqualifying nutrient values requires a notional value for total energy intake. Standard 1.2.8 of the Code specifies a value of 8700 kJ as representing the energy content of the average adult diet. This represents sedentary activity in adults. The value is used as the current basis for percentage daily intake calculations on the Nutrition Information Panel.

### *Proportion of food intake*

Calculations of the proportion of foods likely to contribute to intake of disqualifying nutrients have been based on previous work in the United Kingdom.

The United Kingdom Government has issued advice around the proportion of certain risk-increasing nutrients in the diet, in the form of *Guideline Daily Amounts* (GDAs) and *Rules of Thumb*. These concepts were designed to help consumers interpret nutrition labelling, and provide guidelines for five nutrients, including sodium, saturated fat and total sugars. The GDAs are based on population dietary goals, and provide a single goal figure for men and women for each nutrient, for example: sodium is set at 2.5g for men and 2g for women, and saturates are set at 30 g for men and 20 g for women. The *Rules of Thumb* provide guidance as to which amounts of food constitutes ‘a lot’ and ‘a little’ of the GDAs. The proportions for ‘a lot’ and ‘a little’ were initially reported as one-thirtieth (or 3%) and one-fifth (20%)<sup>20</sup> GDA respectively. These figure were based on:

- The proportion of foods which qualify as having ‘a little’ and ‘a lot’ of the nutrients. The particular cut-off points ensure that approximately one-third of foods had a lot of the nutrient, one-third had a little and one-third had an intermediate amount.
- Similarity with the criteria for nutrition claims set by other relevant bodies, in this case the Food Advisory Committee in the United Kingdom and Codex.

For the health claim disqualifying criteria, the midpoint between ‘a little’ and ‘a lot’ for the Rules of Thumb has been used as a basis for determining the proportion of the daily intake for each disqualifying nutrient, that could be expected to be in a serve of food. Midway between ‘a lot’ (3%) and ‘a little’ (20%) is 11.5%. The midpoint corresponds with an assumption that 9 serves of foods in the daily diet would contribute the nutrient of interest. More recent information from the United Kingdom indicates that the criteria for ‘a lot’ are now set at 25%, therefore calculations on these figures were also carried out. Midway between 3% and 25% is 14%. This revised midpoint corresponds with an assumption that 7 serves of foods in the daily diet would contribute the nutrient of interest. The figure of seven serves of food seems to be a reasonable average amount to use as the basis of calculations.

To benchmark these midpoints, a simple analysis of a dietary pattern that complied with good health recommendations of the Australian Guide to Healthy Eating was undertaken. The foods that could contribute saturated fat, sodium and total sugars are shown in Table 5.3.2 below. Note that one food can be a source of more than one disqualifying nutrient.

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<sup>20</sup> Recent information from the United Kingdom indicates that the criteria for ‘a lot’ is now set at 25%.

**Table 5.3.2: Number of serves of recommended foods and sources of disqualifying nutrients for men and women, aged 19-60 years**

	<b>Cereals</b>	<b>Veg</b>	<b>Fruit</b>	<b>Dairy</b>	<b>Meat</b>	<b>Extras</b>	<b>TOTAL</b>
Total diet	5-6	6	3	3	1	0-2	19-20
Sodium contributors	5	1	0	1	1	1	9
Saturated fat contributors	0	0	0	3	1	2	6
Total sugars contributors	1	0	3	2	0	1	7

*Calculations*

Table 5.3.3 provides the calculations used to establish two sets of criteria for cut off points according to the United Kingdom GDA ‘a lot’ values of 20 and 25 % and based on a selected energy intake of 8700 kJ/day. The criteria have been rounded to provide a figure that will be easier to use.

