ATTACHMENT 6

REGULATORY FRAMEWORK FOR NUTRITION, HEALTH AND RELATED CLAIMS

Specific content claims and general level health claims and exceptions and exemptions to 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.

Attachment 6 deals with specific content claims (Part 1) and specific general level health claims and exceptions and exemptions to generic application (Part 2).

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), 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 content and 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.

PART 1: NUTRITION CONTENT CLAIMS

Chapter 1: Introduction

The regulatory framework for nutrition content claims is given in Chapter 2 of Attachment 5 and a summary of the criteria for nutrition content claims and general level health claims is given in Appendix 5.2 to Attachment 5.

This attachment provides the rationale and assessment around the criteria stated in Appendix 5.2 to Attachment 5. That is, a discussion follows on specific criteria associated with the use of terms such as 'source', 'good source', 'reduced', 'low' as applied to particular nutrients.

Chapter 2: 'Free' Claims

2.1 Proposed Approach At Draft Assessment

Claim	Preferred criteria (and conditions)
'Free' (for all nutrients except gluten, lactose and cholesterol).	No provisions.
'Gluten free' and 'lactose free'	See Standard 1.2.8, Clauses 15 and 16 of the Code.
Cholesterol free	The food must meet the requirements for 'low (in) saturated fat'.

2.2 Background

'Free' claims refer to claims that are 'free' of a specific nutrient; for example 'fat free', 'sugar free', 'cholesterol free', 'salt free'. It does not include qualified free claims; for example, '99% fat free'.

2.3 Relevant International Approaches

The Australian Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC), United States of America (USA), Canada, Codex, the United Kingdom (in terms of Food Standards Agency guidelines) and the European Union proposal permit small defined tolerances for 'free' claims in relation to fat, sugar and salt. CoPoNC, Canada, United States and Codex also permit insignificant amounts for 'cholesterol free' and 'calorie free' with the exception that CoPoNC has no provision for 'calorie free'. This approach is based on using 'free' as a descriptor of physiologically insignificant components. Sometimes it is based on the level of the nutrient that is at or near the reliable limit of detection for the nutrient in food, while at other times it is the technically unavoidable residual level of the nutrient left after processing (for example, 'sugar free').

'Gluten free' and 'lactose free' claims in Standard 1.2.8 are slightly different to other content claims in that they are defined by a 'no detectable' provision, because of their relevance to public health and safety. That is, commercial analytical methods have limitations in their ability to detect certain gluten equivalent fractions that are toxic to individuals with coeliac disease such as barley hordeins (and therefore malted barley products) and oat avenins. Products may thus contain some gluten but in laboratory analysis reveal 'nil detected' gluten levels. A 'no detectable' provision is therefore the correct regulatory measure.

2.4 Inconsistencies With Fair Trading Laws

The Australian *Trade Practices Act 1974* and the New Zealand *Fair Trading Act 1986* prohibit conduct that is false, misleading or deceptive and apply to the supply of food in trade and commerce. The Australian Competition and Consumer Commission and the New Zealand Commerce Commission, which administer the respective Acts, both interpret 'free' claims as meaning that none of the substance should be present in the food, irrespective of food regulations and codes of practice. This therefore creates potential inconsistency between fair trading legislation and CoPoNC. In resolving the situation, Food Standards Australia New Zealand (FSANZ) must give priority to preventing misleading or deceptive conduct, thereby aligning with fair trading laws.

2.5 Australian Competition And Consumer Commission And New Zealand Commerce Commission Preferred Approach

FSANZ met with the Australian Competition and Consumer Commission and the New Zealand Commerce Commission on several occasions in relation to the issue of 'free' claims. On 10 May 2004 an agreed position was to not stipulate criteria for 'free'; that is, to stay silent in respect of unqualified 'free' claims. Claims would therefore be regulated through fair trading laws, and manufacturers would be able to use 'free' claims provided they are consistent with these requirements. There is a precedent for this in the labelling of genetically modified foods and 'free' claims, where the *Australia New Zealand Food Standards Code* (Code) is silent on the use of such claims.

2.6 Consumer Research

FSANZ's qualitative consumer research on nutrition content claims (FSANZ 2003a) revealed that participants in focus group discussions had favourable attitudes towards 'free' claims – they were viewed as definitive and non-comparable claims.

Some regarded them as a quick and easy tool to use, while others used the nutrition information panel to verify the claim and to look for nutrient trade-offs. Unprompted reactions were that 'free' means 'nil' and, upon discussion, all groups unanimously confirmed that 'free' should mean 'zero' because that is the common meaning and it was unacceptable to have 'nutritional insignificance' for some claims (for example, fat and sugar) but not for others (for example, gluten and lactose).

2.7 Preferred Options At Initial Assessment

FSANZ preferred option for 'free' claims at Initial Assessment was to stay silent, thereby allowing such claims when they are true. Submitters to the Initial Assessment Report were asked whether 'free' claims should be permitted and whether they agreed with FSANZ's preferred criteria.

2.8 Issues Raised By Submitters

The majority of submitters agreed with the approach to permit 'free' claims. The main reasons for their support were that:

- they provide useful consumer information and identifiers for specific diets;
- there is international recognition of 'free' claims; and
- there would be consistency with Codex.

Some submitters noted the value in the market place for products making 'free' claims. In particular, National Foods noted a total dollar value of A$31 million for the Yoplait 'no fat' brand. According to the Confectionery Manufacturers of Australasia the value of the 'sugar free' category in Australia is in excess of A$ 220 million and in New Zealand is estimated at NZ$ 53 million.

There were a few submitters (from industry and the public health sector) who opposed the use of 'free' claims, on the grounds that they may be misleading or confusing.

In response to the question regarding FSANZ's preferred approach for 'free' claims, submitters, mainly from public health and government sectors, agreed that there should be no provisions, whereas the same number of submitters, but mainly from the industry sector recommended that 'free' claims should include tolerances. The main arguments put forward were:

- inconsistency with Codex, where tolerances are recommended;
- that tolerance levels are physiologically, clinically and nutritionally insignificant;
- inconsistency with a 'no detectable' principle in the Code for 'gluten free' and 'lactose free' claims;
- that many manufacturers have built businesses in response to consumer demand for 'free' products. The present proposal will therefore disadvantage consumer choice;
- that there have been no known complaints from consumers about 'sugar free' products containing small amounts of sugar. Many manufacturers believe that consumers do understand the 'free' claims concept;
- that the nutrition information panel can act as a disclaimer; and
- that analytical methods are becoming increasingly sensitive, so limits of detection could be specified; otherwise these claims will not be used by industry.

Most government agencies and public health organisations tended to agree with FSANZ's view that 'free' claims should only be permitted if they comply with fair trading law. Some of these submitters recommended that reference to the requirement for compliance of 'free' claims with fair trading legislation is included in the Standard/Guideline. The Australian Competition and Consumer Commission noted that 'nutritional insignificance' could be just as accurately conveyed in a positive and truthful manner by claims such as 'contains less than 1% fat'.

2.9 Assessment and Rationale

FSANZ's approach to 'free' claims is to stay silent as proposed in the Initial Assessment Report, with the exception of claims in relation to gluten, lactose and cholesterol. While the majority of submitters opposed FSANZ's approach, the rationale is that the Australian Competition and Consumer Commission's and New Zealand Commerce Commission's interpretation of 'free' is that 'free' means 'zero'. Consistency with fair trading laws will therefore be assured.

FSANZ cannot justify the qualification of 'free' claims from a public health perspective other than for gluten and lactose because dietary guidelines can be achieved by consuming diets low in risk increasing nutrients. 'Gluten free' and 'lactose free' claims will be allowed providing these substances are not detectable.

A 'cholesterol free' claim will also be specified; not because of the 'free' issue, but because a 'low saturated fat' disqualifying criterion is required to justify the claim from a public health perspective (see Chapter 11 on cholesterol claims).

Manufacturers can use alternative claims to 'free' such as '99.5% fat free' or 'contains less than 1% fat'. Although CoPoNC does not permit 'x % free' claims on foods other than fat, FSANZ proposes to extend this permission to sugar claims in order to facilitate the re-labelling of products that are currently carrying 'sugar free' but contain small amounts of sugar. The criteria for 'x% sugar free' will be the same as for 'low sugar'.

Chapter 3: Comparative Nutrition Content Claims

3.1 Proposed Approach At Draft Assessment

Claim	Preferred criteria (and conditions)
'Reduced', 'less than'	A claim stating that the content in energy or one or more nutrients has been reduced, may only be made where the reduction in content is at least 25% compared to a reference food. The identity of the reference food and the difference in the quantity of the energy or claimed nutrient in the claimed food compared to the quantity in the reference food must be indicated. The claim must be presented so that all elements of the claim are in one place.
'Increased'	A claim stating that the content in one or more nutrients, other than vitamins and minerals, has been increased, may be made where the product meets the conditions for the claim 'source of' and the increase in content is at least 25% compared to a reference food. The identity of the reference food and the difference in the quantity of the claimed nutrient in the claimed food compared to the quantity in the reference food must be indicated. The claim must be presented so that all elements of the claim are in one place.

3.2 Background

Comparative claims are those claims that compare a food with a similar food or class of foods. Examples of comparative claims are those using the terms 'reduced', 'increased', or 'less than'.

3.3 Relevant International Approaches

A minimum percentage reduction of 25% for 'reduced' claims is the approach taken by Codex, CoPoNC, Canada, the USA and the United Kingdom (in terms of the Food Standards Agency guidelines) for energy, sodium and nutrients other than micronutrients. The European Union proposal is for 30% (except for micronutrients where a 10% difference in the reference values is acceptable) and for sodium/salt where a 25% difference is permitted. The repealed *New Zealand Food Regulations 1984* permitted a reduction of 33%.

For 'increased' claims, other than vitamins and minerals, the proposed European Union regulation is that the product must meet the conditions for the 'source of' claim and the increase in content must be at least 30% compared to a similar product. Canada and the USA do not provide criteria for 'increased' claims. In Canada though, 'more protein' and 'more fibre' relate to the 'source' claim and a 25% increase compared to a reference food, while in the USA 'more', 'added', 'extra' or 'plus' claims can be made in relation to vitamins, minerals, protein, dietary fibre and potassium, provided there is 10% or more of the Daily Value per reference amount. In CoPoNC, dietary fibre is the only nutrient with criteria for 'increased'; the criteria relate to the 'high fibre/good source' claim. Standard 1.3.2 sub-clause 4(b) of the Code prohibits the comparison of the vitamin or mineral content of food, except where specifically permitted.

Most countries and Codex stipulate that a statement must accompany the comparative claim on the label. The statement, which must appear in close proximity to the claim, must compare the food with a reference food in terms of the amount of difference (in percent or fraction terms).

CoPoNC requires a comparison statement on the label stating the reference food and the difference between the nutrient about which the claim is made in the food and in the reference food. Finally, CoPoNC only permits comparative claims between foods of the same food group or foods that may substitute for one another in the diet. For example, comparative claims can be made between foods such as beef and chicken, potatoes and rice or orange juice and apple juice, but comparisons between foods such as milk and fruit juice or fruit and nuts are not encouraged.

3.4 Label Monitoring and related research

Williams *et al*. (2003) found that a quarter of all 'reduced' claims (n=110) were not compliant with CoPoNC, as they did not state the reference food and the percent reduction. However FSANZ's study of labels collected in 2003 found that none of the 'reduced' (n=13) or 'increased' (n=1) claims were non-compliant with CoPoNC (FSANZ, unpublished).[1]

[1] Williams et al (2003) investigated of the use of nutrition content claims in Australia. FSANZ commissioned research on use of nutrition content and health claims in Australia and New Zealand (FSANZ, in press). The design and outcomes of these studies differed in a number of respects - their sampling regime, food categories covered, the geographical areas where samples were obtained, the years when the studies were performed, the sample size and the type of claims analysed. The levels of compliance against CoPoNC were higher in the

La Fontaine (2004) conducted a study on the energy density of foods carrying 'reduced fat' claims in Australia. The mean energy density for the 63 'reduced fat' foods examined was 7.7 ± 5.5 kJ per g compared to 10.2 ± 6.5 kJ per g for 63 full fat equivalent foods. The difference between full fat and 'reduced fat' foods translates to a mean 24.5% reduction in energy. However, the standard deviation was large, indicating that there is considerable variability amongst products and therefore some products had considerably less than 25% reduction compared to the mean of the full fat products. In particular, certain brands of potato chips, peanut butter and chocolate cookies were identified as having less change in energy density than predicted. The authors noted that there did not seem to be any distinguishing characteristics of products that were either higher or lower in energy density than predicted. In their conclusion they stated that, 'food regulations in relation to 'reduced fat' claims need to be tightened to include energy density criteria and to ensure that the marketing of 'reduced fat' products does not imply that the products are 'guilt-free' or that they will promote weight loss.' FSANZ has concluded from this research that clear recommendations in relation to reference foods are required. It is noted that the move from a voluntary code to a standard may result in stronger compliance and enforcement of this provision.

3.5 Consumer Research

FSANZ's qualitative consumer research on nutrition content claims (FSANZ, 2003a) revealed that there was a high level of scepticism around comparative claims and a great deal of confusion as to how they related to terms such as 'low', 'lite', 'diet' and 'high' as well as how they related to public health recommendations. This confirms the results of a previous quantitative study, which found that only 11% of respondents identified a 'reduced in salt' claim on a product as containing more salt than a similar food with a 'low salt' claim (FSANZ, 2003b). Because of dissatisfaction with the degree of ambiguity around 'reduced' claims, some participants in the qualitative research suggested that the percentage reduction should be stated (i.e. '% reduced' or 'reduced from X% to Y%'). Consumers had fewer concerns with 'increased' claims because they assumed product alterations related to 'risk decreasing' rather than 'risk increasing' nutrients. They were also less concerned with 'less than' claims because these were quantified (e.g. 'less than 5 g of sugar').

There have been anecdotal reports that consumers are often misled into assuming that 'fat free', 'low fat' and 'reduced fat' foods are 'guilt-free' and therefore able to be eaten in large quantities. There appears to be very few studies that have examined this issue. Shide and Rolls (1995) found that information about the fat content on a food influenced subsequent energy intake. That is, normal-weight women who received yoghurt labelled 'low fat' consumed significantly more energy during a subsequent lunch than they did after they received yoghurt with a similar energy content but labelled 'high fat'. Miller et al., (1998) also provide partial support. In an investigation of the effect of 'fat free' potato chips with and without nutrition claims, they found that 'restrained' women (as determined by the Three-Factor Eating Questionnaire) ate significantly more of the 'fat free' chips than the regular chips when the information was provided. However the increase did not negate the reductions in fat and energy associated with eating the 'fat free' chips.

FSANZ study than in the study of Williams et al and the distribution of different types of claims varied between the studies. Because of the number of differences in study design it is difficult to determine the reasons for the different outcomes.

Also disclosing that the chips were 'fat free' did not cause 'unrestrained' women to eat significantly more chips compared to the regular chips.

FSANZ explored the issue of disqualifying criteria with consumers participating in focus groups (FSANZ, 2003a). Overall the concept was not well supported. Participants felt that consumers look for different claims for different reasons, so it would be impossible to apply disqualifying criteria. Also participants were aware of fat, salt and sugar trade offs (FSANZ, 2001, 2003a). The majority of people in FSANZ's (2003a) study therefore decided that as long as there was enough information on the package to evaluate the claim, disqualifying criteria were not needed. Many participants were also concerned as to how shoppers would become aware of new regulations if disqualifying criteria were introduced. The authors of the study did, however, acknowledge that it was difficult to draw conclusive findings about consumers' perceptions of disqualifying criteria because the topic was not well understood.

3.6 Preferred Option At Initial Assessment

FSANZ preferred option for comparative claims at Initial Assessment was that:

- the comparison should be based on a relative difference of at least 25% in the energy value or relevant nutrient content;
- the identity of the reference food and the percent, fraction or amount of difference in energy value or nutrient content should be indicated adjacent to the comparative claim; and
- claims should only be made between foods of the same food group or foods that may substitute for one another in the diet.

3.7 Issues Raised By Submitters

At Initial Assessment, submitters were asked whether these comparative claims should be permitted and whether they agreed with FSANZ's preferred criteria. They were also asked whether there should be an additional criterion that relates to energy when 'reduced' and 'less than' claims are made in relation to total fat and sugar. This question was raised on the basis of a recent study that demonstrated that food carrying 'reduced fat' claims were significantly lower in energy density than full fat equivalents as discussed above in Section 3.4 (La Fontaine, 2004). Submitters who were in support of an additional criterion were asked to specify criteria that should apply and any evidence to support their approach. Nearly all submitters supported the permission of comparative claims on the grounds that they are consistent with national dietary guidelines and therefore assist consumers in choosing healthier options within a food category, they have been in use for many years and they are permitted claims internationally.

The majority of submitters also agreed with the preferred criteria on the basis that they are consistent with Codex and are in keeping with the findings of consumer research. However the following points were also raised:

- an additional requirement should apply that relates to a minimum absolute nutrient content difference to prevent manufacturers from making a claim based on a trivial difference (e.g. a product with 3% sugar should not carry a comparative claim if the reference food has 4% sugar);

- manufacturers should not be prevented from making claims such as 'we have reduced the fat content of product X by 5%';
- the requirement that the difference in energy value or nutrient content must be stated adjacent to the comparative claim should not be mandatory;
- consideration should be given to permitting comparisons between foods representing different meal occasions and different food groups. In some cases the comparisons may not necessarily be appropriate substitutions (e.g. a comparison of the folate content in peas with a range of other folate-containing foods including orange juice will provide);
- 'substitute' foods need to be clearly defined. The proposed definitions for 'nutritional equivalence' and 'substitute food' and the qualifying criteria that were raised in the Initial Assessment Report for A500 – Addition of Calcium to Cereal-Based Beverages were recommended; and
- no synonyms should be permitted for 'reduced' and 'increased'. If synonyms are permitted then there should be a requirement for the percentage difference to be declared adjacent to the descriptor. Some submitters also argued that 'less than' and 'more than' claims should not always constitute comparative claims as they could simply be statements of fact about the nutrient content within a food.

3.8 Energy As An Additional Criterion

3.8.1 Issues Raised By Submitters

Submitters were divided on the use of energy as an additional criterion for comparative claims relating to total fat and sugar. Some submitters, representing government, public health and industry groups, agreed with an additional criterion. The main reasons for this were that consumers perceive 'low fat' and 'low sugar' products as also being low in energy, there are a number of 'low fat' and 'reduced fat' foods which do not have a concomitant reduction in energy (La Fontaine *et al*., 2004; Crowe *et al*., 2004), studies suggest that total daily energy intake is affected by the energy density of foods (Westerterp-Plantenga, 2004; Stubbs *et al*., 2000; Porrini *et al*., 1995) and a reduction in energy content would be prudent given the significance of the obesity epidemic in Australia and New Zealand. Submitters suggested the following:

- criteria based on energy ranges provided in the scientific literature in order to prevent over consumption of high-energy density foods. In particular, application of energy ranges provided by Rolls and Barnett (2003) could provide a disqualifying criterion such that foods making comparative claims must contain no more than 1700 kJ per 100 g. The disqualifying criteria should also relate to nutrients such as sugar, fat, fibre and sodium because FSANZ's (2003b) quantitative food labelling study showed that consumers focussed primarily on fat and appeared to have difficulties assessing the significance of relative differences between nutrients;
- criteria for fat and carbohydrate (not fat and sugars). Starches that have been added as fillers in 'low fat' foods have a higher glycaemic index than sucrose and offer no additional nutritional benefits;
- a criterion of 'at least 25% reduction in kilojoules/energy' for consistency with the required reduction in macronutrients;
- a percentage decrease in energy content that is proportional to the decrease in fat/sugar content ;

- the energy level must be significantly less than the reference food. If the energy is not reduced then the product label must clearly state that it is not lower in energy than a comparative food. The percentage reduction should be set to allow for acceptable increases in protein, fibre, and carbohydrates;
- criteria based on energy points rather than kilojoules as most people do not relate to kilojoules and they are cumbersome to add up;
- a reference to the energy value should apply for micronutrients that are 'reduced', the reference being x% less energy than the reference food; and
- dietary modelling should assist in determining a disqualifying criterion for energy for different food categories. It is noted that 'reduced sugar' breakfast cereals are unlikely to have a 25% reduction in energy as the sugar may be replaced by grain content.

Submitters who opposed an additional criterion for comparative claims were mainly from the food industry. The main reasons for opposing the criterion were that:

- there is no demonstrated market failure. Council of Australian Governments principles state that new regulation should only apply to correct market failure;
- La Fontaine et al., 2004 showed that for fat reduced foods there was an overall decrease in energy content of approximately 25%;
- energy content information is clearly displayed on the nutrition information panel. If consumers are not using the nutrition information panel then education is required;
- participants in a FSANZ (2003a) study did not consider disqualifying criteria to be necessary;
- some consumers are interested in fat and sugar levels, irrespective of energy content. For example energy levels are irrelevant if consumers pay attention to sugar claims for dental health;
- it blurs the distinction between a specific nutrient claim and an energy claim;
- a disclosure statement is unnecessary as nutrition information panels are a requirement on food products. Also a disclosure statement will not fit on small sized packs; and
- disqualifying criteria should apply to content claims overall.