**Table 5.3.3: Calculations used to determine criteria for health claims**

GDA based on an energy intake of 8700 kJ	Criteria One – 11.5% of GDA	Criteria Two – 14% of GDA
20% energy from total sugars 8700 kJ x 0.2 = 1740 kJ from sugars per day 1740/16 kJ/g = <b>108.8g total sugars</b> per day	12.5 g (13 g)	15.225 g (16 g)
12% energy from saturated fat 8700 kJ x 0.12 = 1044 kJ from saturated fat per day 1044/37 kJ/g = <b>28.2 g saturated fat</b> per day.	3.24 g (3.3 g)	3.95 g (4 g)
<b>2300 mg sodium</b> per day	264.5 mg (265 mg)	322 mg (325 mg)

**Modelling of proposed disqualifying criteria for sample foods.**

Table 5.3.4 describes the potential for a variety of foods to be permitted claims according to suppliers’ nominated serving size and the two sets of criteria discussed above. A scan of the supermarket shelves was undertaken to determine the variety of suppliers’ nominated serving size within product categories. A note of the serving sizes was made, then the food composition tables used to calculate the composition of the food types.



**Table 5.3.4: Disqualifying criteria for saturated fat, sodium and total sugars applied to various foods, for two possible models**

Key: t = trace

Underlined foods may or may not be permitted, dependent on serve size.

Foods in *italics* are permitted under the more lenient criteria (2), but excluded under the more stringent criteria (1).

**Dark shaded** foods would not be permitted under either criteria irrespective of chosen serve size.

**Light shaded** nutrient groups indicates were a food would be excluded under that particular criteria or where a food is excluded under both criteria for a single serve size only.

		Criteria 1 (more Stringent)			Criteria 2 (more Lenient)		
<b>Total Sugars:</b>		<b>13 g</b>			<b>16 g</b>		
<b>Sat Fat:</b>		<b>3.3.g</b>			<b>4 g</b>		
<b>Sodium:</b>		<b>265 mg</b>			<b>325 mg</b>		
	Serve size	Total sugars	Sat. Fat	Sodium	Total sugars	Sat. Fat	Sodium
Chocolate coated biscuit	35 g	<b>14.5</b>	<b>5.8</b>	56	14.5	<b>5.8</b>	56
Cream Cracker	35 g	t	2.9	214	t	2.9	214
<i>Biscuit, fruit finger</i>	35 g	<b>14.8</b>	2.0	60.6	14.8	2.0	60.6
Semi sweet biscuit	35 g	4.0	2.7	123	4.0	2.73	123
<i>Bread multigrain</i>	27 g	1.0	t	197	1.0	t	197
	85 g	1.2	0.2	<b>478</b>	1.2	0.2	<b>478</b>
<b>Bread white</b>	37 g	0.7	t	246	0.7	t	246
	74 g	1.4	t	<b>490</b>	1.4	t	<b>490</b>
<b>Bread wholemeal</b>	37 g	0.5	0.1	237	0.5	0.1	237
	74 g	1.0	0.2	<b>474</b>	1.0	0.2	<b>474</b>
Cake sponge plain	30 g	9.4	0.5	108	9.4	0.5	108
Salada crackers	35 g	0.1	2.4	<b>581</b>	0.14	2.4	<b>581</b>
Milo powder	25 g	11.4	1.3	57.5	11.4	1.3	57.5
Orange juice sweetened	200 mL	<b>25.5</b>	t	6	<b>25.5</b>	t	6
<i>Orange juice unsweetened</i>	200 mL	<b>15.4</b>	t	6	15.4	t	6
Just juice orange and apple	200 mL	<b>20.8</b>	t	6	<b>20.8</b>	t	6
Coca-cola	355 mL	<b>38.7</b>	0	42.6	<b>38.7</b>	0	42.6
	200 mL	<b>21.8</b>	t	24	<b>21.8</b>	t	24
	600 mL	<b>65.4</b>	t	72	<b>65.4</b>	t	72
Cocoa pops	$\frac{3}{4}$ cup 30 g	10.9	0.4	225	10.9	0.36	225
<i>Sultana bran</i>	1/2 cup 30 g	6.8	0.1	81	6.8	0.12	81
	$\frac{3}{4}$ cup 45 g	10.2	0.2	121	10.2	0.18	121
Weetbix	2 bis 30 g	1.0	t	87	1.0	t	87
Reduced fat cream cheese	25 g	3.9	2.4	160	3.9	2.4	160
Ice cream soft serve	1 cup	<b>24.9</b>	3.1	68	<b>24.9</b>	3.1	68
<i>Ice cream vanilla</i>	55 g	12.2	<b>3.9</b>	19.2	12.2	3.9	19.2

		Criteria 1 (more Stringent)			Criteria 2 (more Lenient)		
Total Sugars:		13 g			16 g		
Sat Fat:		3.3.g			4 g		
Sodium:		265 mg			325 mg		
	Serve size	Total sugars	Sat. Fat	Sodium	Total sugars	Sat. Fat	Sodium
Milk fluid trim	100 mL	5.2	0.3	54	5.2	0.3	54
	200 mL	10.4	0.6	108	10.4	0.6	108
Milk fluid whole	100 mL	4.4	2.4	37	4.4	2.4	37
	200 mL	8.8	4.8	74	8.8	4.8	74
Egg	1	t	1.7	83	t	1.7	83
<i>Yoghurt, fat reduced, sweetened</i>	100 g	14.8	1.1	41	14.8	1.1	41
	125 g	18.5	1.4	51	18.5	1.4	51
	150 g	22.2	1.6	61	22.2	1.6	61
Yoghurt natural unsweetened	100 g	4.9	0.5	43	4.9	0.5	43
	125 g	6.1	0.6	54	6.1	0.6	54
	150 g	7.3	0.7	64	7.3	0.7	64
Big Mac (1)	1	6.3	11.6	906	6.3	11.6	906
Olive oil	10 mL	t	1.6	t	t	1.6	t
Apricots dried	25 g	11.2	t	9.3	11.2	t	9.3
	50 g	22.4	t	18.5	22.4	t	18.5
Orange raw	1	7.7	t	3	7.7	t	3
Raisin	14 g	9.7	t	7.3	9.7	t	7.3
	140 g	97	t	73	97	t	73
Apricot fruit leather	40 g	57.3	t	2.9	57.3	t	2.9
Fruit roll strawberry	16 g	3.7	t	18	3.7	t	18
	20 g	4.6	t	2.2	4.6	t	2.2
Potato crisps	35 g	0.2	4.9	223	0.2	4.9	223
	40 g	0.2	5.6	255	0.2	5.6	255
	50 g	0.3	7	319	0.3	7	319
Chocolate, dark	20 g	10.4	3	11	10.4	3	11
	25 g	13	3.7	13.7	13	3.7	13.7
	45 g	23.4	6.7	24.7	23.4	6.7	24.7
	50 g	26	7.5	27.5	26	7.5	27.5
Chocolate, milk	20 g	10.7	3.5	24	10.7	3.5	24
	25 g	13.5	4.5	30	13.5	4.5	30
	45 g	24.2	7.9	54	24.2	7.9	54
	50 g	27	8.9	60	27	8.9	60
Jam berry fruit	10 g	6.7	0	1.6	6.7	0	1.6
Jelly beans	46 g	32.9	0	12	32.9	0	12
Marshmallow	45 g	32	0	12	32	0	12
Corn kernels boiled	1 cup 173 g	7.6	0.1	4	7.6	0.1	4
	67 g	2.9	t	2	2.9	t	2
Tomato raw	1	3.4	t	5	3.4	t	5
Baked beans in tomato sauce	210 g	11.8	0.2	2730	11.8	0.2	2730
	300 g	16.8	0.3	3900	16.8	0.3	3900
Chicken	1 breast	0	3.1	122	0	3.1	122
Chicken	1 leg	0	0.8	48	0	0.8	48
<i>Rump steak grilled</i>	160 g	0	3.7	84	0	3.7	84
Beef mince, lean stewed	1 cup	0	4.1	63	0	4.1	63
Cheese edam	20 g	t	3.4	120	t	3.4	120
	25 g	t	4.25	150	t	4.3	150

## **Analysis of modelling data**

The data in Table 5.3.4 illustrates the importance of suppliers' serving size in determining a food's ability to comply with two sets of criteria: serving sizes varied by up to 100 fold between brands (for example raisins). Some bread suppliers nominated one slice as a serve size, others nominated two. Some milk producers nominated 100 mL as a serve, others nominated 200 mL. In the case of bread and whole milk, according to both sets of criteria, only those suppliers nominating the lower serving size would be permitted to make a claim. Chocolate, yoghurt, cheese and dried fruits are other foods for which the ability to meet the criteria would depend on the suppliers' nominated serving size.