3.8.2 Assessment And Rationale

FSANZ proposes to retain comparative claims. In order to ensure consistency with international and Codex criteria, as well as ensuring a minimum absolute difference, it is recommended that the criteria be based on a relative difference of at least 25% in the energy value, sodium or relevant nutrient content (other than for micronutrients) in comparison with the reference food. For 'increased' claims, the food must also meet the criteria for a 'source' claim prior to enrichment in order to ensure that a minimal amount of the nutrient is present and only foods that naturally contain the nutrient can make the claim. The definition of a 'reference food' is discussed in Attachment 5, Chapter 2, Section 2.12.

Furthermore, FSANZ's consumer research (FSANZ 2003a, 2003b) demonstrates that consumers do not differentiate between 'low' and 'reduced' claims. Although they were aware that the product was healthier than the original, there was a high level of scepticism about the claim and a view that such claims required verification from the nutrition information panel. As a result of this research FSANZ has considered additional risk management options, consistent with the principles outlined in Attachment 5, Chapter 2, Section 2.3. FSANZ identified four options:

Option 1
A disclosure statement must be included.

Option 2
Disqualifying criteria are specified.

Option 3
Where a comparative claim is made, the claim states the identity of the reference food; and the content of the claimed nutrient in the reference food and in the claimed food (e.g. 'reduced fat. This cheddar cheese is reduced in fat compared to similar cheddar cheese products from 35% to 24%). The claim must be presented so that all elements of the claim are in the one place.

Option 4
Where a comparative claim is made, the identity of the reference food and the percent, fraction or amount of difference should be indicated adjacent to the comparative claim (e.g. 'reduced fat. This product contains 25% less fat than whole milk). The claim must be presented so that all elements of the claim are in the one place. This is the *status quo*.

Consideration of options

In terms of option 1, there are few consumer research studies that have examined the effectiveness of disclosure statements when specific nutrition content claims are made and those that are available are inconsistent. Some studies indicate that overall, disclosure statements are not effective at addressing the issue of favourable nutrient claims on products containing high levels of risk increasing nutrients (FTC, 1998, FSANZ, unpublished), although very blatant statements (e.g. 'this product is high in saturated fat') appear to have some impact (FTC, 1998). Andrews *et al*., (2000), however, found that exposure to advertisements with nutrition disclosures are significantly more effective than no disclosure, although none of three types of disclosure statements tested totally removed consumer misconceptions. Also disclosure statements are moderated by consumers' level of nutrition knowledge as well as the type of claim being made (Andrews *et al*., 2000, Burton *et al*., 2000). FSANZ concludes that there is sufficient evidence to indicate that disclosure statements are not effective in addressing misconceptions that arise from comparative claims and therefore they will not be required.

In terms of option 2, there is a paucity of evidence to justify the use of disqualifying criteria for comparative claims. Shide and Rolls (1995) provide evidence for a need while Miller et al (1998) provides partial support. There would be a considerable impact on the food industry if disqualifying criteria were applied and it would restrict consumer choice. 'Reduced fat' foods can play a role in providing choice for individuals ready to adopt a lower-fat diet. Such foods can make a positive impact on nutrient intake that may reduce the risk of chronic disease (Sigman-Grant, 1997). FSANZ considers there is not enough evidence at this stage to justify this option.

Option 3 demonstrates to the consumer that a reduction has occurred compared to a reference food and that the food is not necessarily 'low' in a nutrient or energy. This option retains consumer choice of products and may reduce consumer confusion about foods carrying comparative claims not being low or high in a nutrient. However, this wording was considered to add a layer of complexity for consumers.

Furthermore, the magnitude of risk to consumers arising from their misunderstanding of comparative claims was not considered sufficient to justify this additional requirement.

Option 4 alone does not provide any new addition to the current situation in Australia and therefore will not clarify the claim any further for consumers. However the new proposed requirement to state the %DI for the claimed nutrient and for energy provides consumers with additional information to make an informed choice and, as part of the standard, will encourage compliance and be enforceable. Therefore FSANZ's proposed option is to adopt the requirements as currently set out in CoPoNC.

Chapter 4: 'Diet' Claims

4.1 Proposed Approach At Draft Assessment

Claim	Preferred criteria (and conditions)
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 a) the food must contain at least 40% less energy compared to the same quantity of the reference food; and b) there must be a reduction in energy content of at least 170 kJ per 100 g or 80 kJ per 100 mL; and c) the claim states the identity of the reference food and the difference between the energy value of the food and the reference food; d) The claim must be presented so that all elements of the claim are in one place.

4.2 Relevant International Approaches

Specific provisions for 'diet' claims are stipulated in CoPoNC and the now repealed *New Zealand Food Regulations 1984*. The existing criteria for 'diet' claims in CoPoNC permit two alternatives:

1. The food must comply with the regulations for a 'low joule' claim in Volume 1 of the Food Standards Code; or
2. The food must meet the following conditions:

    a) the energy content of the food must not be more than 60% of the energy content of the same quantity of the reference food; and
    b) there must be a reduction in energy content of at least 170 kJ per 100 g of food, or 80 kJ per 100 g of liquid food, compared with the same quantity of the reference food; and
    c) there must be a statement of comparison with the reference food.

The repealed *New Zealand Food Regulations 1984* permitted the claim if the food was a meal replacement for a weight reduction or weight maintenance diet; or conformed to 'low energy' regulations (New Zealand Food Regulations 241) or 'low energy' and 'reduced energy' claims (New Zealand Food Regulations 13b and 13c).

In the USA, 'diet' claims are generally defined in Part 105 - Foods For Special Dietary Use. 'Diet', 'dietetic', 'artificially sweetened' and 'sweetened with non-nutritive sweetener' are permitted claims if they are not false or misleading and if the food is labelled 'low calorie' or 'reduced calorie' or if it bears another permitted comparative calorie claim. Where 'diet' is contained in the brand name of a specific food product that was marketed before October 25, 1989 (e.g. 'Diet Coke'), the term can continue to be used as part of the brand name provided it is not false or misleading. Soft drinks marketed after October 25 1989, however, may use the term 'diet', and provided they are in compliance with the regulations relating to Foods For Special Dietary Use and the requirements for a disclosure statement when the levels of certain nutrients exceed specified amounts.

In Canada, 'diet' claims are also regulated under Foods For Special Dietary Use (B.24.001). 'Diet' and 'dietetic' are permitted as part of the brand name of the food if it is labelled 'free of energy', 'low in energy', 'reduced in energy', 'lower in energy' or 'free of sugars'.

The 'diet' claim is not on the European Union's proposed list of exhaustive content claims, nor is it permitted on foods intended for use in energy-restricted diets for weight reduction. Codex does not define criteria for this claim.

4.3 Relevance Of 'Diet' Claims To Other Claims

Criteria for 'diet', 'light/lite' and 'reduced energy' are not radically different. When 'light/lite' refers to energy content (and this is not always so), then a food must meet the criteria for 'low energy' or 'reduced in energy'. When a 'reduced in energy' claim is made the product must have a reduction in energy content of at least 25% compared to a reference food. For 'diet' claims the reduction must be at least 40% and there must be a reduction of at least 170 kJ per 100 g of food or 80 kJ per 100 g of liquid food compared with same quantity of the reference food.

FSANZ is presently proposing to prohibit slimming claims but to permit weight management claims as general level health claims if they can be substantiated. Such claims will therefore have to meet general level health claim disqualifying criteria. In the new context of health claims, 'diet' claims could therefore be confused with weight management claims.

4.4 Consumer Research

FSANZ's qualitative consumer research (FSANZ, 2003a) found that participants in focus groups viewed 'diet' claims as the least trustworthy, most ambiguous and most irrelevant of all the claims examined. It was associated with weight loss products and therefore deemed useful only for people who are on weight loss 'diets'. Participants found the claim ambiguous because they believed the criteria were different for different product categories (for example, in soft drinks, 'diet' drinks were thought to be low in calories, contain artificial sweeteners and possibly some sugar; but in yoghurts the view was that they had artificial sweeteners and less milk or fat). Overall, many viewed the claim as a 'nothing' term and as being similar to 'light' claims in terms of its ambiguity. Others viewed it as being an 'old' term because they saw claims as being much more specific nowadays (for example, '99% fat free').

Lastly, participants had difficulty differentiating how 'light/lite' and 'diet' differed from 'low', 'reduced' and 'less than'. Most could not suggest how the terms could be distinguished from each other. Most consumers felt that the only way to correctly interpret these claims would be to compare with another product that did not carry the specified claim.

4.5 Preferred Options At Initial Assessment

FSANZ's preferred approach for 'diet' claims at Initial Assessment was that products must meet the conditions for 'low joule' and the average energy content of the food must not be more than 80 kJ per 100 mL of beverages or other liquid foods and no more than 170 kJ per 100 g of solid or semi-solid foods. It was felt that CoPoNC criteria allow 'diet' claims on foods that are potentially high in energy content (although reduced compared to similar products) and are therefore misleading to consumers.

At Initial Assessment, submitters were asked whether the 'diet' claim should be permitted and if so, whether they agreed with FSANZ's preferred criteria.

4.6 Issues Raised By Submitters

Some submitters supported permission of the 'diet' claim, although this was opposed by others. The range of reasons for support for such a claim included that:

- they are well established and have been used extensively;
- there is long-term wide consumer acceptance of the term 'diet' on products consumed for reducing energy and sugar intake, with consumers actively seeking such products;
- 'diet' products may assist some individuals with weight reduction and/or maintenance;
- the term only applies to a small number of food products/categories;
- disallowing 'diet claims would disadvantage manufacturers, particularly when whole product lines have been established on the claim.

Some public health and government agencies did not support the permission for 'diet' claims on the grounds that they are misleading. Submitters outlined that:

- 'diet' properly refers to the total food intake of an individual;
- the claim implies that energy control is the prime component of a diet;
- the claim is an implied health claim as demonstrated by consumer associations with weight loss;
- the term 'diet' is ambiguous and can be misleading as no one food creates a 'diet'; and
- there is potential for confusion with 'slimming' claims.

Submitters, however, expressed very diverse views regarding the criteria for 'diet' claims. Of those submitters who opposed the recommendation to make the criteria more stringent, the majority preferred the CoPoNC criteria. Other stakeholders agreed with the proposed criteria to tighten the criteria for 'diet' claims as they considered that foods relatively high in fat and/or sugar should not be able to make 'diet' claims.

Nearly all submitters who supported the permission of 'diet' claims but opposed FSANZ's preferred criteria at Initial Assessment were from the food industry. In particular, Nestlé noted the value of their rapidly growing 'diet' brand.

Many of their chilled dairy products and desserts, whilst significantly lower in fat, sugar and energy than comparison foods, would not meet the more stringent criterion and may not be able to carry a 'diet' claim. Nestlé argued that they are unable to meet the alternative criterion without loss of texture and taste, which would make these products unacceptable for consumers. They also stated that people who are on weight loss or weight management diets should not be discriminated against.

Overall, Nestlé objected to the proposed recommendation in the Initial Assessment Report on the grounds of possible loss of market, cost impact of re-educating consumers due to loss of an established brand name, consumer loss of choice, deterrence of more healthy product innovation in desserts and snacks, loss of intellectual property associated with loss of trademark and the health benefits of these products for some consumers. Nestlé's submission also noted that consumers who use these products '… are conscious about what they eat (i.e. their overall diet). Their goal is to enjoy sensible, healthy eating and they are aware that fat and sugar play a part in maintaining a healthy diet'.

4.7 Assessment And Rationale

FSANZ's approach to 'diet' claims has changed from that at Initial Assessment. The recommended approach is to retain the CoPoNC criteria and to also apply the general level health claim disqualifying criteria. This takes account of the Policy Guideline as it will protect public health, will assist in promoting industry initiatives that promote healthy food choices and will not be more trade restrictive than necessary. Also there will be consistency with the approach to weight management claims, which should minimise the potential for consumers to be misled. Finally consumers who like to use 'diet' products as a 'treat' option will continue to be able to enjoy them.

It is further recommended that the labelling requirements for the 'reduced' criteria for 'diet' claims be consistent with the requirements for the comparative claims as set out in Section 3.1. That is, that 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.

Chapter 5: 'Light/Lite' Claims

5.1 Proposed Approach At Draft Assessment

Claim	Preferred criteria (and conditions)
Light or Lite	The characteristic that makes the food 'light/lite' must be stated adjacent to the claim, regardless of whether the term applies to energy, a nutrient or a non-nutritional characteristic of the food. If the claim relates to a nutrient or energy or salt, then the food must comply with the conditions for the corresponding 'reduced' nutrition content claim. The claim must be presented so that all elements of the claim are in the one place.

5.2 Relevant International Approaches

CoPoNC requires that the characteristic that makes the food 'light' be stated on the label. If the term is used as part of the name of the food or is used on the label to describe the food and refers to energy or a nutrient, it is considered to be a nutrient claim.

The food must comply with conditions for the corresponding 'reduced' or 'low' claim, when the claim refers to a nutrient or energy. The repealed *New Zealand Food Regulations 1984* had the same criteria for 'light' as for 'diet'.

Codex notes that in all instances, 'light' should follow the same criteria as for 'reduced' and include an indication of the characteristic that makes the food 'light'. The European Union's proposal is the same as for Codex. Canada's requirements are that the claim must only be made in relation to 'reduced' in energy or fat and that a statement of the reduction for calories or fat or both be made, depending on the reduction that meets the criteria for the claim. Criteria in the United States are dependent on the amount of calories from fat in a food. When equal to or more than 50%, the fat must be reduced by at least 50% per reference amount; when less than 50%, the fat must be reduced by at least 50% or the calories must be reduced at least one-third per reference amount. Meals must meet the 'low fat' or 'low calorie' criteria.

5.3 Label Monitoring Studies

The University of Wollongong's study on nutrition content claims (Williams *et al*., 2003) found that of 70 'light' or 'lite' claims, 69% did not include a statement of the characteristic that is light, as stipulated in CoPoNC. In addition, there were five nutrient claims for 'light' made where no values had been declared in the nutrition information panel. These claims were also inconsistent with CoPoNC guidelines.

Although there were 13 'light' or 'lite' claims found in the sample of 542 claims surveyed in the FSANZ's food label monitoring survey (FSANZ, unpublished), none of these claims were found to be non-compliant with CoPoNC guidelines.

As noted in the footnote to Section 3.4, the reason for the discrepancy between these two studies is not known.

5.4 Consumer Research

FSANZ's qualitative consumer research (2003a) showed that consumers used 'light/lite' claims but with different levels of understanding. Some groups, termed 'inquirers' in this study, were overwhelmingly negative towards these claims, viewing them as ambiguous, misleading, confusing and/or outright 'trickery'. However, less well-informed or label-educated consumers regarded them as an attractive and easy way to identify a healthier version of the product. Some participants in the study identified the claim with fat and sugar, but the majority were uncertain and confused as to what the term referred to. In the absence of clarity, most consumers assumed that the claim referred to the nutrient in the food that most needed reducing, and the default assumption was that 'light/lite' referred to fat. The notion of confusion and scepticism is confirmed by results from earlier FSANZ qualitative (FSANZ, 2001) and quantitative (FSANZ, 2003b) studies.

There was a general unprompted view that the claim should be accompanied by a comparative claim (for example, 'has less fat than our normal ice cream'). Therefore, when prompted, participants favoured a statement in conjunction with the claim that identifies the nutritional or non-nutritional characteristic of the food to which the claim refers. Participants felt this would increase their understanding of the claim and the credibility of the claim.

Respondents also felt that the disclaimer should be in a font and colour that was equally as noticeable as the claim, though they did not believe it had to be exactly the same size and colour as the claim.

5.5 Preferred Options At Initial Assessment

At Initial Assessment, FSANZ proposed that 'light/lite' claims should state the characteristic that makes the food 'light/lite' adjacent to the claim, regardless of whether the term applies to energy, a nutrient or a non-nutritional characteristic of the food. If the claim relates to a nutrient or energy, then the food must comply with the conditions for the corresponding 'low' or 'reduced'.

Submitters to the Initial Assessment Report were asked whether these 'light/lite' claims should be permitted and if so, whether they agreed with FSANZ's preferred criteria.

5.6 Issues Raised By Submitters

Some submitters to the Initial Assessment Report supported permission of these claims. The main reasons for their support were that these claims are currently widely used in the market and to not permit them would cause considerable problems for industry and for consumers who use this claim. Other submitters, however, did not support their permission and expressed concerns about the potential for 'light/lite' claims to confuse and mislead consumers.

There were some submitters (mainly from industry) who agreed with all of the preferred criteria for light/lite claims; others did not agree with all or some of these criteria. Although agreeing with the preferred criteria, one submitter requested clarification on the meaning of the words 'adjacent to', noting the impact this could have on industry. Submitters from the food industry and New Zealand government suggested that the criteria should only refer to one category, either low or reduced; otherwise it is confusing for consumers. Some public health submitters suggested that the characteristic referred to should be adjacent to the claim in a font type and colour the same as the claim.

5.7 Assessment And Rationale

FSANZ believes 'light/lite' claims are justifiable because they have been widely used in the market place for many years, they are used internationally and most submitters support them. However because research has demonstrated that many consumers are confused by the claim, a requirement to state the characteristic that makes the food 'light/lite' regardless of whether it refers to energy, a nutrient or a non-nutritional characteristic is necessary. FSANZ also believes that a condition around the placement of this requirement is needed (i.e. the requirement must be 'adjacent to the claim') in order to clarify the meaning of the claim for consumers.

FSANZ is also revising the nutrition criteria at Draft Assessment so that 'light/lite' claims only refer to 'reduced' claims rather than 'reduced' or 'low' as canvassed in the Initial Assessment Report. This will provide consistency with Codex and the European Union; will reduce the variation in criteria and will therefore potentially minimise confusion amongst consumers. It is also highly likely that where products meet criteria for claims in relation to 'low', manufacturers would wish to promote such a claim.

Chapter 6 - Energy Claims

6.1 Proposed Approach At Draft Assessment

FSANZ proposes the following claims and criteria for 'energy'.

Claim	Preferred criteria (and conditions)
Low calorie, low joule, low energy (as per Std 1.2.8 Clause 14)	The average energy content of the food is no more than 80 kJ per 100 ml for liquids and no more than 170 kJ per 100 g for solids. 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.
Reduced calorie, reduced joule, reduced energy	The comparison should be based on a reduction of at least 25% in the energy value. The identity of the reference food and the difference between the energy value in the reference food and in the claimed food must be indicated. The claim must be presented so that all elements of the claim are in one place.
Calorie free	No provisions.

6.2 Policy Context

Recommendations for energy intake for groups or individuals must take into account all the factors contributing to balance between intake and expenditure (Truswell *et al*., 1990). Recommendations for intakes of energy are difficult because of the wide range of requirements, even in individuals with the same age, sex, weight, height and general pattern of activity (Truswell *et al*., 1990).

In the Dietary Guidelines for Australians (NHMRC, 2003) there are no specific guidelines for energy, although they are indirectly related to several guidelines. They include:

- consume only moderate amounts of sugars and foods containing added sugars;
- limit saturated fat and moderate total fat intake; and
- prevent weight gain: be physically active and eat according to your energy needs.

The New Zealand guideline for energy is to 'Maintain a healthy body weight by eating well and by daily physical activity' (Ministry of Health, 2003).

6.3 Label Monitoring

The data from the Williams *et al*. (2003) survey of 6662 Australian products collected in 2001 and the 2003 Food Label Monitoring Survey (FSANZ, unpublished) indicate a high level of compliance for these claims.

6.4 Preferred Options At Initial Assessment

FSANZ's preferred criteria for energy claims at Initial Assessment were:

- Low calorie, low joule, low energy: the average energy content of the food is no more than 80 kJ per 100 ml of beverages or other liquid foods and no more than 170 kJ per 100 g of solid or semi-solid foods.

For claims relating to 'calories', the energy declaration in the nutrition information panel must be expressed as calories as well as kilojoules.

- Reduced calorie, reduced joule, and reduced energy: the comparison should be based on a relative difference of at least 25% in the energy value. The identity of the reference food and the percent, fraction or amount of difference in energy value should be indicated adjacent to the comparative claim. For claims relating to 'calories', the energy declaration in the nutrition information panel must be expressed as calories as well as kilojoules.

- Calorie free: no provisions.

Submitters to the Initial Assessment Report were asked whether these energy claims should be permitted and whether they agreed with FSANZ's preferred criteria.

6.5 Permission for energy claims

6.5.1 Issues Raised At Initial Assessment

Some submitters agreed that all the 'energy' claims identified in the Initial Assessment Report should be permitted. There was a range of reasons in support of this view including that:

- there has been a history of use of these claims in the marketplace and no evidence to of market failure;
- they are useful in providing consumers with information to assist in identifying lower energy foods in order to reduce energy intake; and
- they are useful in supporting nutritional guidelines that encourage people to reduce energy intake and government initiatives in relation to combating the increasing problem of obesity.

A few submitters (representing public health and industry) indicated that they did not support 'calorie free' claims being permitted. However, these submitters did not provide any reasons as to why these claims should not be permitted.

6.6 'Low Calorie', 'Low Joule' And 'Low Energy' Claims

6.6.1 Relevant International Approaches

These claims were revised as a part of the review of Food Standards in Australia and New Zealand during the development of the Code. 'Low joule' claims and claims to the same effect are prescribed in Standard 1.2.8 of the Code. The criteria are based on 'per 100 g' and are consistent with criteria in Codex, the United Kingdom, the European Union proposal and the repealed *New Zealand Food Regulations 1984*. United States and Canadian criteria use reference amounts as the basis of their conditions, although Canada has additional criteria per labelled serving which is consistent with the criteria for solids in Codex and the Code. The United Kingdom has exceptions for intense sweeteners and products that consist of a mixture of an intense sweetener and other substances that, when compared on a weight-for-weight basis, is significantly sweeter than sucrose.