Comparison of the two criteria shows that the more liberal criteria would result in the inclusion of foods such as rump steak, edam cheese, sweetened fat reduced yogurt, vanilla ice cream, chocolate milk, fruit finger biscuits and unsweetened orange juice. These foods would be excluded under the tighter criteria.

## **Conclusion**

Taking account of the basis for the calculations and the impact on current foods, criteria 2 provides reasonable opportunity for foods to bear health claims.

**The recommended criteria, on a per serve basis, are that the food must not exceed the amounts specified for the following risk increasing nutrients:**

**Saturated fat: 4 g**

**Sodium: 325 mg**

**Total sugars: 16 g**

## Detailed Information Around Sugar Intakes and Types of Sugars

There has been considerable international interest in guidelines for sugar intakes and the World Health Organization and Food Agricultural Organization have issued advice around reduction of dietary sugar intakes. An added sugars intake of less than 10% of total energy intake is recommended in their March 2003 report *Diet, Nutrition and the Prevention of Chronic Disease*.

The term ‘sugars’ can be applied as disqualifying criteria in two primary ways – total sugars or added sugars.

### Total sugars

The term ‘total sugars’ is conventionally used to cover monosaccharides (glucose, fructose) and disaccharides (sucrose, lactose<sup>21</sup>). This term therefore encompasses sugars that occur naturally within foods, such as fruits and vegetables, as well as refined sugars added during the processing of foods.

There are a number of factors supporting the use of total sugars as the basis for a third disqualifying criteria.

- The background material and evidence underpinning the Australian Dietary Guideline focus primarily on total sugars. The material recognizes that other subsets of sugar types are used elsewhere in the literature, including *intrinsic* (inside the cell matrix) and *extrinsic* sugars (outside the cell matrix), as well as *non-milk extrinsic* sugars (sugars that are outside the cell matrix, excluding lactose) – but notes that these terms have not gained wide acceptance. The category of *added sugars* receive mention during the discussion in the Dietary Guidelines, particularly in the context of beverages, notably soft drinks, however, total sugars remain the focus of the chapter.
- Sugars that occur naturally in foods and refined sugars that are added to the diet both contribute to energy intake, and therefore to the potential for overweight and obesity – major health concerns in Australia and New Zealand. Naturally occurring and refined sugars are both digested, absorbed and processed by the body through the same mechanism. However, it is also recognised that various sugar-containing foods may produce differing glycaemic effects in the body. This depends on a number of factors working together, not simply the chemical type of sugar in the food or the amount of sugar in the food.
- There are practical advantages to FSANZ using total sugars as the basis for determining disqualifying criteria. Most databases report total and some individual sugars.

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<sup>21</sup> Consideration could be given to an option to exclude lactose from total sugar calculations. Lactose is the natural sugar component of dairy foods and is not generally regarded as a significant contributor to deleteriously high sugar intakes. Exclusion of lactose would be consistent with current dietary advice promoting the inclusion of dairy foods (low-fat, low-sugar) in diets. However, there are practical NIP labelling implications around excluding lactose from sugar figures, similar to those outlined for added sugars.

Knowledge of the amount of added sugars remains the province of the suppliers. To that end, FSANZ notes that the CSIRO analysis of total and added sugars intake reported in the Australian National Nutrition Survey required development of a database based on inference from food composition data including individual sugars content.

### Added sugars

‘Added sugars’ are a subset of total sugars and refers to sugars that are added to food products during processing or manufacture. These are generally refined sugars.