Similarly the European Union is developing criteria for tabletop sweeteners, although the proposed recommendation is 4 kcal (17 kJ) per dose unit equivalent to one teaspoon of sugar.

6.6.2 Issues Raised At Initial Assessment

The majority of submitters specifically stated their agreement with the criteria for 'low' energy claims proposed at Initial Assessment. Some submitters noted that the 'low' energy claims criteria and conditions are consistent with those reviewed and incorporated into Standard 1.2.8 of the Code. However it was also considered that the criteria for 'low' energy claims had been set too high.

A small number of stakeholders queried whether the criteria for 'low' energy claims should be on a per 100 g/mL basis, as proposed, or on a per serve basis. Some of these submitters supported the criteria being on a per serve basis only whilst others supported the use of both per 100 g/mL or per serve. A submitter suggested that it was more beneficial to relate energy intake to serving sizes because some foods (such as chewing gum) are produced for the market in quantities of less than 100 g and it is unlikely that 100 g of such a product would be consumed in one sitting.

However, the Australian Competition and Consumer Commission noted that consumers could be confused by claims based on per serve such as 'less than 1 calorie per serve' when the serving size is dependent on the container size or another amount determined by the manufacturer. It was suggested that this could be overcome if serving sizes are defined in accordance with the Australian Guide to Healthy Eating. The submitters who made this suggestion also stated that they support the criteria being based on per 100 g/mL until serving sizes are standardised in the Code.

6.6.3 Assessment And Rationale

Given that 'low joule' claims were revised as part of the review of Food Standards in Australia and New Zealand and that the Code criteria are consistent with criteria in Codex, it is recommended that the existing criteria in Standard 1.2.8 be retained. The unit of measure for energy claims will therefore continue to be based on 'per 100 g/mL' on the basis of the rationale that is provided in Attachment 5, Chapter 2.

6.7 'Reduced Calorie', 'Reduced Joule' And 'Reduced Energy' Claims

6.7.1 Relevant International Approaches

Codex and countries other than the European Union require a 25% reduction in energy content compared to a reference food. Most countries have additional criteria. In Canada and the USA, the reference food must not be 'low calorie' while in Australia, CoPoNC states that the food must contain at least 170 kJ less energy per 100 g of food, or 80 kJ less per 100 g liquid food, compared with the reference food. The European Union has proposed a 30% reduction and there must be an indication of the characteristic that make the food reduced in total energy.

6.7.2 Issues Raised At Initial Assessment

The majority of submitters specifically stated their agreement to the criteria proposed for 'reduced' energy claims at Initial Assessment.

A small number of submitters raised concerns that 'reduced' energy claims are confusing for consumers and could be potentially misleading. It was considered that content claims such as 'low in' that have absolute criteria have more meaning for consumers and therefore they did not support 'reduced' comparative claims. Whilst another submitter did not outwardly oppose the use of 'reduced' energy claims they did not support the use of terms such as 'lower calories' instead of 'reduced'. They suggested if synonyms for 'reduced' were not accepted, FSANZ should reassess whether voluntary provisions could apply instead of the condition relating to specifying the percentage of the reduction adjacent to the term.

It was noted that the criteria for 'reduced' energy claims are consistent with Codex and other comparative nutrition claims.

6.7.3 Assessment And Rationale

The rationale for 'reduced' claims is provided in Chapter 3. In terms of the criteria, it is recommended that the same criteria apply to 'reduced energy' as for other 'reduced' claims in order to provide consistency. CoPoNC has additional conditions for this claim (food must contain at least 170 kJ less energy per 100 g of food or 80 kJ less per 100 g liquid food compared with the same quantity of reference food), but as argued under Proposal P234 - Criteria and Conditions for Making Nutrition Content and Related Claims, this is considered unnecessarily complicated from a consumer education perspective.

6.8 'Calorie Free' Claims

6.8.1 Relevant International Approaches

Canada, the USA, the European Union and Codex all stipulate small tolerances for 'energy/calorie/joule free' claims. CoPoNC does not provide any criteria.

6.8.2 Issues Raised At Initial Assessment

Some submitters (four public health and three industry) did not support 'calorie free' claims being permitted and it was believed that these claims could be misleading if used on products that do not normally provide caloric energy, such as water.

A smaller number of submitters generally supported 'calorie free' claims being permitted but suggested that FSANZ should develop criteria. It was suggested that the criteria be based on the Codex Guidelines for Use of Nutrition Claims relating to energy free claims (≤4 kCal (17 kJ) per 100 mL for liquids) or the Canadian provisions (< 5 kcal (21 kJ) per reference amount and per labelled serving). Another suggestion was that the criteria be specified as zero/nil or an agreed low figure such as <1 kJ per 100 g/mL.

6.8.3 Assessment And Rationale

The rationale for FSANZ's approach to 'free' claims is provided in Chapter 2. For consistency, it is recommended that no provisions be applied to this claim.

6.9 'Positive Energy' Claims

6.9.1 Relevant International Approaches

Positive energy claims are not specified in CoPoNC. They are, however, currently regulated under Standard 2.9.4 – Formulated Supplementary Sports Foods. No country or Codex has criteria around the general use of positive energy claims except Canada, which permits:

- 'source of energy/calorie' claim: at least 100 Calories or 420 kJ per reference amount and per labelled serving); and
- 'more energy/calorie claims': at least 25% more energy totalling at least 100 more calories or 420 more kJ:

    (a) per reference amount of the food, than the reference amount of the reference food of the same food group or the similar reference food;
    (b) per 100 g, than 100 g of the ref food of same food group or similar ref food, if pre-packaged meal.

6.9.2 Issues Raised At Initial Assessment

Whilst positive energy claims were not discussed in the Initial Assessment Report, a small number of industry submitters provided comments with respect to these types of claims. These comments were that 'good/excellent source of energy' claims should be permitted whilst another submitter did not support these claims on the basis that consumers already consume more than their daily energy needs. However if permitted, it was suggested that these claims only be allowed on appropriate products such as supplementary sports drinks and formulated meal replacements.

6.9.3 Assessment And Rationale

Because energy claims are not specified on the pre-approved list of nutrient function statements and given the increasing prevalence of obesity, no criteria for positive energy claims are recommended. Such claims will therefore be managed under fair trading provisions of food and fair trading laws.

Chapter 7: Protein Claims

7.1 Proposed Approach At Draft Assessment

FSANZ proposes the following claims and criteria for protein.

Claim	Preferred criteria (and conditions)
'Source of protein'	≥5 grams of protein per serving
'Good source of protein'	≥10 grams of protein per serving
'Increased protein'	The food must contain not less than 5.0 g protein per serving of food before the food is enriched with protein and there must be a minimum increase of 25% in protein compared to a reference food. The identity of the reference food and the difference between the protein content in the reference food and in the claimed food must be indicated. The claim must be presented so that all elements of the claim are in one place.

7.2 Policy Context

7.2.1 Australia

Dietary guidelines and national nutrition surveys indicate that inadequate protein intake is not considered to be of concern in Australia. The dietary guideline to 'include lean meat, fish, poultry and/or alternatives' (such as eggs, liver, kidney, shellfish, legumes, nuts and nuts pastes, and certain seeds such as sunflower and sesame seed), whilst not a specific recommendation about protein per se, does however outline the food categories considered to be some of the most significant sources of protein in the Australian diet (NHMRC, 2003).

The current recommended adult nutrient intake for protein is based on a value of 0.75 g/kg body weight/day. For men all ages, 55 g/day is recommended and for women 45 g/day. In pregnancy, an additional 6 g/day is recommended and in lactation, an additional 16 g/day. According to the 1995 National Nutrition Survey, Australian men were consuming, on average, 109 g of protein and women 74 g per day (Australian Bureau of Statistics, 1995).

7.2.2 New Zealand

Protein is considered necessary for building and repairing body tissue (Ministry of Health, 2003). The 2003 New Zealand Food and Nutrition Guideline for Healthy Adults to 'include lean meat, poultry, seafood, eggs or alternatives' highlight the main sources of protein for New Zealanders (Ministry of Health, 2003).

Like Australia, inadequate protein intake is not a concern in New Zealand diets. The National Nutrition Survey found that the dietary protein intake of most adults was almost double the Reference Nutrient Intake (from the United Kingdom Daily Reference Value) for both men and women (Russell *et al*., 1999) and contributed 15–16% of total energy. The New Zealand Recommended Dietary Intake for protein for adults is 0.75 g/kg/day, which equates to approximately 11–15% of total energy (Ministry of Health, 2003).

7.3 Relevant International Approaches

There is no consistency between countries and Codex in terms of the basis for the criteria for protein claims. The different approaches depend largely on the extent to which protein quality criteria have been taken into consideration in order to assure minimal protein values of processed foods and to provide standards of quality for commercial food products.

United States criteria, except for foods for infants under one year of age, are based on a 'corrected amount of protein' determined using the protein digestibility corrected amino acid score. This score, however, underestimates the quality of very high quality protein sources, such as milk, eggs, meat and fish, which may have an impact, particularly when these are used as complementary sources of protein (for example, milk with cereal).

In contrast to the United States approach, protein claims in Canada continue to be based on protein quality via the protein efficiency ratio. The protein efficiency ratio is the weight (in grams) gained per gram protein consumed.

Codex criteria are based on percentages of the Nutrient Reference Value per 100 g or per 100 ml or per kcal or per serving. The United Kingdom legislation and the European Union proposal base protein on a percentage of the energy value of the food.

7.4 Consumer Research

FSANZ's qualitative consumer research (2003a) found that most participants in the focus group had little to say about protein claims (such as 'high in', 'low in' and 'source of'). Participants either ignored or avoided them because they said they had no dietary need for such claims. The claims were considered relevant for sports people and occasionally for those who are underweight.

7.5 Label Monitoring

The University of Wollongong (Williams *et al*., 2003) demonstrated that in 2001 a small percentage of products across a range of product categories were carrying protein claims (mostly 'source' (30%), 'high' (29%) and 'good source' (22%) claims). Different criteria were being used, although most foods (88%) met the Australian Food Standards Code (Volume 1) requirements. Since at the time of FSANZ's survey of 2003 labels Volume 1 of the Code had been repealed there was no assessment of protein claims in relation to compliance with the Code (FSANZ, unpublished).

7.6 Preferred Options At Initial Assessment

FSANZ's preferred criteria for protein claims at Initial Assessment were:

- Source: ≥5 grams of protein per serving; and ≥12% of energy value of the food must be provided by protein.
- Good source: ≥10 grams of protein per serving; and ≥20% of energy value of the food must be provided by protein.

Submitters to the Initial Assessment Report were asked whether these protein claims should be permitted. If they agreed the claims should be permitted, they were asked if they agreed with FSANZ's preferred criteria.

7.7 Source Of Protein

7.7.1 Relevant International Approaches

Codex, Canada and the European Union proposal all provide for 'source of protein' claims. Codex's criteria are ≥10% Nutrient Reference Value per 100 g (solids) and ≥5% of nutrient reference value per 100 mL (liquids) or 5% of nutrient reference value per 100 kcal or 10% of nutrient reference value per serving. The European Union proposed criteria are for ≥12% of the energy value of the food provided by protein.

If a nutrient reference value is replaced by Dietary Reference Value on the basis that that is what is referenced in the Code (table to sub clause 7(3) of Standard 1.2.8) and the values in the table were calculated by converting percentage Dietary Reference Value (protein = 50 g) to grams, the criteria would equate to ≥2.5 grams of protein per 100 mL or ≥5 grams of protein per 100 g. Examination of the food composition tables reveals that the main sources of protein would meet the criteria except for milk. In addition, foods such as sponge cakes, mars bars, milk chocolate, condensed or evaporated milk and sausage rolls would qualify.

Using Codex criteria of 10% of the Nutrient Reference Value per serving and a protein reference value of 50 g, the per serving equivalent would be ≥5 g protein per serving. Milk with serve sizes of 125 ml would qualify, as would yoghurts with a serve size greater than 100 g, most cheeses and breads, baked beans, nuts, soy milks, cooked pastas and noodles without meat or cheese, some cakes, soups and breakfast cereals and all other expected sources of protein. The European Union proposed criteria of ≥12% of the energy value of the food provided by protein, produces similar foods to Codex's per serve criteria. Most milks and yoghurts qualify for a 'source of' claim.

7.7.2 Issues Raised By Submitters

The majority of submitters agreed that 'source of protein' claims should be permitted.

A number of submitters noted that while protein is not in short supply and is not implicated in the development of the most prevalent diet related diseases, protein claims may be relevant for specific groups such as the frail and elderly, those recovering from illness, vegetarians and sports people.

There was a smaller number of submitters (from industry and the public health sector) who did not support the permission of 'source of protein' claims. Reasons given for this were that low protein intake is not an issue in Australia and New Zealand and that too many foods meet the criteria for 'source of protein' claims.

Regarding the criteria for 'source of protein' claims, views were mixed with slightly more submitters who responded to this issue agreeing with FSANZ's preferred criteria for 'source of protein' claims than disagreeing. Those submitters who did not support FSANZ's preferred criteria were from industry.

Some of those industry submitters not in support of FSANZ's preferred criteria for 'source of protein' claims did not support the combined criteria proposed) and considered it to be sufficient for either of the criteria to be satisfied. Reasons for support of this view included that:

- this approach would accommodate the different nutritional needs of sub-groups of the population including infants, adolescents and men, and accommodate the practicalities of serving size;
- the combined criteria appear to be a combination of Codex and European Union requirements, therefore in the interests of international harmonisation it is considered that both requirements be adopted only as alternatives; and
- if 5g of protein is recognised as the sufficient amount to qualify for a 'source of protein' claim, whether it is obtained from a food with a large or a small serving size is irrelevant, therefore the dual criteria are unnecessary. It was considered that FSANZ's view that it is necessary to have a combination of per serve and percentage energy from protein to prevent food with large serving sizes but low protein levels from making a claim is theoretical and not clearly identified and demonstrated.

Other industry submitters noted that they did not support the criteria in relation to the percent of energy from protein requirement and some recommended that FSANZ should consider basing the criteria on a per 100 g basis. In contrast, other submitters, predominantly government submitters who agreed with FSANZ's preferred criteria, noted that they particularly agreed with the combined criteria.

7.7.3 Assessment And Rationale

It is recommended that 'source of protein' claims should be regulated, given that:

- there are nutrition guidelines for protein;
- criteria are needed to support the protein health claim that is specified in the pre-approved list of nutrient function statements (refer to Attachment 8);
- the claim was strongly supported by submitters;
- there are specifications for 'source' claims internationally;
- consistency will be ensured where claims are being made; and
- the claim may have particular relevance for certain groups of the population.

The criterion of at least 5 g of protein per serve of food being proposed by FSANZ for 'source of protein' claims, is 10% of the reference value in Standard 1.2.8 for protein. This is consistent with the approach taken in the Code for 'source of' claims for vitamins and minerals and with the criterion in Codex. Submitters were not opposed to this criterion.

7.7.4 Basis For Criteria In Relation To 'Source Of Protein'

It is proposed that the unit of measure for protein claims should be per serve in order to provide consistency with other risk decreasing nutrients such as vitamins and minerals and dietary fibre. Per serve recognises the contribution provided by different foods as it identifies the amount that an average person actually consumes. At Initial Assessment it was thought that a second criterion using percentage of energy from protein would add value as some relatively large serving sizes of relatively low quality protein foods can make claims otherwise. However, on further analysis it appears to add minimal benefit as foods such as certain soups and wheat based noodles; pastas and gnocchi can still make 'source of protein' claims.

FSANZ acknowledges that because serving sizes are not standardised, a manufacturer could determine a size that is advantageous to making a claim.

For instance hot fried potato chips with a standard serve size of 140 g has only 4.34g protein; if the serve size is increased to 170 g then a claim can be made as it will contain approximately 5.27 g protein. FSANZ therefore intends to monitor serving sizes to determine whether manufacturers are selecting them in order to meet the criteria for content claims.

7.8 Good Source Of Protein

7.8.1 Relevant International Approaches

Codex requirements for 'high protein' are twice their requirements for 'source of protein' claims. 'High protein' claims are permitted in Canada (equivalent to Canada's 'source of protein' claims), have been proposed in the European Union (≥20% of energy from protein, which is equivalent to the United Kingdom's 'rich/excellent source of protein' claim) and are in the repealed *New Zealand Food Regulations 1984* (>33% more protein compared with the normal counterpart and >15 g protein per serving and a statement of comparison with the named normal counterpart).

Codex criteria for 'high protein' translate to ≥5 grams of protein per 100 mL or ≥10 grams of protein per 100 grams. Examination of the food composition tables reveals that foods such as red meats, poultry, fish, shellfish, cheese, eggs, seeds, most nuts and some legumes and breakfast cereals qualify. Milk does not qualify but foods that can contribute significantly to saturated fat intake such as meat pies, hamburgers and pizzas topped with meat, and foods with small serving sizes such as cocoa and coffee powder meet the criteria.

Using Codex criteria of 20% of the Nutrient Reference Value per serving and a protein reference value of 50 g, the 'per serving' equivalent would be ≥10 g protein per serving. Similar foods are represented in this category as given for per 100 g, except that nuts, seeds, legumes and breakfast cereals do not meet the per serve criteria. Also some protein-enriched milks would be included if the serve size is 250 ml as well as flavoured milks packed in 500 ml and marketed as a single serve. The European Union's proposed criteria of ≥20% of energy from protein, includes some milks and yoghurts.

7.8.2 Issues Raised By Submitters

As for 'source of protein' claims, the majority of submitters supported that 'good source of protein' claims should be permitted, whilst a very small number opposed these claims being permitted.

With regards to the criteria for 'good source of protein' claims, there were slightly more submitters, from various stakeholder groups who agreed with FSANZ's preferred criteria than submitters, all of who were from industry who disagreed with one or more aspects of the criteria. Most of the reasons provided by submitters for disagreeing related to the use of the combined criteria as discussed in the 'source of protein' claims section above.

Some industry submitters considered the figures for the amount of protein per serve and the amount of energy from protein for 'good source/high in protein' claims should be double that of 'source of protein'. It was suggested that the doubling could be achieved by increasing the 'good source' energy from protein figure or by reducing the 'source' energy from protein figure.

It was also suggested that the criteria should be lowered to at least 8 g of protein per serve, as this would allow milk to qualify for a 'high protein' claim, which is a food recognised in the Australian Guide to Healthy Eating as a 'good source of protein'.

7.8.3 Assessment And Rationale

The decision to permit 'good source of protein' claims and the basis for the criteria is the same as provided for 'source of protein'. A criterion of more than 10 g protein per serve is proposed as it is twice that of 'source of protein', which is the approach adopted by Codex for protein.

7.9 Other Protein Claims

7.9.1 Relevant International Approaches

Other protein claims are permitted internationally but there is no consistency in the claims. For instance 'low protein' is provided in the now repealed *New Zealand Food Regulations 1984* and in Canada, 'very high protein/excellent source of protein' are given in Canada and the United Kingdom and 'more protein' is regulated in Canada and the United States. In the European Union, it is proposed that 'increased' claims should be permitted provided they meet the 'source' claim and have a 30% increase in the claimed nutrient.

7.9.2 Assessment And Rationale

Although there were few products making 'increased protein' claims in the label monitoring study by Williams *et al*. (2003), FSANZ recommends that criteria for 'increased protein' claims be specified to ensure that a minimum requirement is met and for consistency with other risk decreasing nutrient content claims. The recommended criteria are the same as those for other increased claims (see Chapter 3). That is, the food must meet the criteria for a 'source' claim prior to enrichment in order to ensure that a minimal amount of protein is present and that only foods that naturally contain the nutrient can make the claim. The food must also have a relative increase of 25% compared to a reference food. The identity of the reference food and the difference between the protein content in the reference food and in the claimed food must be indicated. The claim must be presented so that all the elements of the claim are in the one place.

7.10 Meal type products

As noted in Section 5.5.6 (Claims in Relation to Meals) of the Proposal P293 Draft Assessment Report, FSANZ considers that specific provisions should be given to meal type products where the criteria are based on 'per serve'. However FSANZ is not proposing to recommend specific qualifying criteria for protein claims in relation to meal type products for the reasons outlined in Attachment 6, Chapter 10.5.1.

Chapter 8: Fat Claims

8.1 Proposed Approach At Draft Assessment

FSANZ proposes the following claims and criteria for fat.

Claim	Preferred criteria (and conditions)
Low (in) fat	≤3 g per 100 g solid food; and ≤1.5 g per 100 ml liquid food.
Reduced (in) fat	The comparison should be based on a relative reduction of at least 25% in the fat content. The identity of the reference food and the difference between the fat content in the reference food and in the claimed food must be indicated. The claim must be presented so that all elements of the claim are in one place.
Fat free	No provisions.
% fat free	The food must meet the requirements specified for the 'low fat' claim.

8.2 Policy Context

8.2.2 Australia

The Dietary Guidelines for Australian Adults recommend limiting saturated fat and moderating total fat intake (NHMRC, 2003). The 1995 National Nutrition Survey estimated that mean total fat intake of adult Australians contributed to one-third of total energy, which represented a slight decline between 1983 and 1995 (Australian Bureau of Statistics, 1995).

8.2.3 New Zealand

The New Zealand Food and Nutrition Guidelines for Healthy Adults recommend preparing foods or choosing pre-prepared foods, drinks and snacks with minimal added fat, especially saturated fat (Ministry of Health, 2003). The 1997 New Zealand National Nutrition Survey showed that 35% of energy came from fat in the diet of both males and females, a reduction of 2.5% since 1989 (Russell *et al*., 1999). The New Zealand Nutrition Taskforce (1991) set a guideline of 30–33% of energy from total fat. The Food and Nutrition Guidelines for Healthy Adults also set out criteria for considering the lower limits of acceptable fat intake (Ministry of Health, 2003).

8.3 Preferred Options At Initial Assessment

At Initial Assessment, FSANZ proposed the following claims and criteria for fat:

- Low (in) fat: ≤3 g per 100 g solid food; ≤1.5 mL per 100 mL liquid food.
- Reduced (in) fat: the comparison should be based on a relative difference of at least 25% in the fat content. The identity of the reference food and the percent, fraction or amount of difference in fat content should be indicated adjacent to the comparative claim.
- Fat free: no provisions.
- % fat free: the food must meet the requirements specified for the 'low fat' claim.

Submitters to the Initial Assessment Report were asked whether these fat claims should be permitted and whether they agreed with FSANZ's preferred criteria. They were also asked if there should be an additional criterion that relates to energy for 'reduced fat' claims, and if so, what criteria should apply and what evidence supports such an approach.

8.4 'Low (In) Fat'

8.4.1 Relevant International Approaches

Codex, the United Kingdom and the European Union proposal set the criteria at ≤3 g fat per 100 g solids or ≤1.5 g fat per 100 ml liquid food. CoPoNC criterion for solids is the same as this, but for liquids the criterion is ≤1.5 g per 100 g liquid food. In the United States, the solids criterion is also ≤3 g fat per 100 g for meal and main dishes. Criteria for Canada and for foods other than meal and main dishes in the United States are generally based on reference amounts.

Participants in FSANZ's consumer research (FSANZ, 2003a) used 'low' claims interchangeably with 'reduced', though after more focused discussion and a word sort exercise, they tended to agree that 'low' was probably lower than 'reduced' and referred to products intrinsically low in the claimed nutrient.

8.4.2 Issues Raised By Submitters

There was no opposition by submitters for the permission of 'low fat' claims. The majority of submitters also agreed with the criteria that were proposed at Initial Assessment for 'low fat' claims, however a small number of submitters did not entirely agree with these criteria.

Some submitters from industry and public health sectors agreed with the criteria for single foods only, and suggested that there should be a separate 'low fat' criterion for main dishes and meal type products that takes into account the combination of a protein source plus vegetables and cereals. A value of 5 g of fat or less per 100 g was suggested for this criterion.

Meat and Livestock Australia did not agree with the proposed criteria because the criteria did not recognise the unique role of non-carbohydrate containing animal foods such as meat. They argued that meat is a high quality protein source, which still provides an impressive level of essential nutrients without a high level of fat, but it is unrealistic to expect it to meet the 'low fat' criterion as foods with a different mix of nutrients can. A separate criterion of a maximum of 10 g fat per 100 g for meat, poultry and fish was suggested.

Another suggestion was for more clarity regarding the criterion to use for foods that don't clearly fit into the liquid category such as a 'pour-able' salad dressing, ice cream and chunky soups. It was felt that inconsistencies between weights and measures legislation and with New Zealand might result in differing claims. In relation to this, it was also stated that the criterion for liquid food does not fit well for foods with small serving sizes such as sauces, and additional criteria of ≤1.5 g per 100 ml liquid food where the serving size exceeds 100 mL; and ≤3 g per 100 ml liquid food where the serving size is less than 100 mL were suggested.

8.4.3 Assessment And Rationale

It is proposed that the existing CoPoNC criteria of ≤3 g for solids and ≤1.5 g for liquid foods for 'low fat' claims be retained as they are consistent with Codex criteria and were supported by most submitters. The unit of measure for fat claims will be based on 'per 100 g/mL' on the basis of the rationale that is provided in Attachment 5, Chapter 2, Section 2.5.

No other country has requirements for specific food categories other than Canada and the USA, where the criteria are expressed per reference amount. In such cases separate criteria are provided per 100 g for meals and main dishes (the criteria for solid foods are the same as CoPoNC) and for foods that are less than 50 g.

8.5 'Reduced (In) Fat'

8.5.1 Relevant International Approaches

The preferred criterion of a minimum reduction of 25% is the approach taken by CoPoNC, Canada, the United States and Codex. CoPoNC has further conditions that require a reduction of at least 3 g of fat per 100 g of food but this was previously considered by FSANZ in an earlier assessment of health claims and was deemed to be unnecessarily complicated from a consumer education perspective.

8.5.2 Issues Raised By Submitters

Almost all of the submitters who responded to the question relating to permission for this claim agreed that 'reduced fat' claims should be permitted. Reasoning provided for not supporting this claim was that they are likely to mislead consumers as the food making the claim may still contain high quantities of fat.

Although the majority of submitters that responded to the question relating to criteria agreed with the criteria that were proposed by FSANZ at Initial Assessment, there were a few submitters who did not fully support these criteria. Their recommendations were that:

- there should also be a requirement for an absolute reduction in fat content, to prevent comparisons with a low fat product resulting in a difference in fat content that is nutritionally insignificant and therefore misleading;
- only foods with a specified level of fat, e.g. 5 – 10 g per 100 g, should be able to make this claim; and
- manufacturers should be able to choose whether or not to declare the actual fat content in conjunction with the claim.

For comments from submitters regarding an additional criterion relating to energy, refer to Chapter 3, Section 3.8.

8.5.3 Assessment And Rationale

The rationale for criteria of a 25% reduction in fat content is the same as the rationale for other comparative claims (refer to Chapter 3). FSANZ does not recommend the additional conditions specified in CoPoNC (there must be a reduction of at least 3 g of fat per 100 g of food) as it is inconsistent with the approach for other 'reduced' claims and poses problems from a consumer education perspective. The rationale for not including an additional criterion relating to energy for 'reduced fat' claims is also discussed in Chapter 3.

8.6 'Fat Free'

8.6.1 Issues Raised By Submitters

There was considerable support for the permission of 'fat free' claims. Some submitters agreed with FSANZ's proposed criteria for 'fat free' claims. Others (all from industry) recommended that the criteria currently in CoPoNC should be used instead. Reasons given for this recommendation included the promotion of international trade, harmonisation of international food standards and avoiding financial losses from established brands that are based on current 'fat free' criteria, which might be disallowed under the new Standard.

8.6.2 Assessment And Rationale

The rationale for FSANZ not specifying criteria for 'fat free' claims is the same for other 'free' claims (refer to Chapter 2, Section 2.9).

8.7 'Percent (%) Fat Free'

8.7.1 Relevant International Approaches

New Zealand Food Regulations 1984, CoPoNC, the United States, Canada, and Codex all require '% fat free' claims to meet the requirements for 'low fat' claims in their respective regulations. The United Kingdom's Food Standards Agency guidelines state that '% fat free' claims should not be made and the European Union propose that the claim should be prohibited. Canada and the United States have additional requirements for '100% fat free'.

FSANZ's qualitative consumer research on the issue of '% fat free' (FSANZ 2003a) demonstrated that consumers were positive about these claims as they considered them to be exact and therefore reliable. They also felt it was easier to make food comparisons. The limitation was that the claims did not immediately tell the consumer how much fat was in the product as few consciously looked beyond the percentage to think about the amount of fat they would be consuming from the product. FSANZ's previous quantitative research found that 75% of consumers said that '94% fat free' meant the food was a 'low fat food', whereas only 16% described it as a 'medium fat food' (FSANZ, 2003b).

8.7.2 Label Monitoring

The 2003 Food Label Monitoring Survey (FSANZ, unpublished) found that of the 220 claims made under CoPoNC, 66 were 'x% fat free' claims. Of the six claims that were found in this survey to be inconsistent with the criteria in CoPoNC, five were 'x% fat free' claims.

8.7.3 Issues Raised By Submitters

The majority of submitters supported permission of this claim, however there were some submitters who wanted '% fat free' claims to be prohibited. Reasons provided by submitters for not supporting permission of these claims were that they have the potential to mislead consumers, are misused in the market place and do not provide any more information than the 'low fat' claim. Some submitters noted that there was the highest level of non-compliance with the criteria in CoPoNC for this claim, based on the research of Williams *et al.* (2003).

Excluding the submitters that preferred that this claim be prohibited, the majority of the remaining submitters supported the criteria that were proposed by FSANZ in the Initial Assessment Report for '% fat free' claims. A small number of submitters (mainly industry) however did not agree with the criterion that the food must meet the requirements specified for the 'low fat' claim, and some recommended additional criteria.

In addition to recommending that this claim be prohibited, other recommendations from submitters were that:

- the criteria should be replaced with one that allows these claims on foods containing not more than 10% fat in solid foods and not more than 5% fat in liquid foods, because if all foods fell within this fat range, it would result in a diet consistent with dietary advice for fat to provide only 20%-30% of energy;
- in addition to the proposed criterion, there should be a disclosure statement about the energy/total fat content of the food accompanying the claim; and
- the claim should be permitted to any level that the manufacturer feels is acceptable in marketing terms.

8.7.4 Assessment And Rationale

'X% fat free' claims are considered to be warranted as consumers are positive about claims that are definitive and they have been in the market place for a number of years. FSANZ's recommendation to limit such claims to foods that meet the criteria for 'low fat' claims prevents consumers from being misled. The provisions are consistent with Canada and the USA and were widely supported by submitters from all sectors.

Chapter 9: Saturated And *Trans* Fatty Acids Claims

9.1 Proposed Approach At Draft Assessment

FSANZ proposes the following claims and criteria for saturated and *trans* fatty acids.

Claim	Preferred criteria (and conditions)
Low (in) saturated fatty acid/ Low in saturated and *trans* fatty acid	≤1.5 g in total of saturated and *trans* fatty acids per 100 g of solids; ≤0.75 g in total of saturated and *trans* fatty acids per 100 ml of liquids.
Reduced (in) saturated fatty acid	The food contains at least 25% less saturated fatty acids as the same quantity of reference food. The food contains no more *trans* fatty acids as the same quantity of reference food. The identity of the reference food and difference between the saturated fatty acids content in the reference food and in the claimed food must be indicated. The claim must be presented so that all the elements of the claim are in one place.
Reduced in saturated and *trans* fatty acids	The food contains at least 25% less saturated and *trans* fatty acids as the same quantity of reference food. Both saturated and *trans* fatty acids are reduced relative to the same quantity of reference food. The identity of the reference food and the difference between the saturated fatty acids and *trans* fatty acids content in the reference food and in the claimed food must be indicated. The claim must be presented so that all the elements of the claim are in one place.

9.2 Policy Context

9.2.1 Australia

The Dietary Guidelines for Australian Adults recommend limiting saturated fat and moderating total fat intake. Saturated fatty acids are the predominant type of fatty acid in dairy products, in some meats, and in palm oil and coconut oil (NHMRC, 2003).

Trans fatty acids are a form of unsaturated fatty acid where the hydrogen atoms around a carbon-carbon double bond are orientated in a *trans* configuration rather than a *cis* configuration. *Trans* fatty acids occur naturally in ruminant fat and are also created during some manufacturing processes such as the partial hydrogenation of liquid edible oils to make margarine.

There is evidence to show that consumption of diets containing saturated fatty acids and *trans* fatty acids, particularly *trans* mono-unsaturated fatty acids, in comparison with other fatty acids, increase the concentration of total and low-density lipoprotein cholesterol, and lower high-density lipoprotein cholesterol (EFSA, 2004).

The 1995 National Nutrition Survey showed that saturated plus *trans* fatty acid intakes by Australians averaged over 12.5% of energy (Australian Bureau of Statistics, 1995). A population average of saturated plus *trans* fatty acid intakes of 10% of total energy is recommended in the Dietary Guidelines for Australian Adults (NHMRC, 2003).

9.2.2 New Zealand

Food and Nutrition Guidelines for Healthy Adults (Ministry of Health, 2003) recommend preparing foods or choosing pre-prepared foods, drinks and snacks with minimal added fat, especially saturated fatty acids. Data collected from the National Nutrition Survey (Russell *et al*., 1999) showed that saturated fat contributed 15% of energy in the diets of men and women. This figure is higher than the target set by the New Zealand Nutrition Taskforce of a maximum of 12% of total energy intake from saturated fatty acids and *trans* fatty acids (Nutrition Taskforce, 1991).

9.3 Preferred Approach At Initial Assessment

At Initial Assessment, FSANZ proposed the following claims and criteria for saturated and *trans* fatty acid claims:

- Low (in) saturated fat/Low in saturated and trans fat: ≤1.5 g in total of saturated and trans fatty acids per 100 g of solids; ≤0.75 g in total of saturated and trans fatty acids per 100 ml of liquids. The nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7).
- Reduced (in) saturated fat/Reduced in saturated and trans fat: the comparison should be based on a relative difference of at least 25% in the saturated and trans fatty acid intake. The identity of the reference food and the percent, fraction or amount of difference in fat content should be indicated adjacent to the comparative claim.

- The nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7).
- Saturated fat free: no provisions.

At Initial Assessment FSANZ asked submitters whether these saturated and *trans* fat claims be permitted and whether they agreed with FSANZ's preferred criteria. They were also asked whether there is merit in a disqualifier for 'low in saturated fat/low in saturated and *trans* fat', such as 'saturated fat must not provide more than 10% of energy'.

In addition they were asked if there is justification in considering a new criterion for 'low in saturated fat/low in saturated and *trans* fat' claims, such that the total of saturated fatty acids and *trans* fatty acids comprises no more than 28% of the total fatty acid content of the food, and what the advantages and disadvantages of such a criterion would provide in comparison to FSANZ's preferred option. A question was also asked regarding merit of a disqualifier for 'reduced in saturated fat/reduced in saturated and *trans* fat', such that there should be no increase in *trans* fatty acids.

9.4 *Trans* Fatty Acids

9.4.1 Relevant International Approaches

Canada allows claims for *trans* fatty acids to help consumers make food choices in line with dietary guidance. Criteria for '*trans* fat free' are 0.2 g *trans* fatty acids per reference amount and per labelled serving and 'low' in saturates. Criteria for 'reduced *trans* fat' are a 25% minimum reduction in *trans* fatty acids; no increase in saturated fatty acid content and the reference food must be 'low' in saturated fatty acids. The reference food and the percent, fraction or amount of difference in *trans* fatty acid content must be indicated adjacent to the most prominent comparative claim.

No other country or Codex has provisions for '*trans* fat' claims.

There are no estimates of total *trans* fatty acids intake in Australia or New Zealand based on the latest national nutrition surveys. Mean *trans* fatty acids intake in Australia for males and females respectively has been estimated at 6.4 g and 4.4 g/day (Noakes, 1994). In New Zealand, a 1995 study estimated *trans* fatty acids consumption to be 5.4 g and 3.4 g/day for males and females respectively. This study was based on 1989/90 New Zealand Life in New Zealand data; the major food sources of *trans* fatty acids were butter, margarine and milk (Lake, 1995) (margarine mean *trans* fatty acids 16%). In Canada the consumption of *trans* fatty acids is estimated to be about 8 g/day, representing about 10% of total fat intake. According to Canada, this level of consumption is higher than the USA and considerably higher than in Europe.

9.4.2 Issues Raised By Submitters

The majority of submitters who commented generally on the permission for *trans* fatty acids claims were in support of them. A small number of submitters however, specifically opposed claims relating to *trans* fatty acids. Reasons provided by submitters for opposing these claims included that:

- they are not consistent with Codex or internationally;
- public awareness of trans fats is not high and could lead to confusion; and
- naturally occurring *trans* fats are not linked to adverse health conditions and some are associated with a positive health claim. This claim would only be supported if the definition includes *trans* fatty acids derived from non-animal sources.

In relation to the last point, some industry submitters recommended that the definition of *trans* fatty acids be amended to include *trans* fatty acids from non-animal sources only, and to exclude *trans* fatty acids from natural sources.

It was also recommended by some submitters from the industry and public health sectors that there should be provisions for 'low *trans* fat' and 'reduced *trans* fat' claims to be made separately from saturated fatty acids claims, with the criteria the same for both claims. This would allow liquid oils to make a 'low *trans* fat' claim. A new criterion was suggested for 'reduced *trans* fat claims': 'the comparison should be based on a relative difference of at least 25% in the *trans* fatty acid content and no increase in saturated fatty acid content'.

9.4.3 Assessment And Rationale

FSANZ have not proposed criteria for *trans* fatty acid claims in isolation from saturated fatty acid claims because there have been no daily reference values established for *trans* fatty acids on which to base these criteria. *Trans* fatty acids claims could, however, be made in conjunction with saturated fatty acids claims (for example, 'low in saturated and *trans* fat'), given that the criteria include *trans* fatty acids.

The definition of *trans* fatty acids will remain as it is currently in the Code at this stage. During 2004 FSANZ carried out a literature review of *trans* fatty acids. The results suggested that *trans* fatty acids from partially hydrogenated vegetable sources increase cardiovascular disease risk, whereas ruminant *trans* fatty acids may decrease or not affect the risk of cardiovascular disease (EFSA 2004, Stanley 2004). These studies should be considered with care, as the results have been difficult to interpret. There is a low amount of *trans* fatty acids in animal products compared to partially hydrogenated oil and the amount consumed may not be enough to show an effect; moreover the fatty acid profile of animal products is higher in saturated fatty acids than partially hydrogenated oils and may confound the results (EFSA, 2004). It was concluded that there is no difference in the risk of cardiovascular disease from the consumption of total, ruminant and industrial *trans* fatty acids when the intake is below 2.5 g/day (NDA, 2004).

9.5 'Saturated Fat Free'

9.5.1 Relevant International Approaches

Both Canada and the USA include *trans* fatty acids in their criteria for 'saturated fat free' claims. Canada requires less than 0.2g *trans* fatty acids per reference amount and the USA require les than 0.5g *trans* fatty acids per reference amount. No other countries or Codex include *trans* fatty acids in their criteria for 'saturated fat free' claims.

9.5.2 Issues Raised By Submitters

The majority of submitters did not specifically comment about 'saturated fat free' claims but generally supported permission for saturated and *trans* fats claims. Some of these submitters recommended that a notion regarding conformity with fair trading practices should be added to the criterion for this claim. Other submitters suggested that provisions should be specified for 'saturated fat free' claims such as the criteria in Codex (not more than 0.1 g per 100 g or 100 mL). There was a small number of submitters who stated that 'saturated fat free' claims should not be permitted.

9.5.3 Assessment And Rationale

The rationale for FSANZ not specifying criteria for 'saturated fat free' claims is the same for other 'free' claims (refer to Chapter 2).

9.6 'Low In Saturated Fatty Acids' And 'Low In Saturated And *Trans* Fatty Acids'

9.6.1 Relevant International Approaches

CoPoNC criteria for 'low saturated fat ' claims are consistent with Codex for solid foods (≤1.5 g saturated fat/100 g solids) and also for liquids (≤0.75 g), except that the Codex criterion for liquids is per 100 ml whereas the CoPoNC criterion is per 100 g. In the United Kingdom, the Food Standards Agency's guidelines stipulate ≤1.5 g per 100 g (solids) or per 100 ml (liquids). In addition, CoPoNC requires that foods comply with the conditions for a 'low fat' claim.

Canada's recent revision of 'low saturated fat' criteria includes *trans* fatty acid content (≤2 g saturated and *trans* fatty acids combined per reference amount and per labelled serving). The United States is currently considering criteria for *trans* fat too and whether statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, should be provided as a footnote in the nutrition panel or as a disclosure statement in conjunction with the claim. In addition, Codex, the United States, Canada, the European Union proposal and the United Kingdom Food Standards Agency guidelines all set disqualifying criteria around the percentage of energy from saturated fat. The *New Zealand Food Regulations 1984* claim for 'low saturated fat' was the same as the *New Zealand Food Regulations 1984* claim for 'reduced saturated fat'.

9.6.2 Issues Raised By Submitters

There were no submitters who specifically opposed permission of a 'low (in) saturated fat' claim. The majority of submitters were also in support of a combined 'low in saturated and *trans* fatty acids' claim, however some submitters were opposed to claims regarding *trans* fatty acids in general (refer to Chapter 9, Section 9.4).

The criteria proposed at Initial Assessment for a 'low saturated fat' claim were favoured by most submitters although a smaller number of submitters (from the public health, government and industry sectors) disagreed with these criteria because they would exclude foods such as margarines, oils, nuts and seeds from making this claim and therefore these criteria were not in line with national dietary guidelines.

Most submitters also agreed with FSANZ's preferred criteria for the 'low in saturated and *trans* fat' claim; however some disagreed. The main reason provided by the submitters who disagreed was that they did not agree with the definition of *trans* fatty acids (refer to Chapter 9, Section 9.4)

Submitters were divided in their opinion on whether to include the criterion that the total of saturated fatty acids and *trans* fatty acids comprises no more than 28% of the total fatty acid content of the food. The following reasons were given for disagreeing with the inclusion of this criterion:

- it would exclude lean red meat products from making low saturated fat claims even though these products are low in saturated fat in terms of grams per 100 g;
- it is not consistent internationally;
- the proposed criterion is confusing and appears to be there to suit margarine manufacturers – food standards should not be made to suit manufacturers of particular products;
- it may increase total fat consumption and concomitantly total kilojoule consumption;
- the actual saturated fatty acid content of low saturated fat foods would be on a sliding scale depending on the fat content of the food. Also the wide range of 'low saturated fat' foods would be inconsistent and confusing to manufacturers and consumers; and
- only trans fat that is not naturally occurring should be limited.