Use of added sugars as the basis for a disqualifying criteria is supported by a number of factors:

- Added sugars are used as the basis for public health guidelines by several countries/bodies:
  - The New Zealand Government’s dietary advice relates to added sugars. It aims to limit the contribution of this category of sugars to energy intakes. The Ministry of Health ‘Food and Nutrition Guidelines for Health Adults’ guideline statement number three reads – *Prepare foods or choose prepared foods, drinks and snacks... with little added sugar; limit your intake of high sugar foods.* Under Part II of the guide, during discussion of carbohydrates, it is noted that sucrose and other free sugars should be restricted to no more than 15% of total energy due to the potential problems associated with excess energy and dental caries. The health concerns underpinning the guideline are therefore the same as those for the Australian Dietary Guidelines, however in this case they are focused on the subset of *added* sugars, rather than total sugars.
  - Other international dietary advice also focuses particularly on added sugars. The World Health Organisation and Food Agricultural Organization recommendation for sugars intake is that no more than 10% of energy is derived from added sugar. Similarly, the US Food and Nutrition Board of Institute of Medicine recommends an intake limit based on added sugars, of no more than 25% of energy from this source.
- A disqualifying criteria based on added sugars would avoid a potential disadvantage to foods with naturally high levels of sugars, such as fruits and vegetables and milk. If total sugars are the basis for the disqualifying criteria, these types of foods, containing naturally occurring sugars, may be inadvertently excluded from making claims. Foods such as fruits and vegetables are significant sources of vitamin and minerals as well as dietary fibre, and current dietary advice aims to increase their intake. Therefore a disqualifying criteria based on total sugars could indirectly penalize the types of foods that the population are encouraged to consume.

The major disadvantage of developing criteria based on ‘added sugars’ is the practical aspect of a suitable database.

### **Current Endorsement Programs proposed to be Pre-approved by FSANZ**

#### **National Heart Foundation - Tick Food Information Program**

##### *Overview of Endorsement Program*

The Tick Food Information Program, represented by the ‘Tick’ logo is endorsed by the National Heart Foundation. It is a self-funding public health program and is represented by a certification trademark. The Tick Program aims to promote the development and sale of foods that are consistent with healthy eating. The Tick can only be used in association with a food product which has been approved by the Heart Foundation as meeting particular criteria.

The Tick Program contains nutritional criteria that are specific to product categories (approximately 60 categories). Approved foods are generally lower in saturated fat, sodium and where appropriate, kilojoules, and higher in fibre than other products of a similar type. The Program incorporates both qualifying and disqualifying criteria for nutrients in product-specific categories.

##### **Rationale for Pre-Approval**

FSANZ considers that the National Heart Foundation fits within the draft definition of ‘endorsing organisation’ as it is a non-profit organisation and is formed for nutrition and health purposes. The Tick Program fits within the draft definition of ‘endorsement’ as it distinguishes food in relation to its nutrition and health features from other foods not certified by the Heart Foundation. The Tick Program is also a certification trademark.

Foods that are identified with the ‘Tick’ are consistent with healthy eating patterns as recommended in the following nutrition policies and guidelines, including:

- The *Dietary Guidelines for Australian Adults* (2003);
- The *Australian Guide to Healthy Eating* (1998); and
- The *New Zealand Food and Nutrition Guidelines for Healthy Adults* (2003).

Both the Australian and New Zealand dietary guidelines contain recommendations to limit saturated fat intake and to choose foods that are low in salt. The NHF criteria governing limits on the levels of saturated fat and sodium for specified food categories are therefore consistent with these guidelines. Similarly, the NHF criteria for dietary fibre, particularly in relation to the ‘cereal and cereal products’ category reflect Australian and New Zealand dietary guideline recommendations to ‘eat plenty of cereals’. The Australian dietary guidelines in particular, discusses the role of dietary fibre in the context of decreased risk of coronary heart disease and some cancers, and in achieving dietary targets for lower fat consumption and hence weight maintenance.

## **Glycemic Index Limited – Glycemic Index Symbol Program**

### *Overview of Endorsement Program*

The Glycemic Index Symbol Program (GISP), represented by the ‘Glycemic Index Tested’ logo is endorsed by Glycemic Index Limited (GIL). GIL is a non-profit organisation formed by the University of Sydney, Diabetes Australia, and the Juvenile Diabetes Research Foundation. ‘Glycemic Index Tested’ is a certification trademark.