Other submitters supported the new criterion (as an alternative criterion) mainly because it would allow nuts, oils and high oil foods to make a 'low saturated fat' claim; and because it is more in line with national dietary guidelines.

It was suggested that provision could be made for two criteria from which manufacturers can choose. The suggested criteria were either:

- a value based on grams of fatty acids per 100 g of solids (as in FSANZ's preferred criteria); or
- the total of saturated and *trans* fatty acids comprises no more than a certain percentage of the total fatty acid content of the food (suggestions ranged from 20% to 28% to 30%).

9.6.3 Assessment And Rationale

The Dietary Guidelines for Australians (NHMRC, 2003) and the New Zealand Food and Nutrition Guidelines (Ministry of Health, 2003) provide a valid basis for retaining nutrition content claims for saturated fat claims.

FSANZ's recommendation is to retain the criteria proposed at Initial Assessment (≤1.5 g in total of saturated fatty acids and *trans* fatty acids per 100 g). Foods such as vegetable oils, nuts and avocadoes that do not meet this criteria can make alternative claims in relation to fatty acids, for example claims in relation to polyunsaturated fatty acids and monounsaturated fatty acids. The requirement in CoPoNC for the food to meet the 'low fat' criteria has been removed because it is the type of fats consumed that relate to many of the physiological and health outcomes, rather than total fat consumption (NHMRC and Ministry of Health, 2005).

Both New Zealand and Australian dietary guidelines discuss *trans* fatty acids, although there are no daily values provided for consumption of *trans* fatty acids. The New Zealand Food and Nutrition Guidelines (Ministry of Health, 2003) refer to the adverse metabolic effects of *trans* fatty acids, noting that these effects are similar to the effects of saturated fatty acids on plasma cholesterol. The Dietary Guidelines for Australian Adults also state that *trans* fatty acids appear to behave similarly to saturated fatty acids in raising plasma low-density lipoprotein cholesterol. FSANZ therefore proposes to consider *trans* fatty acids in the criteria for 'low saturated fat' claims. Also, based on this rationale, it would be misleading to consumers to have 'low saturated fat' claims on foods that contain relatively 'high' amounts of *trans* fatty acids, and therefore FSANZ has proposed the same criteria for both 'low saturated fat' and 'low in saturated fat and *trans* fat' claims.

An alternative criterion of the total of saturated fatty acids and *trans* fatty acids of no more than 28% of total fatty acids, was suggested by FSANZ at Initial Assessment. This criterion is no longer recommended as further analysis reveals it would allow high fat foods with a high polyunsaturated fatty acids content to make 'low saturated fat' claims, whereas the lower fat version of the same food may not be able to make this claim, e.g. steamed fish may not be able to make a 'low saturated fat' claim but the same fish fried in a vegetable oil may be able to.

9.7 Disqualifier For 'Low In Saturated Fat/Low In Saturated And *Trans* Fat'

9.7.1 Relevant International Approaches

Codex, the United States, Canada, the European Union proposal and the United Kingdom Food Standards Agency guidelines all set disqualifying criteria around the percentage of energy from saturated fat for 'low saturated fat' claims. For instance Codex, the United Kingdom Food Standards Agency, the United States and the European Union proposal have a condition that the saturates provide ≤10% of total energy, whereas Canada's recent criterion is ≤15% energy from saturated and *trans* fatty acids per reference amount and per labelled serving.

9.7.2 Issues Raised By Submitters

There were equal numbers of submitters who supported and opposed a disqualifier (such as 'saturated fat must not provide more than 10% energy', as suggested by FSANZ at Initial Assessment) for 'low in saturated fat/low in saturated and *trans* fat' claims.

A small number of submitters agreed with the disqualifier suggested and some submitters noted that at this level nuts and vegetable oils would not qualify for a claim, so a level of 15% of energy from saturated fat was recommended. It was also noted that this may permit other foods that predominantly contain saturated fats, such as pastries, to make a 'low saturated fat' claim, so it may be more appropriate to consider levels for food groups and categories or a ratio of poly, mono and saturated fatty acids.

Reasons given by submitters, who were predominantly from industry, for opposing the use of a disqualifier included that:

- if the statement is true or substantiated it should be permitted;
- it would add complexity;

- it is not consistent with FSANZ's precedent and objectives of the review of the Code and with FSANZ's other actions of removing criteria;
- the information is available in the nutrition information panel; and
- it is unrealistic that saturated fat provides no more than 10% of energy content for foods making 'low' claims.

9.7.3 Assessment And Rationale

It is recommended that no disqualifying criteria should be included in the conditions for 'low in saturated fat' and 'low in saturated and *trans* fat' claims. As outlined in Figure 5.5 in Attachment 5, Chapter 2, Section 2.3, there is no evidence of consumers being misled by these claims and therefore no need to set additional criteria. This approach will allow continued industry innovation to develop healthier food choices.

9.8 'Reduced In Saturated Fatty Acids' And 'Reduced In Saturated And *Trans* Fatty Acids'

9.8.1 Relevant International Approaches

A 25% minimum reduction of saturated fat is provided for all comparative claims in CoPoNC, Canada and the United States. Additional criteria also apply in these countries but they are not the same. For instance, Canada stipulates that there must not be an increase in the content of *trans* fatty acids; and that the percent, fraction or amount of difference in saturated fatty acid content must be indicated adjacent to the most prominent claim. Canada and the USA also require that the reference food is not a 'low saturated fat' food.

CoPoNC, however, specifies that there must be a reduction of at least 2 g saturated fatty acid per 100 g of food compared with the same quantity of reference food (or 1 g saturated fatty acids per 100 g of liquid food) and either ≤20% of the fatty acid portion may be derived from saturated fatty acids and ≥40% of *cis*-monounsaturated and *cis*-polyunsaturated fatty acids or ≤15% of total energy may be derived from saturated fatty acids.

Additional criteria for the United States relate to disclosure statements if cholesterol and total fat exceed certain levels. They are also currently considering criteria for *trans* fat too and whether statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, should be provided as a footnote in the nutrition panel or as a disclosure statement in conjunction with the claim.

9.8.2 Issues Raised By Submitters

Almost all submitters supported permission for 'reduced in saturated fat' claims however a small number did not support these claims because they believed that they have the potential to confuse or mislead the consumer. Most submitters were in support of the combined 'reduced saturated and *trans* fatty acids' claim.

Of the submitters who responded to the question relating to criteria, the majority favoured FSANZ's preferred criterion for a 'reduced saturated fat'; however some submitters did not agree with this criterion, mainly because they considered it was not clearly expressed. The following criterion was therefore suggested:

'the comparison should be based on a relative difference of at least 25% in the saturated fatty acid content and no increase in *trans* fatty acid content'.

It was noted that this criterion also includes the disqualifier that there be no increase in the *trans* fatty acid content per 100 g (as opposed to proportionate increases in fatty acid ratios), as discussed below.

It was considered by some submitters that the criterion for 'reduced saturated and *trans* fat' claims was not clearly expressed and the following criterion was recommended:

'there must be a reduction in both saturated and *trans* fatty acid contents and the comparison should be based on a relative difference of at least 25% in the combined saturated and *trans*'.

9.9 Disqualifier For 'Reduced In Saturated Fatty Acids/Reduced In Saturated And *Trans* Fatty Acid Claims

9.9.1 Issues Raised By Submitters

The majority of submitters supported the use of a disqualifier (such as that there is no increase in *trans* fatty acids) for 'reduced in saturated fat/reduced in saturated and *trans* fat' claims, however there some submitters specifically opposed to this type of disqualifier.

Reasons provided by submitters for supporting a disqualifier for 'reduced saturated/*trans* fat' claims were that the criteria should not allow for the substituting of saturated fats with *trans* fats because they have similar metabolic effects and gram for gram, *trans* fats are potentially more harmful.

Disadvantages of this disqualifier noted by submitters were that:

- it is not consistent with Codex so possible trade barriers would need to be considered;
- it could be confusing to manufacturers as a reduction in saturated fat is likely to cause a proportionate increase in fatty acid ratios; and
- an increase in tran*s* fats from animal sources may provide positive health benefits.

9.9.2 Assessment And Rationale

The rationale for criteria of a 25% reduction in saturated fatty acids content is the same as the rationale for other comparative claims (refer to Chapter 3).

FSANZ proposes an additional requirement for no increase in *trans* fatty acids instead of a reduction in the combined amount of *trans* fatty acids and saturated fatty acids, on the same basis that Canada did not favour criterion that related to the combined amount of saturated and *trans* fatty acids. This was because foods with no reduction in saturated fatty acids (or even an increase) could carry the claim (for example, a food with 2 g saturated and 4 g *trans* fatty acids could be modified to contain 2.5 g saturated and 2 g *trans* fatty acids and could therefore be labelled 'reduced in saturated fatty acids').

Chapter 10: Unsaturated Fatty Acid Claims

10.1 Proposed Approach At Draft Assessment

Claim	Preferred criteria (and conditions)
Polyunsaturated and monounsaturated fatty acids	No change from current prescription (Standard 1.2.8). Will review once new Nutrient Reference Values are adopted.
Omega fatty acids	As above

10.2 Policy Context

The scientific evidence supporting monounsaturated, polyunsaturated and omega fatty acids claims was considered during the review of the *Australia New Zealand Food Standards Code* and has more recently been reviewed in dietary guidelines in Australia and New Zealand.

Humans can synthesise monounsaturated fatty acids from saturated fatty acids and carbohydrates; deficiency does therefore not occur. However humans and other animals have little ability to synthesise certain polyunsaturated fatty acids, such as linoleic acid, from other fatty acids, such as stearic or oleic acids. These essential fatty acids must be provided by the diet.

Of the countries considered, Australia and New Zealand are the only ones that have provisions for polyunsaturated fatty acids and monounsaturated fatty acids claims, as given in Standard 1.2.8 of the Code.

10.3 Polyunsaturated Fatty Acids

10.3.1 Australia

The Australian 1995 National Nutrition Survey (Australian Bureau of Statistics, 1995) showed that mean intakes of polyunsaturated fat in adults contribute 4.5% of total energy. The Dietary Guidelines for Australian Adults (NHMRC, 2003) recommend that intakes of these fatty acids be in the range of 6–8% of total energy. In addition, due to the low intake of long chain omega-3 polyunsaturated fatty acids (approx. 200 mg from fish and a few vegetable oils), it is recommended that intake of these fatty acids should be doubled as a measure to reduce the risk of coronary heart disease.

10.3.2 New Zealand

Results from the 1997 New Zealand National Nutrition Survey (Russell *et al*., 1999) showed that 5% of total energy was provided from polyunsaturated fatty acids, which falls short of the target of 6–10% of total energy set by the New Zealand Nutrition Taskforce (1991).

10.4 Monounsaturated Fatty Acids

10.4.1 Australia

Replacing saturated fatty acids with monounsaturated fatty acids lowers total and low-density lipoprotein cholesterol although not to the same extent as polyunsaturated fatty acids (National Heart Foundation Australia, 1999). The Australian National Heart Foundation notes there is little evidence that monounsaturated fatty acids have an independent effect on coronary outcomes. The National Heart Foundation Australia's position statement recommends that a proportion of dietary saturated fatty acids should be replaced by monounsaturated fatty acids as a strategy for reducing the intake of saturated fatty acids.

In adult Australians, present intake levels of monounsaturated fats are around 11.5% and would appear to be satisfactory except in individuals who need to reduce fat as part of body weight management (NHMRC, 2003).

10.4.2 New Zealand

In New Zealand, the 1997 Survey (Russell *et al*., 1999) showed monounsaturated fat provided 12% and 11% of energy in men and women respectively. This is within the range of 10–20% set by the New Zealand Nutrition Taskforce (Nutrition Taskforce, 1991).

10.5 Preferred Approach At Initial Assessment

At Initial Assessment, FSANZ proposed the following claims and criteria for polyunsaturated, monounsaturated and omega fatty acids:

- Polyunsaturated or monounsaturated fatty acid content of a food: See Standard 1.2.8, clause 12 of the Code. Also, the nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7).

- In relation to omega-3 fatty acids: See Standard 1.2.8, sub-clauses 13 (1), (2) and (3) of the Code. Also, the nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7), and the source of omega-3 fatty acids in accordance with sub-clause 13(5) and the editorial note following sub-clause 13(6).

- Good source of omega-3 fatty acids: See Standard 1.2.8, sub-clause 13(4) of the Code. Also, the nutrition information panel must include declarations of the trans, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7), and the source of omega-3 fatty acids in accordance with sub-clause 13(5) and the editorial note following sub-clause 13(6).

- In relation to omega-6 or omega-9 fatty acids: See Standard 1.2.8, sub-clause 13(6) of the Code. The nutrition information panel must include declarations of the *trans*, polyunsaturated and monounsaturated fatty acid content of the food in accordance with Standard 1.2.8 sub-clauses 5(4) and 5(7), and the editorial note following sub clause 13(6).

At Initial Assessment, FSANZ asked submitters whether these polyunsaturated, monounsaturated and omega fatty acid claims should be permitted and whether they agreed with FSANZ's preferred criteria.

Submitters were also asked if the Code should be clarified in relation to polyunsaturated and monounsaturated fat claims, with the following two possible options proposed by FSANZ:

- the provisions should only relate to 'source of' claims in order to ensure consistency with omega-6 and omega-9 claims; and
- there should be provisions for 'source', 'good source' and 'increased' claims to ensure consistency with other content claims.

10.6 Polyunsaturated and Monounsaturated Fatty Acid Claims

10.6.1 Issues Raised By Submitters

The majority of submitters that responded to the question relating to permission for these claims supported their permission.

Of the submitters who responded to the question relating to the proposed criteria, most also agreed with the current provisions for polyunsaturated and monounsaturated fatty acid content claims as prescribed in Standard 1.2.8. Of these submitters most also agreed that these criteria could be clarified, with some submitters supporting that there should be provisions for 'source', 'good source' and 'increased' claims, in order to achieve consistency with other nutrition content claims. There were also some submitters who were in favour of 'source' and 'good source' claims, but not 'increased' claims.

Some industry submitters also recommended that provisions for 'source', 'good source' and 'increased' should be reviewed for all fatty acid claims including omega fatty acids, to ensure consistency with other nutrition content claims as well as across all fatty acid claims.

10.6.2 Assessment And Rationale

Dietary guidelines in New Zealand and Australia and other scientific and government sources provide scientific evidence to support retention of polyunsaturated fatty acids and monounsaturated fatty acids claims (NHMRC, 2003; Ministry of Health, 2003).

Although there was some support from submitters for the criteria specified in the Code and also for the criteria to be clarified for all fatty acids, FSANZ will not progress this issue any further due to the development of new Nutrient Reference Values for Australia and New Zealand. The draft Nutrient Reference Values provide values for the intake of dietary fats, in particular the essential fatty acids linoleic acid and alpha-linolenic acid, and the long-chain fatty acids docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), and docosapentaenoic acid (DPA) (NHMRC and Ministry of Health, 2005).

Recommendations for monounsaturated fatty acids and polyunsaturated fatty acids intakes are based on the beneficial partition of dietary fatty acids in the context of total fat intake as well as functional properties.

To assess the validity of a health claim the recommended maximum intake of saturated fatty acids, as well as recommended maximum and minimum intakes of polyunsaturated fatty acids, and the relative contribution of the different types of fatty acids to total energy intake must be considered.

As these values have not been finalized, it would not be appropriate to develop new criteria for claims for polyunsaturated fatty acids and monounsaturated fatty acids until the new Nutrient Reference Value become available.

10.7 Omega Fatty Acid Claims

10.7.1 Relevant International Approaches

Only Australia, New Zealand and Canada have requirements for omega fatty acid claims. Canada has criteria for 'source of' omega-3 fatty acids and 'source of' omega-6 fatty acid claims; however, these criteria are different to those contained in the Code in that they are based on grams of omega-3 or omega-6 fatty acids per reference amount and per labelled serving and there is no disqualifying criterion. Australia and New Zealand also have criteria for a 'good source' of omega-3 fatty acids claim.

There are two categories of omega-3 fatty acid: short chain (i.e. alpha-linolenic acid) and long chain (eicosapentaenoic acid, docosahexaenoic acid). Alpha-linolenic acid is an essential fatty acid required for eicosanoid synthesis, while there is some evidence that long-chain omega 3 fatty acids reduce the risk of cardiovascular disease (Hooper *et al.*, 2005). Fish and fish oils high in long-chain omega 3 fatty acids have been linked to reduced risk and mortality from coronary heart disease (Kris-Etherton *et al.*, 2003). The conversion of alpha-linolenic acid into long-chain omega-3 fatty acids is thought to be poor.

10.7.2 Issues Raised By Submitters

The majority of submitters who responded to the question relating to these claims supported the omega fatty acid content claims as currently prescribed in Standard 1.2.8 and most of these submitters also agreed with the current criteria for these claims.

The inclusion of docosapentaenoic acid in the criteria for omega-3 fatty acid claims was suggested.

It was also recommended that the criteria for omega-3 claims should be doubled, as they are unreasonably low.

In addition it was recommended that the criteria for omega-6 and omega-9 claims should be based on mg rather than as a percentage of the fatty acid content of the food, to be consistent with omega-3 criteria and so that the public will have an informed choice about how much omega-6 and omega-9 they are consuming.

It was suggested that the descriptor 'good' in the 'good source of omega-3 fatty acids' claim might confuse consumers when the food is not a natural source of omega-3 fatty acids.

10.7.3 Assessment And Rationale

Dietary guidelines in New Zealand and Australia provide scientific evidence to support retention of omega fatty acid claims (NHMRC, 2003; Ministry of Health, 2003).

Although there was some support from submitters for the criteria specified in the Code and also for the criteria to be clarified for all fatty acids, FSANZ will not progress this issue any further due to the development of new Nutrient Reference Values for Australia and New Zealand. The draft Nutrient Reference Values provide values for alpha-linolenic acid, and for the total of the long chain omega-3 fatty acids docosahexaenoic acid, eicosapentaenoic acid, and docosapentaenoic acid (NHMRC and Ministry of Health, 2005).

Recommendations for intake of omega-3 fatty acids are subject to similar criteria as those made for total monounsaturated fatty acids and polyunsaturated fatty acids. Because the ration of omega-3 to omega-6 fatty acids appears to be very important, assessing appropriate criteria for claims based on omega-3 fatty acids must also take recommendations on omega-6 fatty intake into account, and consider omega-3 intakes in the context of the total dietary lipid profile recommended. Unless the criteria for a claim are carefully determined, certain foods might qualify for a claim even so a serving may provide little available omega-3 fatty acid, while others may be disqualified due to high energy densities, even though their intake may be of benefit to the consumer.

As these values have not been finalized, it is currently not appropriate to develop new criteria for claims for omega fatty acids. This will also help to maintain consistency with the polyunsaturated fatty acids and monounsaturated fatty acids claims and criteria.

Chapter 11: Cholesterol Claims

11.1 Proposed Approach At Draft Assessment

FSANZ proposes the following claims and criteria for cholesterol.

Claim	Preferred criteria (and conditions)
Cholesterol free	The food must comply with the conditions for a nutrition content claim in relation to low saturated fat.
Low (in) cholesterol	≤20 mg cholesterol per 100 g. The food must comply with the conditions for a nutrition content claim in relation to cholesterol free.
Reduced (in) cholesterol	The food must comply with the conditions for a nutrition content claim in relation to cholesterol free. The food contains at least 25% less cholesterol as the same quantity of reference food. The identity of the reference food and the difference between the cholesterol content in the reference food and in the claimed food must be indicated. The claim must be presented so that all elements of the claim are in one place.

11.2 Policy Context

11.2.1 Australia

Dietary cholesterol only occurs in animal fats, which are also the major sources of saturated fatty acids in the diet (Australian Bureau of Statistics, 1995).

There is moderate evidence that dietary cholesterol increases total cholesterol and low-density lipoprotein cholesterol but substantially less so than saturated and *trans* fatty acids (NHF of Australia, 1999). Australian public health policy recommends a reduction in saturated fat intake, which will bring about smaller cholesterol intakes, as these two lipid classes usually occur in the same foods (NHMRC, 2003).

11.2.2 New Zealand

The New Zealand Nutrition Taskforce (Nutrition Taskforce, 1991) does not have a separate recommendation for cholesterol, given its lesser role as a determinant of low-density lipoprotein cholesterol, and there is no mention of cholesterol in the Food and Nutrition Guidelines for Healthy Adults (Ministry of Health, 2003).

11.3 Consumer Research

FSANZ's consumer research (FSANZ 2003a) found that only consumers with a special interest in blood cholesterol or heart disease, or those in the upper age groups paid any attention to cholesterol claims. People with high blood cholesterol or heart disease tended to be highly knowledgeable about reading labels and using the nutrition information panel to evaluate products. Few based their product choice solely on cholesterol claims; instead most used fat claims and the saturated fat information in the nutrition information panel. There were various opinions about cholesterol claims: those with diagnosed cholesterol and heart disease conditions were not concerned with a prohibition, whereas regular or infrequent dietary cholesterol 'watchers' were more concerned because they tended to rely more heavily on cholesterol claims as they did not understand the importance of saturated fat. A smaller group objected to a prohibition because of the 'big brother' approach, which they saw as always changing. 'Cholesterol free' was the only cholesterol claim that was deemed 'reliable'.

11.4 Preferred Approach At Initial Assessment

A prohibition on all cholesterol claims was recommended at Initial Assessment on the basis that the Dietary Guidelines for Australian Adults (NHMRC, 2003) and the New Zealand Nutrition Taskforce (1991) place a greater emphasis on reducing the intake of saturated fats, rather than dietary cholesterol, as a strategy to reduce coronary heart disease. There was also the belief that consumer knowledge about the relationship between blood cholesterol and dietary cholesterol is poor. The Initial Assessment Report acknowledged that efforts to harmonise with international practice was not a priority in this instance; rather the priority was consideration of current scientific evidence about the links between dietary cholesterol and health. It also stated that there is little harmony in existing criteria for cholesterol claims between countries that currently provide for cholesterol claims.

11.5 'Low In Cholesterol' Claims

11.5.1 Relevant International Approaches

CoPoNC, Canada, Codex and the United States have all defined criteria for 'low cholesterol' claims on the basis of no more than 20 mg cholesterol per 100 g food (in the United States, such criteria only apply to meals, while they only apply to solids under Codex).

In each instance, with the exception of Codex, there are additional conditions accompanying the above criteria, but no harmony between them. *New Zealand Food Regulations 1984* was less than 20 mg cholesterol per specified serving and at least one-third less than the normal named counterpart. The United Kingdom prohibits 'low cholesterol' claims.

11.5.2 Issues Raised By Submitters

A number of submitters supported FSANZ's proposal to prohibit 'low cholesterol' claims, however in comparison, there were slightly more submitters who supported that 'low cholesterol' claims be permitted. Some of these submitters suggested alignment with CoPoNC criteria instead of prohibition of these claims.

Reasons provided by submitters for supporting prohibition of cholesterol claims in general were mainly based around current evidence which indicates that dietary cholesterol only has a limited affect on influencing blood cholesterol levels, such that claims relating to dietary cholesterol result in consumer confusion.

In support of permitting cholesterol claims in general, submitters commented on a long history of use of such claims and reliance on them by consumers.

11.6 'Reduced In Cholesterol' Claims

11.6.1 Relevant International Approaches

CoPoNC, the *New Zealand Food Regulations 1984* and Canada have provisions for 'reduced cholesterol' claims, but there is no consistency in these provisions.

11.6.2 Issues Raised By Submitters

A number of submitters supported the prohibition of 'reduced cholesterol' claims, however more submitters were opposed to this. Many of these submitters suggested using the criteria in CoPoNC and consistency with 'reduced' criteria for other nutrition content claims.

11.7 'Cholesterol Free' Claims

11.7.1 Relevant International Approaches

Canada's criteria are similar to the United States (<2 mg cholesterol per reference amount and per labelled serving), but different to those in CoPoNC, which is again different to Codex criteria.

11.7.2 Issues Raised By Submitters

Once again there were some submitters who supported FSANZ's proposal to prohibit 'cholesterol free' claims but more submitters supported the permission for 'cholesterol free' claims.

11.8 Assessment And Rationale

Claims in relation to dietary cholesterol will be permitted but a disqualifying criterion relating to the food being 'low in saturated fatty acids' has been added. Reasons for the use of this disqualifying criterion are that dietary guidelines place a greater emphasis on reducing the intake of saturated fats rather than dietary cholesterol; as well as the belief that consumer knowledge about the relationship between blood cholesterol and dietary cholesterol is poor and therefore there is potential for these claims to be misused and to mislead consumers.

This is a change from the recommendation made in the Initial Assessment Report, which was to prohibit all cholesterol claims, because specifying criteria (including disqualifying criteria), will not result in a detrimental impact on public health and thus this risk management option is aligned to risk.

The criteria of ≤20 mg per 100 g for 'low cholesterol' claims is consistent with the criteria in CoPoNC, Canada, Codex and the United States and this criteria was suggested by a number of submitters. The rationale for criterion of a 25% reduction in cholesterol content is the same as the rationale for other comparative claims (refer to Chapter 3). The rationale for FSANZ not specifying any further criteria in addition to the saturated fat criterion mentioned above, for 'cholesterol free' claims is the same for other 'free' claims (refer to Chapter 2).

Chapter 12: Carbohydrate Claims

12.1 Proposed Approach At Draft Assessment

FSANZ proposes that there will be no provisions specified for carbohydrate claims.

12.2 Policy Context

12.2.1 Australia

The Dietary Guidelines for Australian Adults do not provide specific comment on carbohydrates (NHMRC, 2003).

12.2.2 New Zealand

The 1991 New Zealand Nutrition Taskforce target for percent energy from carbohydrate is 50–55% (Nutrition Taskforce, 1991). The National Nutrition Survey demonstrated that adults consume less than this, with 45% of energy being provided by carbohydrates for males and 47% for females (Russell *et al*., 1999). The Food and Nutrition Guidelines for Healthy Adults encourage adults to achieve a desirable carbohydrate intake by increasing consumption of vegetables, fruits, legumes, and breads and cereals. Non-starch polysaccharides are encouraged in preference to sugars (Ministry of Health, 2003).

12.3 International Comparison Of Claims And Use Of Carbohydrate Claims

No country or Codex specifies carbohydrate claims except for Canada, which is currently phasing them out. The *New Zealand Food Regulations 1984* did have specific criteria for carbohydrate claims, namely 'low carbohydrate', but these regulations have been repealed.

The rationale for excluding positive carbohydrate claims in most countries and in Codex is that they would be misleading, if not ambiguous, in that they do not allow for the distinction between high levels of complex carbohydrates and high levels of sugars.

12.4 Label Monitoring

A University of Wollongong study (Williams *et al*., 2003) carried out on food labels collected from Australian supermarkets in 2001 found that 3.1% of all foods collected carried claims relating to carbohydrate. Foods with the highest frequency of carbohydrate claims were breakfast cereals (51.9%) and muesli bars (31.9%) and nearly all carbohydrate claims were on cereal products. The most common claim found in relation to carbohydrate was 'high' (61.3%), followed by 'source/contains/with/supplies/tick/giving' (19%), then 'rich in'/'rich source' (14.3%). Other carbohydrate claims were 'good source', 'excellent source', 'ideal source', 'packed with', 'replaces', 'natural', and 'made from 15 carbohydrates'.

In the FSANZ label monitoring survey carried out in 2003 (FSANZ, unpublished), 1.9% of 1262 products made carbohydrate claims. Of these carbohydrate claims, 12.5% were 'source of', 58% were 'high in'/'rich' and 17% related to complex carbohydrates. Other claims made were 'carbohydrate modified' (one product), and claims relating to the energy of carbohydrates (two products).

12.5 Consumer Research

FSANZ's (2003a) consumer research found that participants had little interest in carbohydrate claims. Awareness of carbohydrate claims was lower than protein claims, but both were associated with sports and energy drinks and powders and were thought to be relevant for such people as athletes and body builders.

12.6 Issues Raised By Submitters

At Initial Assessment FSANZ asked if there was merit in including provisions for making carbohydrate claims. Submitters were also asked to provide evidence to support any criteria for preferred 'carbohydrate claims', and to suggest, with the support of evidence, where disqualifying criteria such as maximum sugar levels or minimum fibre levels would be required for foods to carry such carbohydrate claims.

A number of submitters commented that carbohydrate claims are justified on the basis of market pressures (particularly internationally), consumer demand, and scientific developments in the area of carbohydrates, insulin resistance, metabolic syndrome and weight management. Other submitters noted that an increasing number of foods are making 'low' or 'reduced carbohydrate' claims and, without definition of these claims, there is great potential for consumers to be misled. Submitters also considered that carbohydrate claims should be regulated in line with other content claims for consistency. The submitters in support of provision of criteria for carbohydrate claims were mainly from industry but also included some submitters from the public health sector and the New Zealand government.

It was recommended that FSANZ raise a separate proposal to address the issue of carbohydrate claims and the criteria for making these claims, given the complexities around the relationships between carbohydrate, sugars, fibre and the Glycaemic Index (GI).

Other submitters did not support the inclusion of provisions for making any carbohydrate claims. These submitters were from the public health and government sectors. Several of these submitters considered that these claims are potentially confusing for consumers, as they may not distinguish between sources and types of carbohydrate and GI/GL claims. Some submitters stated that there is no justification for carbohydrate claims while others noted that there is no specific reference to carbohydrate claims in Dietary Guidelines and they are of little interest to consumers. It was also noted that in Canada, recent changes to food regulations have resulted in carbohydrate claims being prohibited.

An assessment of the regulatory management for individual carbohydrate claims is provided under each of the claim headings below.

12.7 'Low Carbohydrates'

12.7.1 Relevant International Approaches

No country or Codex specifies 'low carbohydrate' claims except for Canada, which is currently phasing them out. The *New Zealand Food Regulations 1984* did have specific criteria but these regulations have been repealed.

12.7.2 Issues Raised By Submitters

A number of submitters considered that the provision of criteria for 'low carbohydrate' claims is justified. It was noted that there are a number of 'low carbohydrate' foods on the market in New Zealand, many of which are imported, and it is important to have some form of definition to ensure a fair and level playing field. It was also pointed out that products that contain bulking agents such as polydextrose might have lower carbohydrate and sugar levels than the standard product.

There was some variation in the criteria proposed by submitters for making low carbohydrate claims. A criterion of 5 g carbohydrate or less per serve was recommended. Also recommended was a criterion of less than 10 g carbohydrate per serve, based on dietary modelling conducted by Diabetes Australia through GI Ltd for the GI Tested Program.

Whilst some submitters were opposed to low carbohydrate claims, they advised that if such claims are approved, the following criteria should apply:

- the energy value of a low carbohydrate food must be less than that of the conventional equivalent and there should be a comparison to reflect this on the label;
- if a low carbohydrate claim is made in respect of foods that are inherently low in carbohydrates, then the claim should refer to the whole class of food and not just one brand;
- foods that make a low carbohydrate claim should be prohibited from making claims in respect to the GI of the food. If the carbohydrate content is reduced sufficiently to make a low carbohydrate claim, then the nutritional relevance of GI becomes less meaningful; and
- any accompanying wording should be consistent with the claim – for example statements such as 'the food is a good source of energy' should not be permitted.

There was some opposition to low carbohydrate claims. For some of these submitters this was on the basis of their potential to mislead consumers and that it would reinforce consumer misconceptions that carbohydrates are inherently 'fattening'. It was noted that the focus should be on improving consumers' understanding of appropriate, high quality carbohydrates, as opposed to less nutritious forms. Other submitters commented that consumer interest in weight loss may encourage an excessive use of low carbohydrate claims, potentially adding to consumer confusion about healthy, balanced diets. Also, low carbohydrate diets are not in line with public health guidelines.

12.7.3 Assessment And Rationale

There is a paucity of scientific evidence to support a 'low carbohydrate' diet on a population basis. While clinical trials comparing low carbohydrate diets with low fat diets consistently show that, on average, people can lose more weight on a low carbohydrate diet in the first six months, the advantage appears to disappear over a year (Foster *et al*., 2003). There are no recommendations to consume a diet that is low in carbohydrates in dietary guidelines in either Australia or New Zealand; rather the consumption of carbohydrates is encouraged via a number of nutritious foods.

Recently, public interest in 'low carbohydrate' diets appears to have resulted in an increase in 'low carbohydrate' claims being used, though there are no data available to justify this. The Australia Consumers' Association identified 34 'low carbohydrate' products in the market place and noted that a wide range of criteria were being used, some of which were no different to reference foods (Choice, 2005). Also some of the claims were being made in food categories that are generally regarded as 'treat foods' (e.g. biscuits, chocolate, sweet syrups and ice cream). Despite this, FSANZ does not propose to set criteria for such claims because by setting 'low' criteria FSANZ may not be protecting public health as the long term effects of encouraging people to consume diets low in carbohydrates have not yet been established. This approach is consistent internationally. Where there are clear cases of misleading behaviour, fair trading issues should prevail.

12.8 'Reduced Carbohydrate'

12.8.1 Relevant International Approaches

No country or Codex has provisions for this claim. The *New Zealand Food Regulations 1984*, which has been repealed permitted the claim provided the product contained at least one-third less carbohydrate compared with its normal counterpart, there was a statement of comparison with its counterpart and less than 5% of the energy of the food was derived from carbohydrate.

12.8.2 Issues Raised By Submitters

The majority of submitters who supported provision of criteria for 'reduced carbohydrate' claims, however there was some opposition to provision for these claims.

Of those submitters that supported carbohydrate claims, it was considered that reduced carbohydrate claims should be prohibited, as these claims do not support the Dietary Guidelines for Australian adults, which encourage the consumption of carbohydrate foods.

It was further stated that such claims reinforce consumer misconceptions that carbohydrates are 'fattening'.

The majority of submitters that recommended criteria for 'reduced carbohydrate' claims suggested that these claims be permitted if the food contains at least 25% less carbohydrate than its normal counterpart. It was also advised that if such claims are permitted, the energy content of the food should be less than 50% of its normal counterpart, in addition to the 25% reduction in carbohydrate content.

12.8.3 Assessment And Rationale

FSANZ does not recommend criteria for 'reduced carbohydrate' for the reasons given for not establishing criteria for 'low carbohydrate'.

12.9 'Source Of Carbohydrate'

12.9.1 Relevant International Approaches

No country or Codex specifies a 'source of' claim except for Canada, which has provisions for 'source of complex carbohydrates'. It is currently phasing this claim out.

12.9.2 Issues Raised By Submitters

The majority of submitters supported the inclusion of criteria for 'source of carbohydrate' claims, however some submitters were opposed to this.

A suggestion was made that the product contain at least 10 g carbohydrate per serve, which is based on the amount needed to elicit a glycaemic response.

12.9.3 Assessment And Rationale

The rationale for not providing carbohydrate claims is that national nutrition guidelines encourage the consumption of certain types of carbohydrates, such as vegetables, legumes, fruits and cereals that are preferably wholegrain, rather than carbohydrate per se. FSANZ has therefore not specified a carbohydrate health claim on the pre-approved list of nutrient function statements (refer to Attachment 8). Carbohydrate claims, other than on sports foods are not regulated internationally and there is no clear evidence that they mislead consumers. Concern has, however, been expressed by public health professionals that claims such as 'source of carbohydrate' are misleading, if not ambiguous, in that they do not allow for the distinction between high levels of complex carbohydrates and high levels of sugars and consumers could easily confuse them with the issue of Glycaemic Index and Glycaemic Load. Providing criteria might only act to encourage the food industry to promote such claims.

Finally, FSANZ has proposed criteria for wholegrain claims as part of this Proposal. Foods high in wholegrains are high in complex carbohydrates but also contribute other important nutrients such as dietary fibre, vitamins and minerals. The consumption of wholegrain foods is consistent with food and nutrition guidelines. Therefore claims relating to wholegrains are considered a better approach than 'source of carbohydrate' claims.

12.10 'Good Source' Of Carbohydrates

12.10.1 Relevant International Approaches

No country or Codex specifies 'good source of' or 'high' claims that relate to carbohydrates.

12.10.2 Issues Raised By Submitters

The majority of submitters supported the provision of criteria for 'high carbohydrate' claims, however some submitters opposed these provisions.

The majority of submitters who made recommendations for criteria for 'high carbohydrate' claims recommended that the food contain greater than 65% of energy from carbohydrate. This recommendation was made on the basis that common foods that are high in carbohydrate (such as banana, white bread, white rice, pasta, boiled potato) exceed 65% of energy from carbohydrate. Alternative suggestions were a criterion of 55% of energy or more from carbohydrate; and that the food should contain 20 g carbohydrate per serve, which is based on the amount of carbohydrate in a serving of breakfast cereal, white bread/rice and foods traditionally considered by nutritionists to be high in carbohydrate.

12.10.3 Assessment And Rationale

FSANZ approach to 'good source/high carbohydrate' claims is to stay silent for the same reasons as given for 'source of carbohydrate'.

12.11 'Increased' Carbohydrates

The majority of submitters were in support of the inclusion of criteria for 'increased carbohydrate' claims: however some opposed the inclusion of these criteria. FSANZ cannot justify criteria for 'increased carbohydrate' for the same reasons as given for 'source of carbohydrate'.

12.12 Disqualifying Criteria

12.12.1 Issues Raised By Submitters

A small number of submitters indicated that they did not support the use of disqualifying criteria in relation to sugar levels, however even less submitters were in support of these. It was noted that many foods that are high in carbohydrate are also high in sugar (for example, fruit and milk), while some products such as sports drinks may be deliberately formulated with levels of sugar to promote rapid replacement of glycogen.

A reason for not supporting the inclusion of minimum fibre levels for carbohydrate claims was because not all foods that may make carbohydrate claims are a source of fibre (for example, white rice).

12.12.2 Assessment And Rationale

Because FSANZ does not intend specifying any carbohydrate claim, there is no need for disqualifying criteria.

Chapter 13: Sugar Claims

13.1 Proposed Approach At Draft Assessment

FSANZ proposes the following claims and criteria for sugar.

Claim	Preferred criteria (and conditions)
Low (in) sugar(s)	≤5 g total sugars per 100 g or; ≤2.5 g total sugars per 100 mL of liquid food.
Reduced (in) sugar(s)	The food contains at least 25% less sugars as the same quantity of reference food. The identity of the reference food and the difference between the sugar content in the reference food and in the claimed food must be indicated. The claim must be presented so that all elements of the claim are in place.
No added sugar/sugars	The claims cannot be made unless: (i) the food contains no added sugars, honey, malt, malt extracts; and (ii) the food contains no added concentrated fruit juice or deionised fruit juice, unless the food is standardised under Standard 2.6.1 – Fruit Juice and Vegetable Juice or 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks; and (iii) if the food naturally contains sugars, the claim states that the food contains naturally occurring sugars; and (iv) the claim is present so that all the elements of the claim are in the one place.
Unsweetened	(i) the food complies with the conditions for a nutrition content claim in relation to no added sugar; (ii) the food contains no intense sweeteners, sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol.
Sugar free	No provisions.
% sugar free	The food must meet the requirements specified for the 'low sugar' claim.

13.2 Policy Context

The Dietary Guidelines for Australians (NHMRC, 2003) include advice to 'consume only moderate amounts of sugars and foods containing added sugars'. This is consistent with the New Zealand Food and Nutrition Guideline that advises people to prepare foods or choose pre-prepared foods, drinks and snacks with little added sugar and to limit intake of high-sugar foods (Ministry of Health, 2003).

The Dietary Guidelines for Australian Adults (NHMRC, 2003) conclude that the evidence for sugar's role in the aetiology of dental caries is strong. The Food and Nutrition Guidelines for Healthy Adults (Ministry of Health, 2003) state that because the impact of sugars on dental caries is dependent on many factors, health promotion initiatives should also emphasise fluoridation, adequate oral hygiene and reduced frequency of sucrose intake.

The Dietary Guidelines for Australian Adults state there is no evidence that, for most Australians, consumption of up to 15–20% of energy as sugars is incompatible with a healthy diet. Consumption of greater amounts than this could lead to a decrease in the overall nutrient density of the diet.

13.3 Preferred Approach At Initial Assessment

At Initial Assessment, FSANZ proposed the following claims and criteria for sugar.

- Low (in) sugar(s): ≤5 g total sugars per 100 g of food; ≤2.5 g total sugars per 100 mL of liquid food. The nutrition information panel must include a declaration of the presence or absence of dietary fibre in accordance with sub-clauses (5) and (7) of clause 5 of Standard 1.2.8 of the Code.
- Reduced (in) sugar(s): the comparison should be based on a relative difference of at least 25% in the sugar content. The identity of the reference food and the percent, fraction or amount of difference in fat content should be indicated adjacent to the comparative claim. The nutrition information panel must include a declaration of the presence or absence of dietary fibre in accordance with sub-clauses (5) and (7) of clause 5 of Standard 1.2.8 of the Code.
- No added sugar/sugars: the claims cannot be made unless the food contains no added:

  i. hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or
  ii. starch hydrolysate; or
  iii. glucose syrups, maltodextrin and similar products; or
  iv. products derived at a sugar refinery, including brown sugar and molasses; or
  v. icing sugar; or
  vi. invert sugar; or
  vii. fruit sugar syrup; or
  viii. malt or malt extracts; or
  ix. honey; or
  x. concentrated and/or deionised fruit juice where it does not constitute the essential character of the food; and
  xi. a reference to the declaration of sugars in the nutrition information panel must be made in conjunction with the claim to alert consumers to the sugar content of the food.

- Unsweetened: the claims cannot be made unless the food contains no added:

  i. hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or
  ii. starch hydrolysate; or
  iii. glucose syrups, maltodextrin and similar products; or
  iv. products derived at a sugar refinery, including brown sugar and molasses; or
  v. icing sugar; or
  vi. invert sugar; or
  vii. fruit sugar syrup;
  viii. malt or malt extracts; or
  ix. honey; or
  x. concentrated and/or deionised fruit juice where it does not constitute the essential character of the food; and no
  xi. intense sweeteners; or
  xii. sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol; and
  xiii. a reference to the declaration of sugars in the nutrition information panel must be made in conjunction with the claim to alert consumers to the sugar content of the food.

- Sugar free: no provisions.

Submitters to the Initial Assessment Report were asked whether these sugar claims be permitted and whether they agreed with FSANZ's preferred criteria. In addition they were asked if there be an additional criterion that relates to energy for 'reduced sugar' claims and if so, what criteria should apply and what evidence supports such an approach.