The GI Symbol provides a tool to enable consumers to choose the right amount, and type of carbohydrate for their health and lifestyles. Foods carrying the ‘Glycemic Index Tested’ logo are required to meet the program’s acceptability guidelines, namely:

- The GI must be determined by the Sydney University Glycemic Index Research Service or other approved laboratory using the standardised *in vivo* procedure.
- Must contain at least 10 g carbohydrate/serve.
- Must not be high sources of fat, particularly saturated fat.
- Must be moderate in sodium content.
- Must be a source of dietary fibre (where appropriate).
- Must have a nutritional composition that meets the required nutrient criteria for the relevant food category.

The GI Tested logo cannot be used on high and intermediate GI soft drinks, cordials, confectionery, sugars and syrups (other than jam, honey and other carbohydrate spreads which are eligible if they meet the specific requirements).

### *Rationale for Pre-Approval*

FSANZ considers that GIL fits within the draft definition of ‘endorsing organisation’ as it is a non-profit organisation and is formed for nutrition and health purposes. The GISP fits within the draft definition of ‘endorsement’ as it distinguishes food in relation to its nutrition and health features from other foods not certified by GIL. ‘Glycemic Index Tested’ is also a certification trademark.

The provisions governing limits on the levels of fat (particularly saturated fat), and sodium for specified food categories are consistent with Australian and New Zealand dietary guidelines which recommend limiting saturated fat intake and choosing foods low in salt.

Specifically in relation to GI, the *Dietary Guidelines for Australian Adults* (2003) discusses the benefits of a lower GI diet in protecting against CHD, improving glycaemic control in diabetics and in preventing excess weight gain: ‘Eat plenty of cereals (including breads, rice, and noodles), preferably wholegrain’. The *Dietary Guidelines for Older Australians* (1999) also recommends the consumption of lower GI cereal-based foods: ‘Eat plenty of cereals, breads and pastas – preferably high-fibre foods and those with a lower glycemic index’.

The New Zealand *Food and Nutrition Guidelines for Healthy Adults* (2003) refers to the valuable role of the GI in planning diets for people with diabetes, where it is important that blood glucose levels are maintained within the normal range.

## **Toothfriendly International – ‘Happy Tooth’ logo**

### *Overview of Endorsement Program*

The ‘Happy Tooth’ logo, represented by a smiling tooth/umbrella is endorsed by Toothfriendly International. Toothfriendly International is a non-profit association established for the promotion of dental health and is governed by representatives of the dental profession. The ‘Happy Tooth’ logo is registered as a certification trademark.

The Happy Tooth logo facilitates the recognition of dentally safe products. The logo may be used on packaging and advertising of products that have been scientifically tested and proven to be without significant cariogenic and erosive potential. The test is based on the measurement of pH of dental plaque and saliva, *in vivo* and is based on a critical plaque pH level of 5.7.

### *Rationale for Pre-Approval*

FSANZ considers that Toothfriendly International fits within the draft definition of ‘endorsing organisation’ as it is a non-profit organisation and is formed for nutrition and health purposes. The ‘Happy Tooth’ logo fits within the draft definition of ‘endorsement’ as it distinguishes food in relation to its nutrition and health features from other foods not certified by Toothfriendly International. The ‘Happy Tooth’ logo is also a certification trademark.

Numerous studies have confirmed the relationship between sugar (sucrose) intake and dental caries, which remains a significant public health problem in Australia. The identification of foods that are dentally safe is in keeping with the *Dietary Guidelines for Australian Adults* (2003) which recommends ‘Consume only moderate amounts of sugars and foods containing added sugars’ and The New Zealand *Food and Nutrition Guidelines for Healthy Adults* (2003) which states ‘Prepare foods or choose pre-prepared foods, drinks and snacks with little added sugar; limit your intake of high-sugar foods’.