13.4 Issues Raised By Submitters

The majority of submitters supported permission for sugar claims in general, however there were some public health submitters who were opposed to permission of any type of sugar claim.

The rationale for supporting use of such claims included that they are already well established and may help to reduce sugar consumption in keeping with dietary guidelines; which may be beneficial for people with obesity, diabetes or dental health problems.

The reasons provided by the public health submitters for opposing sugar claims in general were that they have the potential to mislead consumers and that sugars would be replaced by highly refined starches that have a high GI and no nutritional value other then energy, and it is therefore illogical to single out the sugar content of a food as a rationale for food purchasing decisions.

13.5 Assessment

Claims in relation to sugar content are justified on the basis of national dietary guidelines, which include recommendations to consume only moderate amounts of sugar and to limit high sugar foods.

13.6 'Low In Sugar(s)'

13.6.1 Relevant International Approaches

For solid foods, both CoPoNC and the United Kingdom require that a food must not contain more than 5 g total sugars per 100 g of the food in order to make a 'low in sugar(s)' claim. CoPoNC criteria are more stringent than United Kingdom criteria for liquid foods where the serve size of the liquid is expected to be 200 mL or more, in that CoPoNC sets the amount at no more than 2.5 g total sugars per 100 g liquid food and the United Kingdom criterion for liquids is twice that amount. In CoPoNC, for serving sizes less than 200 ml, the criteria are the same as criteria for the solid food. The United States and Codex do not define a criterion here. Criteria are set in the repealed *New Zealand Food Regulations 1984* and in Canada on a different basis as a maximum percentage of energy coming from sugars and maximum percentage sugars on a dry basis, respectively are defined.

13.6.2 Issues Raised At Initial Assessment

Of the submitters who responded to the question relating to criteria, the majority agreed with the criteria that were proposed at Initial Assessment for 'low (in) sugar' claims.

However, some submitters recommended that the criteria should be increased to 5 g per 100 mL for liquid foods. This was suggested to allow for the natural sugars that are present in whole foods such as milk, and for liquid foods where the serving size is less than 100 mL.

The explanation given for the latter suggestion was that inconsistencies between the units of measure used in Australia compared to in New Zealand may result in differing claims (sauces are traditionally in mL in Australia and in grams in New Zealand) and if declared in grams they would more readily meet the 'low in sugar' criteria.

13.6.3 Assessment And Rationale

It is proposed that the existing CoPoNC criteria of ≤5 g for solids and ≤2.5 g for liquid foods (for serving sizes greater than 200 mL) for 'low sugar' claims be retained. This is consistent internationally and was supported by most submitters. The unit of measure for sugar claims will continue to be based on 'per 100 g/mL' on the basis of the rationale that is provided in Attachment 5, Chapter 2.

It is also proposed that there are not separate criteria for liquid foods with a serving size of less than 200 ml. There are no public health reasons to require alternative criteria for different serving sizes and this approach is also consistent with the European Union and United Kingdom who do not specify different criteria for different serving sizes.

13.7 'Reduced Sugar'

13.7.1 Relevant International Approaches

The minimum percentage reduction required to make 'reduced in sugar(s)' claims in CoPoNC, Canada and the United States is 25%. For comparative claims, Codex states 'the comparison should be based on a relative difference of at least 25% in the energy value or nutrient content'. The now repealed *New Zealand Food Regulations 1984* was the only regulation of those considered that set criteria for 'reduced' claims at one-third less than the normal counterpart.

13.7.2 Issues Raised By Submitters

Of the submitters that responded to the question relating to criteria, the majority agreed with the criteria that were proposed at Initial Assessment for 'reduced (in) sugar' claims. However a few submitters did not agree with these criteria. Instead they recommended that there was no need to declare the sugar content in conjunction with the claim, and that there is a relative difference of 30% rather than 25%.

Comments from submitters regarding the use of a criterion relating to energy for 'reduced sugar' claims are included in Chapter 3, Section 3.7.

13.7.3 Assessment And Rationale

The rationale for criteria of a 25% reduction in sugar content is the same as the rationale for other comparative claims (see Chapter 3).

13.8 'No Added Sugar(s)'

CoPoNC refers to the regulations in the Australian *Food Standards Code* where there is a general prohibition on the claim unless the food contains no added sugar or related products (as defined in Standard K1) no added honey (as defined in Standard K2) and no added malt, malt extract or maltose. The repealed *New Zealand Food Regulations 1984* permitted such claims if the food did not contain added carbohydrate sweetener or added sugar alcohol (>1%) as an ingredient in the food.

In the United Kingdom, the United States and Canada the intent of provisions for this claim seem similar to those in New Zealand and Australia (that is, that no sugars or ingredient containing added sugars – or for the United Kingdom 'composed mainly of sugars' – can be added in processing). For the United States and Canada this includes a prohibition on use of enzymes except where the functional effect is not to increase the sugar content of the food. While enzymes do not add 'sugars', when moistened they convert starches (e.g. in barley or wheat) into sugars. The European Union proposal defines the claim in terms of no added monosaccharides or disaccharides or any other food used for sweetening purposes. Codex does not provide criteria for this claim.

The *Australia New Zealand Food Standards Code* provides definitions of sugars (as foods) and related products and honey (Part 2.8). However, it does not make any provisions in regard to claims about sugar. Standard 1.2.8 currently defines sugars as monosaccharides and disaccharides (i.e. nutrients).

At Proposal P234 Draft Assessment, FSANZ proposed that a reference to the declaration of sugars in the nutrition information panel must be made in conjunction with the claim to alert consumers to the sugar content of the food. This approach is consistent with the United States, although the required disclosure statement in the United States is different in that it must indicate that the food is not low or reduced in calories (unless it meets the requirements for a low or reduced calorie food) and must direct consumers' attention to the nutrition information panel for further information on sugars and calorie content. Canada proposed a 'not sugar-free' disclosure statement but later rejected it in light of stakeholders questioning its usefulness and the potential problem for foods sweetened with sugar-alcohols. In such cases they would not contain any sugars yet would have had to carry the disclaimer 'not sugar-free'.

13.8.1 Consumer Research

FSANZ's qualitative consumer research (2003a) found that 'no added sugar' was unequivocally understood to mean the product had only 'natural sugar'. Participants were far less sceptical of 'no added' claims compared to most other claims, so use of the nutrition information panel for verification was considered less necessary. 'No added sugar' claims were believed to be potentially misleading when a product contained a high amount of intrinsic sugar. Reactions to use of three disclosure statements were mixed. 'Inquirers' and those with special health needs felt that disclosure statements that made reference to the nutrition information panel or to the presence of 'natural sugar' were unnecessary. Other consumers responded positively to the 'contains natural sugar' disclosure statement because it removed the ambiguity by clarifying whether the product was free of sugar.

Previous to FSANZ's study on content claims, a food labelling quantitative study (FSANZ, 2003b) found that less than two-fifths of 934 respondents (38%) knew that a 'no added sugar' claims meant the food could be a low, medium or high sugar food.

FSANZ tested the use of a disclosure statement, 'See nutrition information for fat content' on the front of a box of muesli bars that also contained a 'source of dietary fibre' content claim (FSANZ, in press). There was a non significant increase in respondents' understanding of the amount of fat in the product when the disclosure statement was present compared to a control, but about a half of all respondents were incorrect in their judgement. Also some consumers seemed to misconstrue the intent of the statement as about a third of respondents thought that 'the manufacturer is trying to highlight the fat favourably.

13.8.2 Issues Raised At Initial Assessment

Although a number of submitters clearly agreed with all of the criteria for 'no added sugar' claims, there were however, a number of recommendations made in respect to some of the individual criteria for each of these claims, made by the majority of submitters who did not agree with one or more of the proposed criteria. The main recommendations made were that:

- if a product is high in natural sugar but has a 'no added sugar' claim, a disclosure statement is required; or alternatively the product is prohibited from making a 'no added sugar claim';
- the double negative at the start of the criteria ('The claims cannot be made unless the food contains no added:') could be simplified to 'The claims cannot be made if the food contains added:';
- the definition or composition of sugar should be consistent with Standard 2.8.1, in which malt is not included as a sugar (malt contains iron and B vitamins in addition to sugar);
- criterion x needs to be clarified as to whether 'concentrated and/or deionised fruit juice….' is meant or 'concentrated deionised fruit juice and/or deionised fruit juice' (with the latter preferred);
- criterion x needs to be clarified with regard to the words 'essential character of the food part'
- criterion x should be omitted from the 'no added sugar' claim criteria because it is not consistent with the definition of sugars in Standard 2.8.1; or be replaced with 'deionised juice';
- there is clarification as to whether there is any difference between fruit sugar syrup and deionised fruit juice (and is a fruit sugar syrup different to a fruit syrup); and
- the regulatory intent for criteria and conditions for sugar claims are matched with the practical application of food manufacturing.

In addition, some submitters (mainly from industry) recommended that the criteria requiring reference to the sugars in the nutrition information panel is deleted. Reasons for this included that it is not consistent with other nutrition content claim criteria, consumers are now well aware of these panels, research shows that consumers are well aware that naturally occurring sugars could be present in foods making these claims, and this declaration is difficult to fit on small labels such as infant food.

13.8.3 Assessment And Rationale

It is recommended that criteria i to ix, as proposed in the Initial Assessment Report be retained and that criteria x and xi be modified. This is justified because criteria i to viii define sugars as given in Standard 2.8.1. Honey, as defined in Standard 2.8.2 is a sweetener and therefore products containing this ingredient should not be able to make a 'no added sugar' claim. Malt is sold in syrup and powdered forms and contains a lot of sugars, while deionised fruit juice is an alternative way of obtaining non-cane sweeteners as deionising takes out most of the colours and dissolved gums in fruit juices, leaving mainly sugar syrup. Concentrating the clarified juice gives fruit syrup and concentrating the deionised juice gives fruit sugar syrup, both of which contain a lot of sugar.

While malt and malt extract, concentrated fruit juice and/or deionised fruit juice are not sugars, they are nonetheless used for sweetening purposes. Because FSANZ's consumer research shows that consumers consider 'no added sugar' claims to unequivocally mean that a product has only 'natural' sugars, 'with nothing added', other than artificial sweeteners, ingredients that are used for sweetening purposes should not be included where the 'no added sugar' claim is made. This intent is similar to the intent in other countries. For instance, the European Union has proposed that a product must not contain any added mono-or disaccharides or any other food used for its sweetening properties. It is therefore important that a criterion for 'no added sugar(s)' is that the food must not contain any concentrated fruit juice and/or deionised fruit juice where it does not constitute the essential character of the food.

FSANZ proposes to modify the words 'essential character of the food' in criterion x to reflect that the claim is not permitted if concentrated fruit juice and/or deionised fruit juice is added, unless the food is standardised under Standard 2.6.1 or 2.6.2. Criterion x therefore prevents manufacturers from adding fruit juices to foods that are not usually associated with fruit juices in order to make the 'no added sugar(s)' claim.

FSANZ considers that there is a need for a disclosure statement (criterion xi), given that the consumer research outlined above indicates that shoppers do not often use the nutrition information panel for 'no added sugar' claims and that there is potential for shoppers to be misled. As FSANZ's study on nutrition, health and related claims showed that a disclosure statement 'See nutrition information for fat content' did not significantly improve respondents' understanding of the amount of fat in the product and some consumers appeared to misunderstand the intent of the statement, it is recommended that the disclosure statement for a 'no added sugar' claim should instead alert consumers to the presence of naturally occurring sugars as proposed in the European Union. Such a statement makes it clear that the product is not free of sugars.

13.9 'Unsweetened'

As per the conditions for making 'no added sugar' claims, CoPoNC refers to regulations in the Australian Food Standards Code. Accordingly, CoPoNC allows this claim where the product meets the criteria for 'no added sugar' claims and, in addition, it contains no added artificial sweetening substance, no added sorbitol, mannitol, glycerol, xylitol, hydrogenated glucose syrup or isomalt. The repealed *New Zealand Food Regulations 1984* extended the criteria for 'no added sugar' claims in this instance to include the condition that the food also contains no artificial sweetener as an ingredient.

In the United States and United Kingdom 'unsweetened' is permitted where it is a factual statement, though the United Kingdom has additional provisions for condensed milk

13.9.1 Issues Raised At Initial Assessment

Some submitters clearly agreed with all of the criteria for 'unsweetened' claims, however others did not agree with one or more of the proposed criteria for 'unsweetened' claims. Their concerns related to aspects of the 'no added' sugar' criteria (see above).

13.9.2 Assessment And Rationale

It is recommended that 'unsweetened' claims comply with the criteria for a 'no added sugar(s)' claim and that the food should contain no intense sweeteners, sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol. This approach provides differentiation from the 'no added sugar(s)' claim and has consistency with the approach in CoPoNC.

13.10 'Sugar Free'

13.10.1 Issues Raised By Submitters

The number of submitters that agreed that there be no provisions for 'sugar free' claims in the Food Standards Code was similar to the number that did not agree with this proposition. Most of the submitters who thought that criteria should be specified recommended that the criteria currently in CoPoNC for 'sugar free' claims should be used, for the reasons of:

- harmonisation internationally and with Codex;
- certainty for industry, consumers and government;
- costs associated with label changes; and
- to accommodate trace levels of sugars caused by by-products in unintended carryover, these levels being physiologically, clinically and nutritionally insignificant and therefore cannot be considered false or misleading.

Other suggestions for this claim and criteria were to use the criteria in Codex for 'sugar free' claims, to not have criteria but have a notation as to conformity with fair trading legislation, or to use the CoPoNC criteria but state the claim 'very low sugar' rather than 'sugar free'.

13.10.2 Assessment And Rationale

The rationale for FSANZ not specifying criteria for 'sugar free' claims is the same for other 'free' claims (refer to Chapter 2).

13.11 'X Per cent (%) Sugar Free'

Although CoPoNC does not permit 'x % free' claims on foods other than fat, FSANZ proposes to extend this permission to sugar claims in order to facilitate the re-labelling of products that are currently carrying 'sugar free' but contain small amounts of sugar (see Chapter 2). The criteria for 'x% sugar free' will be the same as for 'low sugar'.

Chapter 14: Dietary Fibre Claims

14.1 Proposed Approach At Draft Assessment

At Draft Assessment FSANZ proposes the following claims and criteria for dietary fibre:

Claim	Preferred criteria (and conditions)
Source of fibre	The food must contain not less than 2.0 g dietary fibre per serving of food. For meals/main dish products, the food must contain not less than 5.5 g dietary fibre per serving of food.
Good source of fibre	The food must contain not less than 4.0 g dietary fibre per serving of food. For meals/main dish products, the food must contain not less than 11.0 g dietary fibre per serving of food.
Increased fibre	The food must meet the 'source' criteria*, prior to enrichment with dietary fibre and there must be a minimum increase of 25% in dietary fibre compared to a reference food. The identity of the reference food and difference between the content of dietary fibre in the reference food and in the claimed food must be indicated. The claim must be presented so that all elements of the claim are in one place. *For meals/main dish products, the food must meet the 'source' criteria for meals/main dish products.

14.2 Policy Context

The Dietary Guidelines for Australians (NHMRC, 2003) recommends consumers 'eat plenty of cereals (including breads, rice, pasta and noodles), preferably wholegrain'. This guideline, whilst different to the 1992 Dietary Guidelines (NHMRC, 1992) retains the emphasis on wholegrain due to the growing body of evidence of the health benefits of wholegrain compared to refined cereal products. The New Zealand Food and Nutrition Guidelines for Healthy Adults (Ministry of Health, 2003) recommend a similar approach.

FSANZ is presently reviewing a claim in relation to wholegrain and bran intake and coronary heart disease.

The Dietary Guidelines for Australian Adults (NHMRC, 2003) recommend a high fibre, low fat diet for maintenance of body weight and prevention of obesity.
According to the Dietary Guidelines for Australian Adults (NHMRC, 2003) cereal fibre has been found to improve bowel function by increasing faecal bulk and reducing transit time, resulting in softer, larger stools and more frequent bowel action. The New Zealand Food and Nutrition Guidelines for Healthy Pregnant Women (Public Health Commission, 1995) also note the merit of increasing fibre intakes during pregnancy to avoid constipation that commonly occurs at this time due to specific hormonal changes.

Constipation, diverticular disease and diabetes are common problems in older people. Fibre-rich foods are therefore recommended, though the New Zealand Ministry of Health discourages people from relying on wheat bran as a major source of dietary fibre due to adverse effects on mineral absorption (Ministry of Health, 1996). Awareness of the need to increase fibre intake is high amongst older New Zealanders (Ministry of Health, 1996).

Data from the Australian National Nutrition Survey (Australian Bureau of Statistics, 1995) show that, amongst adults with the highest intakes (those aged 19–24 years of age) on the day of the survey, only 34% of men and 21% of women met recommended intake targets for the cereal group of seven serves per day. According to the Commonwealth Scientific and Industrial Research Organisation, Australians are not eating enough of the healthy protective substances found in wholegrains and other plant foods. The average person consumes about 75% of the relevant dietary fibres considered necessary to protect them properly (CSIRO, 2000).

The New Zealand 1997 National Nutrition Survey (Russel *et al*., 1999) found that the usual mean intake for dietary fibre was 20 g per day, which is lower than the Nutrition Taskforce target of 25–30 g per day (1991). Of this, 10 g of soluble non-starch polysaccharides were consumed, compared to the Taskforce target of approximately a quarter of total dietary fibre (Nutrition Taskforce, 1991).

14.3 Relevant International Approaches

There is little consistency in the criteria for fibre claims across the countries considered in this review. There is also inconsistency in definitions for fibre, which therefore affects the comparability of criteria. In many cases, the criteria and claims do not align. For example, in the United Kingdom a 'high fibre' claim can be made on a food with at least 6 g fibre per 100 g but under CoPoNC main dishes or meal type products are able to be labelled as an 'excellent or very high source of fibre'.

CoPoNC has, and the now repealed *New Zealand Food Regulations 1984* had criteria expressed as dietary fibre (grams) per serving of food; the United Kingdom Food Standards Agency guidelines express it as dietary fibre (grams) per 100 g or per 100 ml or in terms of the reasonable expected daily intake of food; and Codex draft guidelines are per 100 g or per 100 kcal or per serving. The European Union proposal is per 100 g or per kcal. Canada's criterion is per reference amount (which is consistent with the United States) and per labelled serving. For pre-packaged meals and main dish entrees in Canada, at least one ingredient must meet the criteria for the particular fibre claim that is being made.

14.4 Preferred Approach At Initial Assessment

FSANZ did not propose any claims or criteria for fibre at Initial Assessment.

Submitters were asked on what basis criteria for fibre claims should be set, what qualifying criteria should apply to fibre claims, and whether a 'very high fibre' claim is necessary, given that there are no claims for 'very high' for any other nutrient. They were also asked if there should be specific provisions for main dishes and meal type products and if so, what criteria should apply. Lastly submitters were asked whether there was merit in including disqualifying criteria for fibre claims and if so, what nutrients should be considered and what specific criteria should be applied.

14.5 Issues Raised By Submitters

Although not specifically stating the basis on which the criteria for fibre claims should be set, the majority of submitters just stated that they supported the current criteria in CoPoNC (which are based on grams per serving except for meal type products which are based on grams per 100 g), or they mentioned actual criteria that were based on grams per serving.

Those who supported the criteria for fibre claims being based on fibre content per 100 g rather than fibre content per serve were from the government and public health sectors. The main reason for this approach was that it would help overcome problems associated with manufacturers artificially altering the 'normal' serving size to achieve a 'perceived' higher fibre content than is actually present. An alternative option of criteria for fibre content per specific serving sizes was also suggested. Another suggestion was that fibre content should be given for a reasonable serve and also per 100 g, together with a statement in proximity stating the desirable intake of dietary fibre.

14.6 Assessment And Rationale

It is proposed that the unit of measure for dietary fibre claims should be per serve as it recognises the amount of food that an average person actually consumes. This approach provides consistency with other risk reducing nutrients such as vitamins and minerals and protein and with the general level health claim disqualifying criteria.

While manufacturers could potentially select a serving size that is advantageous to making a dietary fibre claim, FSANZ has no evidence to suggest that this is occurring. The serving size and the number of servings in a food are specified on the nutrition information panel, so the information is available to the consumer. Also, while manufacturers can increase their serving sizes to meet the criteria for a dietary fibre content claim, they will be disadvantaged in terms of making a general level health claim because there is less chance that the general level health claim disqualifying criteria will be met.

FSANZ is concerned by the potential for manufacturers to benefit from increasing the serving sizes of their products and will therefore monitor the market place. Should the outcome show that it is necessary, work will be initiated to standardise serving sizes as discussed in Attachment 5, Chapter 3.

14.7 Meal Type Products

14.7.1 Issues Raised By Submitters

A number of submitters (mainly from public health, industry and Australian government sectors) indicated that they supported the use of specific provisions for main dishes and meal type products for fibre claims, whereas slightly fewer submitters (mainly from industry and New Zealand government sectors) indicated that they did not support these provisions.

The majority of submitters that recommended specific criteria for meal type products were in support of retaining the criteria as in CoPoNC. An increase in the qualifying fibre level for main meal products was recommended but no values were suggested).

It was indicated that a clearer definition of a 'meal type product' is needed.

14.7.2 Assessment And Rationale

As noted in Section 5.5.6 (Claims in Relation to 'Meals') of the Proposal P293 Draft Assessment Report, FSANZ considers that specific provisions should be given to meal type products where the criteria are based on 'per serve'. The majority of submitters supported this for dietary fibre claims. Further work is currently under way on refining a model for main dishes and recommended criteria will be tabled at FSANZ19 for Board consideration.