## **NSW School Canteen Association – ‘Healthy Kids’ Product Registration Scheme**

### *Overview of Endorsement Program*

The ‘Healthy Kids’ Product Registration Scheme, represented by the ‘Healthy Kids Registered Product’ logo is endorsed by the New South Wales Canteen Association (NSWCA) to promote healthy foods in schools. The NSWCA is a not-for-profit organisation. ‘Healthy Kids’ registered products are entitled to use the logo on their product literature and are listed in the NSWSCA School Canteen Buyer’s Guide as healthier choices. Only products that meet the Healthy Kids Green or Amber Nutrient Criteria can be registered with the NSWSCA.

The Scheme utilises a tiered approach which categorises foods in different product categories as Green, Amber or Red, based on specified nutrient criteria, primarily fat and sodium content, although calcium and fibre are also considered for some product groups. Energy per serve will also be included in the new criteria which are currently under development. The criteria have been developed in conjunction with health professionals and the food industry. The tiered approach is as follows:



- Green ‘Fill the menu’ – Encourage and promote these foods in the canteen.
- Amber: ‘Select Carefully’ – Do not let these foods dominate the menu and avoid large serve sizes.
- Red: ‘Occasionally’ – Do not sell these foods on more than two occasions per term.

### *Rationale for Pre-Approval*

FSANZ considers that the NSWCA fits within the draft definition of ‘endorsing organisation’ as it is a non-profit organisation and is formed for nutrition, health, community and government purposes. The ‘Healthy Kids’ Product Registration Scheme fits within the draft definition of ‘endorsement’ as it distinguishes food in relation to its nutrition and health features from other foods not certified by NSWCA.

The nutrition criteria that are applied for the purposes of registration as a ‘Healthy Kids’ product are underpinned by a range of nutrition policies, guidelines and recommendations including:

- The *Dietary Guidelines for Children and Adolescents in Australia* (2003);
- The *Australian Guide to Healthy Eating* (1998);
- *Recommended Dietary Intakes for Use in Australia* (1991); and
- NSW Healthy School Canteen Strategy: Fresh Tastes @ School.

The provisions governing limits on fat and sodium content for specified food categories are consistent with recommendations in the *Dietary Guidelines for Children and Adolescents in Australia* (2003) which state ‘Limit saturated fat and moderate total fat intake’ and ‘Choose foods low in salt’. The requirement for minimum levels of calcium to be met for foods in the dairy category, recognises the important role of calcium in the diets of children in the attainment of peak bone mass. Similarly, minimum levels of dietary fibre are specified in certain circumstances. The importance of dietary fibre has discussed previously in the context of reducing the risk of coronary heart disease and some cancers. In children and adolescence, fibre is also important in reducing constipation.

## **Federation of Canteens in Schools (FOCiS) – ‘Star Choice’ Product Registration Scheme**

### *Overview of Endorsement Program*

The ‘Star Choice’ Product Registration Scheme is endorsed by the Federation of Canteens in Schools (FOCiS), a non-profit organisation, representing school canteens nationally. FOCiS is established with the aim of promoting and facilitating the provision of nutritious and healthy food services in school canteens throughout Australia. FOCiS-registered products are promoted to schools and member associations in each State and Territory via a Registered Product List.

FOCiS-registered products must not exceed maximum levels of energy, total fat, saturated fat, sodium and sugar provided in the criteria for the nine food categories specified. Where appropriate, minimum levels of calcium and fibre are also set for specific food categories. High acid and sugar foods, for example, soft drinks and some confectionery lines and fruit leathers are not eligible for registration by FOCiS.

The nutrient criteria have been developed in consultation with state and territory school canteen associations and their nutrition advisors, health and education professionals, and representatives of the food industry.

### *Rationale for Pre-Approval*

FSANZ considers that FOCiS fits within the draft definition of ‘endorsing organisation’ as it is a non-profit organisation and is formed for nutrition, health, community and government purposes. The ‘Star Choice’ Product Registration Scheme fits within the draft definition of ‘endorsement’ as it distinguishes food in relation to its nutrition and health features from other foods not certified by FOCiS.

The nutrition criteria that are applied for the purposes of registration as a FOCiS-registered product are underpinned by a range of nutrition policies, guidelines and recommendations and include:

- The *Dietary Guidelines for Children and Adolescents in Australia* (2003);
- The *Australian Guide to Healthy Eating* (1998);
- *Recommended Dietary Intakes for Use in Australia* (1991); and
- *Healthy Weight 2008, Australia’s Future* (2003); report by the National Obesity Taskforce.

The provisions governing limits on fat and sodium content for specified food categories are consistent with recommendations in the *Dietary Guidelines for Children and Adolescents in Australia* (2003) which state ‘Limit saturated fat and moderate total fat intake’ and ‘Choose foods low in salt’. The requirement for minimum levels of calcium to be met for foods in the dairy category, recognises the important role of calcium in the diets of children in the attainment of peak bone mass. Similarly, minimum levels of dietary fibre are specified in certain circumstances. The importance of dietary fibre has discussed previously in the context of reducing the risk of coronary heart disease and some cancers. In children and adolescence, fibre is also important in reducing constipation.

The provisions governing upper limits for fat and sodium content, and lower limits for calcium and fibre content for specified food categories are consistent with recommendations in the *Dietary Guidelines for Children and Adolescents in Australia* (2003), as discussed in the rationale for the preceding endorsement program. FOCiS also applies disqualifying criteria for high acid and high sugar products. This approach is consistent with the guideline ‘Consume only moderate amounts of sugars and foods containing added sugars’, in recognition of the contribution of these types of foods to dental caries and obesity in children.

### **Coeliac Society of Australia Inc. – Gluten Free Symbol**

#### *Overview of Endorsement Program*

The Gluten Free Symbol is represented by a logo with a map of Australia and a crossed grain, together with the words ‘This product contains no detectable gluten’. It is endorsed by the Coeliac Society of Australia Inc., which is a non-profit organisation.

The Gluten Free Symbol provides a tool to enable individuals with Coeliac disease to readily identify gluten free foods. For a food to be endorsed with the Gluten Free Symbol, it must contain less than 20 ppm gluten. Test results must be provided to the Coeliac Society of Australia.

*Rationale for Pre-Approval*

FSANZ considers that the Coeliac Society of Australia Inc fits within the definition of ‘endorsing organisation’ and the Gluten Free Symbol fits within the definition of ‘endorsement’ as listed in the draft Standard.

FSANZ considers that the Coeliac Society of Australia Inc fits within the draft definition of ‘endorsing organisation’ as it is a non-profit organisation and is formed for nutrition and health purposes. The Gluten Free Symbol fits within the draft definition of ‘endorsement’ as it distinguishes food in relation to its nutrition and health features from other foods not certified by the Coeliac Society of Australia Inc.

The endorsement program is consistent with accepted medical and nutritional advice in Australia, which recommends that a gluten free diet be followed in the treatment of Coeliac disease.

## References

NHMRC (2003) *Dietary Guidelines for Australian Adults*. National Health and Medical Research Council, Commonwealth Of Australia.

NHMRC (2003) *Dietary Guidelines for Children and Adolescents in Australia*. National Health and Medical Research Council, Commonwealth of Australia

NHMRC (1999) *Dietary Guidelines for Older Australians* .National Health and Medical Research Council, Commonwealth of Australia

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

## Acronyms and Abbreviations

<i>Acronym/abbreviation</i>	<i>Explanation</i>
Code	Australia New Zealand Food Standards Code
CoPoNC	Code of Practice on Nutrient Claims in Food Labels
%DI	Percentage Daily Intake
ESADDI	Estimated Safe and Adequate Daily Dietary Intake
FSANZ	Food Standards Australia New Zealand
GI	Glycaemic Index
GL	Glycaemic Load
GDA	Guideline Daily Amounts
kJ	Kilo Joules
LDL - Cholesterol	Low-density Lipoprotein Cholesterol
mmol	Millimoles
NHMRC	National Health and Medical research Council
NRV	Nutrient Reference Value
Policy Guideline	Australia and New Zealand Food Regulation Ministerial Council Policy Guideline on Nutrition, Health and Related Claims
RDI	Recommended Dietary Intake