As noted in Section 5.5.6 (Claims in Relation to Meals) of the Draft Assessment Report, FSANZ considers that specific provisions should be given where the criteria are based on 'per serve'. This therefore applies to claims in relation to dietary fibre. The majority of submitters to the Initial Assessment Report for Proposal P293 supported specific criteria for meal type products for dietary fibre claims.

Attachment 6: Part 2, Chapter 10 provides the rationale for the definition of meals and main dishes as well as the basis by which disqualifying criteria for General Level Health Claims are set. FSANZ considers that the same approach should be examined in relation to qualifying criteria for dietary fibre claims as discussed in Chapter 14.8.2.

14.8 'Source Of Fibre'

CoPoNC uses the criteria ≥1.5 g dietary fibre per serving of food. With main meal or meal type products it increases to ≥2 g dietary fibre per 100 g meal. Canada's criteria are ≥2 g per reference amount and per labelled serving. The United Kingdom Food Standards Agency guidance notes, the European Union proposal and Codex stipulate criteria of ≥3 g per 100 g (Codex also has ≥1.5 g per serve or per 100 kcal and the European Union also has 1.5 g per 100 kcal), while the former *New Zealand Food Regulations 1984* and United States have no criteria.

14.8.1 Issues Raised By Submitters

Although the majority of submitters supported permission for these claims, there were a few submitters who indicated that they did not support the use of this claim. It was argued that the criteria should be raised if the claim is permitted. In particular, an increase was recommended because 1.5 g of fibre only contributes 5% of the total daily fibre intake.

The majority of submitters supported 'source of fibre' claims using the criteria that are currently in CoPoNC. Reasons given for retaining these criteria are that they have been well established in the market place for many years; were arrived at after wide and extensive consultation, and no scientific basis for departure from them has been demonstrated in the Initial Assessment Report.

14.8.2 Meals and Main Dishes

The level of fibre required in a meal or main dish product in order to qualify for a 'source' claim can be calculated on the basis of the amount of the daily requirement which should be contributed by meals and main dishes. This follows the approach for determining the levels set for disqualifying criteria for General Level Health Claims (Attachment 6: Part 2, Chapter 10). The number of serves per day from each food group which should contribute to the fibre intake are derived from the Australian guide to Healthy Eating.

The number of fibre-contributing serves per meal or main dish is calculated as a proportion of the total number of daily contributing serves for that nutrient. Where a range of serves was reached, the midpoint of the range was used (for example for the range 1-2, 1.5 was used). This proportion was then applied to the daily intake recommendation for fibre – 30 g.

Table 1: Number of serves of recommended foods and fibre containing serves from meals and main dishes for men and women, aged 19-60 years.

Number of serves (daily)	Cereals	Veg	Fruit	Dairy	Meat	Extras	TOTAL
Total daily diet	5-6	6	3	0	0	0	14-15
Fibre-containing serves within a meal or main dish	1-2	2		0	0	0	3-4

Calculation:

$$\frac{3.5 \text{ serves}}{14.5 \text{ serves}} \times 30 \text{ g} = 7 \text{ g}$$

Thus, on the basis of this approach a qualifying criteria of 7 g would be derived. However CoPoNC's present criteria for a source claim for dietary fibre for meals is 2 g of dietary fibre per 100 g. Based on an average serve size for a meal type product or a main dish of 210 g (mid-way between the minimum size criteria for these types of products) the fibre level would equate to 4.4 g per serve.

14.8.3 Assessment And Rationale

Although the majority of submitters supported CoPoNC criteria, FSANZ considers the criteria too low in relation to the reference value of 30 g as stated in the Table to subclause 7(3) in Standard 1.2.8. That is, a 'source of dietary fibre' claim is only equivalent to 5% of the daily value. For vitamins and minerals, 10% of the Recommended Dietary Intake or Estimated Safe and Adequate Daily Dietary Intake is required for a content claim; similarly for protein 10% of the reference value is required for a claim in relation to 'source'.

In determining criteria for 'source of dietary fibre' claims, FSANZ considered the dietary fibre content contributed by various foods, international criteria and the fact that national intakes of dietary fibre in Australia and New Zealand are not meeting the recommended levels. FSANZ proposes that the criteria should be at least 2 g dietary fibre per serve. While this equates to only 6.67% of the daily intake, it ensures that a variety of foods will be able to make the claim, thereby providing opportunities for consumers to identify and consume foods that are sources of dietary fibre.

Foods that should qualify for a 'source' claim include legumes, most vegetables and nuts and some fruits, including some processed foods containing these ingredients such as pies, cakes and slices. Many cereals qualify, including fibre-increased white bread, pastas, many noodles and brown rice. Some medium and high sugar breakfast cereals could also make the claim.

For meals and main dish products, the calculated value of 7 g in Chapter 14.8.2 is much higher than current requirements in CoPoNC. In order to ensure that meal type products contribute to the daily intake for dietary fibre, FSANZ recommends a value mid-way between those based on the two approaches discussed in Chapter 14.8.2.

Thus the average of 7 g per serve and 4.4 g per serve is 5.7 g per serve. FSANZ proposed to round this number so that claims in relation to 'source of dietary fibre' for meals and main dish products must have at least 5.5 g dietary fibre per serve.

14.9 'Good Source Of Fibre'

14.9.1 International Criteria

A CoPoNC criterion is ≥3 g dietary fibre per serving except for main dishes or meal type products, which must have ≥4 g dietary fibre per 100 g meal. This is consistent with the draft Codex guideline (≥3 g per serve or per 100 kcal or ≥6 g per 100 g or 100 ml). Criteria for the United Kingdom Food Standards Agency guidance notes and European Union proposal are ≥6 g per 100 g. The *New Zealand Food Regulations 1984* required ≥4 g dietary fibre per serving, at least one-third more fibre compared with its normal counterparts and a statement of comparison with the normal counterpart. Canada also uses ≥4 g dietary fibre per labelled serving as well as per reference amount. The approach is slightly different in the United States in that meals and main dishes must use the 'good source' claims with criteria of 2.5–4.75 g per reference amount for and for all other foods 'high fibre' is used with criteria of ≥5g per reference amount.

14.9.2 Issues Raised By Submitters

The majority of submitters supported permission for 'good source of fibre' using the criteria that are currently in CoPoNC. A recommendation was made, however, that the criteria for a 'good source of fibre' claim needs to be greater than 4 grams of fibre per serve, at least 1/3 more than it's standard counterpart and should include a statement of comparison with the normal counterpart.

14.9.3 Assessment And Rationale

Given that CoPoNC criteria only equate to 10% of the 30 g reference value that is stated in the Table to subclause 7(3) in Standard 1.2.8, FSANZ proposes to increase the value to at least 4 g per serve. Although this only equates to 13.3% of the reference value, it is a realistic incentive for the food industry in terms of assisting in the development of foods that are significant source of dietary fibre and it should also encourage consumers to consume foods that are high in dietary fibre. Foods that should qualify for the claim include cereals, most of which are wholegrains, legumes and some vegetables. Potato crisps and chips and corn crisps also qualify.

For meal type products and main dish products, FSANZ proposes to double the criteria for 'source' claims to provide consistency with the doubling of the criteria for foods other than meal type products and main dish products. This equates to a minimal amount of 11 g per serve.

14.10 'Very High Fibre' Or 'Excellent Source Of Fibre'

14.10.1 Relevant International Approaches

CoPoNC and Canada are the only countries of those considered that have criteria for 'very high fibre' or 'excellent source of fibre'. Both stipulate ≥6 g dietary fibre per serving, although Canada also has a criterion for ≥6 g dietary fibre per reference amount.

14.10.2 Issues Raised By Submitters

Of the submitters that responded to the question relating to 'very high fibre' claims, there were some who did not think that a 'very high fibre' claim was necessary, and slightly less who supported the use of the 'very high fibre' claim.

Reasons given by submitters for supporting 'very high fibre' claims included that:

- they have existed over a long period of time and there has been no market failure or good scientific evidence for them not to be used;
- the claim is currently permitted under CoPoNC;
- such food products are rare;
- manufacturers should be encouraged to produce very high fibre foods;
- there is the potential for benefit for consumers;
- current fibre intake is low/neglected; and
- this claim is appropriate for fibre even if it is not appropriate for other nutrients .

Reasons for not supporting this claim included that:

- it seems unnecessary/irrelevant and too complex/confusing;
- it is not in line with claims for other nutrients; and
- the food is likely to have added fibre, which does not necessarily have the health properties of traditional dietary fibre.

It was also suggested that these claims should be prohibited.

14.10.3 Assessment And Rationale

Opinions from submitters were diverse on the issue of whether to retain specific provisions for 'very high fibre' and 'excellent source of fibre' claims. On consideration, FSANZ proposes to stay silent in order to maintain consistency with the approach for other content claims. It is also consistent with Codex and countries other than Canada.

14.11 'Increased Fibre', 'Fibre Enriched' and' Fibre Added'

14.11.1 Relevant International Approaches

CoPoNC criteria for these claims are the same as for claims for 'high fibre' or 'good source of fibre' except that the claims can only be applied to foods which contain, prior to enrichment with dietary fibre, at least 1.5 g of dietary fibre per serving. There must also be a statement of comparison with the reference food.

Canadian criteria are the same as for their 'source of fibre' claims (≥2 g fibre per reference amount and per labelled serving) except that there must be a minimum 25% increase in dietary fibre, totally ≥1 g fibre. The identity of the reference food and the difference in dietary fibre content must also be stated adjacent to the most prominent comparative claim. Likewise, the United Kingdom and the proposed European Union claims use their 'source of fibre' criteria (United Kingdom: ≥3 g fibre per 100 g or 100 ml or in the reasonable daily intake of a food and a 25% minimum increase in dietary fibre; European Union: ≥3 g fibre per 100 g or ≥3 g fibre per 100 kcal and a 30% minimum increase in dietary fibre).

In CoPoNC the criterion for 'fibre added' claims is that the food must meet the criteria for 'high fibre' claims and must have a statement of comparison with the reference food. The United States stipulates 2.5 g more per serving than a reference food.

14.11.2 Issues Raised By Submitters

The majority of submitters supported the criteria that are currently in CoPoNC for fibre claims. Some submitters however, almost all from the public health sector, indicated that they did not support the use of these claims, although most only implied this by specifically supporting claims other than these. The reasons given were that there are too many fibre claims and removal of these claims would reduce the number of fibre claims that could be made, thereby reducing the potential for confusion amongst consumers and/or complexity. There were no other comments specifically relating to these claims.

14.11.3 Assessment And Rationale

FSANZ proposes to retain 'increased fibre' claims and any claim likely to have the same meaning for the consumer. It provides consistency with the permission for 'increased/more fibre' claims in other countries and allows manufacturers to promote foods that are sources of dietary fibre.

The proposed criteria for 'increased fibre' claims are that the food must contain at least 2 g dietary fibre per serving of food (which is the same criterion as the 'source' claim) prior to enrichment and there must be a minimum increase of 25% in dietary fibre compared to a reference food. This is different to CoPoNC, as CoPoNC aligns the claim with the criteria for 'good source' (at least 3 g dietary fibre per serving of food) and has no criterion for a minimal increase compared to a reference food. The requirement to meet the 'source' criteria provides consistency with the European Union proposal. It ensures that a minimal amount of dietary fibre is present and that only foods that naturally contain the nutrient can make the claim. The 25% increase is consistent with other countries except for the European Union, which proposes a 30% increase in dietary fibre compared to the reference food.

14.12 Disqualifier To Prevent High Fat Foods Making Fibre Claims

Under CoPoNC, fibre claims are discouraged on foods having significant fat content. CoPoNC states that where 30% or more of the food energy is derived from fats, there must be a statement on the label drawing attention to the fat content of the food in the nutrition information panel.

In March 2004, the FSANZ Board approved the Final Assessment Report for Application A495 – Polydextrose as Dietary Fibre and in August 2004 approved the Final Assessment Report for Application A491 – Resistant Maltodextrin as Dietary Fibre. This means that content claims that relate to dietary fibre can be potentially made on foods of low nutritional value. Health claims will not, however, be permitted on such foods because of the general level health claim disqualifying criteria.

At Initial Assessment, it was also noted that the Ministerial Council agreed to a Policy Guideline for the Fortification of Foods with Vitamins and Minerals in May 2004. The policy covers both mandatory and voluntary fortification of food. Ministers agreed that vitamins and minerals can be added to food where there is, for example, demonstrated evidence of a potential health benefit, and it is clear that the fortification of a food will not result in harm. One of the specific order policy principles on voluntary fortification on vitamins and minerals is that:

a. permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand;
b. permission to fortify should not promote increased consumption of foods high in salt, sugar or fat.

FSANZ argued at Initial Assessment that these policy principles could be extended to dietary fibre or to all 'positive nutrients'.

14.12.1 Issues Raised By Submitters

There was an equal split in submitters who responded to the question regarding disqualifying criteria with some supporting the inclusion of one or more disqualifying criteria for fibre claims, as opposed to the others who did not support the use of disqualifying criteria. Reasons given for not supporting the use of disqualifying criteria were:

- there has been no demonstrated market failure (in relation to CoPoNC or the approval of polydextrose) and FSANZ is only theorising that there will be one;
- it would be inappropriate to apply policy principles to foods making fibre claims that were designed for the addition of vitamins and minerals to foods;
- the choice of disqualifying criteria would be arbitrary;
- there are currently no disqualifying criteria in the CoPoNC;
- disqualifying criteria would add complication and would be inconsistent with other decisions by FSANZ with respect to criteria;
- foods high in nutrients such as sugar, fat and energy have a role in a balanced diet and may be legitimate vehicles for fibre consumption which may benefit consumers and provide a mechanism for product differentiation; and
- they may restrict the composition of products that could be manufactured and result in more expensive products because of the use of more expensive ingredients used to replace high fat components.

Some industry submitters commented that they did not support the suggestion for disqualifying criteria for products that contribute ≥30 % energy from fat and ≥10% energy from saturated fat; or the disclaimer for products contributing ≥30 % energy from fat as is currently in CoPoNC. One reason for this is that nutrition information panels are now mandatory and consumers are well aware of their presence.

In contrast, some public health submitters recommended a disclosure statement relating to energy content for high fibre claims, to alert consumers to the energy density of the food.

The reason given by some submitters (from the government and public health sectors) for supporting the use of disqualifying criteria was the approval of polydextrose as a source of dietary fibre, which opens the potential for foods of low nutritional value to make fibre claims.

Of those that supported the use of disqualifying criteria, there was no general agreement on the actual nutrients that should be used as disqualifying criteria. A variety of combinations of energy, fat, saturated fat, *trans* fatty acids, and sodium, sugar were suggested, with the majority of agreement being with the suggestion of fat, sugar and salt/sodium.

Recommendations for disqualifying criteria were that foods making fibre claims should be consistent with dietary guidelines; that the foods that can make fibre claims should not have a poor nutritional profile; and that disqualifying criteria should be consistent with disqualifying criteria for other macronutrients.

Only a few submitters recommended specific disqualifying criteria. These were:

- saturated fat >30% of total energy and sugars >20 g per serve;
- total fat >30% of energy and ≥10% of the average energy content from saturated and trans fatty acids;
- energy/fat the same as CoPoNC, as well as adding 'high sugar' foods;
- total fat >30% of energy or >10% energy from saturated fat; and
- saturated and *trans* fat with the same criteria as for low saturated fat claims, and sugar.

Some industry submitters opposed the use of salt as a disqualifying criterion because almost all commercially available breads and cereals would fail to meet requirements. Total fat as a disqualifying criterion was also opposed, as foods such as avocados and nuts are high in fibre and fat.

14.12.2 Consumer Research

Many participants in a FSANZ qualitative study (FSANZ 2003a) regarded disqualifying criteria as largely unnecessary, particularly when the disqualifying criteria do not relate to the claimed nutrient as the majority viewed it as 'going too far'. The strong majority view in every group was that it was up to the individual consumer to decide what they will make of a content claim and how far they wish to think beyond the claim. Although it was widely agreed that content claims can be misleading, it was also felt that they are generally not untruthful, and that all the information needed to make an assessment about the overall nutritional value of the product is available on the back of the pack.

In terms of understanding the overall nutritional value of the product, FSANZ's quantitative study (FSANZ, 2003b) on food labelling suggested that consumers do not consider a product's overall nutrition value. Evaluative thinking was dominated by fat content to the point that insignificant differences in the fat content between two products overrode large differences that occurred in other nutrients. It may have been that people made assessments based on their own interpretation of what is most important or of most concern.

It is also likely that people were not able to determine the relative value of nutrients (i.e. what nutrient differences should carry more consideration in product selection).

14.12.3 Assessment And Rationale

It is recommended that no disqualifying criteria apply to dietary fibre claims. There is no evidence to suggest that a change in the definition of dietary fibre to include polydextrose and added maltodextrin has resulted in an increase in claims made in relation to dietary fibre on inappropriate foods. There is also no clear evidence that consumers are especially misled by dietary fibre claims. In not applying disqualifying criteria, consistency is provided with the approach to other nutrient content claims as well as with Codex and other countries. The requirement to declare the percentage daily intake (%DI) for energy should assist consumers in indicating the energy density of a food.

There should not be any confusion between content claims made in relation to dietary fibre and health claims that are linked to cardiovascular disease or cancer, as FSANZ is not reviewing a high level claim in relation to dietary fibre. The disqualifying criteria for general level health claims prevent manufacturers making general level health claims on inappropriate foods.

Chapter 15: Salt/Sodium Claims

15.1 Proposed Approach At Draft Assessment

FSANZ proposes the following claims and criteria for salt and sodium.

Claim	Preferred criteria (and conditions)
Low salt/sodium	≤120 mg sodium per 100 g solid food; and ≤120 mg sodium per 100 mL liquid food. The nutrition information panel must indicate the potassium content.
Very low salt/sodium	No provisions.
Reduced salt/sodium	The food must contain at least 25% less sodium as the same quantity of reference food. The identity of the reference food and the difference between the sodium content in the reference food and in the claimed food must be indicated. The claim must be presented so that all elements of the claim are in one place. The nutrition information panel must indicate the potassium content.
No added salt/sodium	The food must contain no added sodium compound and no added salt. The ingredients of the food must contain no added sodium compound and no added salt. The nutrition information panel must indicate the potassium content. If the food naturally contains sodium, the claim must state that the food contains naturally occurring sodium.
Unsalted	The food must comply with the conditions for a nutrition content claim in relation to no added salt.
Salt free	No provisions.

15.2 Policy Context

A reduction in dietary sodium intake will decrease the mean population blood pressure (refer to Attachment 10). FSANZ's review of sodium and blood pressure substantiated that the relationship is associated with reductions in sodium intake in the order of 100 mmol/day, which is equivalent to 2300 mg sodium/day or approximately 5.8 g salt (sodium chloride) per day. Increased potassium intake may also contribute to blood pressure reduction; such effects are greater when sodium intake is high, although sodium restriction alone is associated with statistically significant reductions in blood pressure.

The Dietary Guidelines for Australian Adults (NHMRC, 2003) recommend choosing foods low in salt. In New Zealand, the Food and Nutrition Guidelines for Healthy Adults (Ministry of Health, 2003) advise consumers to prepare foods or choose pre-prepared foods, drinks and snacks that are low in salt and if using salt, to choose iodised salt.

The New Zealand Nutrition Taskforce (1991) recommendations for healthy adults are to reduce dietary sodium intake to 120 mmol per day or less in order to decrease the average blood pressure levels in the general population.

Dietary sodium intake was not included in the National Nutrition Survey (Russell, *et al*., 1999) because of the difficulty in assessing discretionary salt added to food. However, a regional study in New Zealand found a mean sodium excretion of 3105 mg per day, which corresponds to a mean sodium intake of 3473 mg per day (Thomson and Colls, 1998), which is well above the Recommended Dietary Intake (920–2300 mg). In addition, the National Nutrition Survey revealed that approximately 22% of men and 18% of women had high blood pressure (those taking hypertensive medication plus those with a systolic pressure ≥160 mmHg and a diastolic pressure ≥95 mmHg).

15.3 Preferred Approach At Initial Assessment

At Initial Assessment, FSANZ proposed the following claims and criteria for salt/sodium claims.

- Low salt/sodium: ≤120 mg sodium per 100 g food.
- Very low salt/sodium: no provisions.
- Reduced salt/sodium: the comparison should be based on a relative difference of at least 25% in the sodium value. The identity of the reference food and the percent, fraction or amount of difference in sodium value should be indicated adjacent to the comparative claim.
- No added salt/sodium: the food and the ingredients of that food contain no added sodium compound, no added salt or, as the case may be, are unsalted.
- Salt free: no provisions.

Submitters to the Initial Assessment Report were asked whether these salt/sodium claims should be permitted and whether they agreed with FSANZ's preferred criteria. They were also asked if there should be additional criteria for 'no added salt/sodium' claims to address the issue of manufacturers making the claim on products that are not low in sodium. Two criteria were provided for comment regarding their usefulness:

1. The label or advertisement must include a statement adjacent to the claim drawing attention to the sodium content of the product as outlined in the nutrition information panel (for example, 'See nutrition information panel for sodium content'); or
2. The food must be 'low in salt'.

15.4 'Low (In) Salt/Sodium'

15.4.1 Relevant International Approaches

The Code, CoPoNC, *New Zealand Food Regulations 1984* (now repealed), European Union proposal and Codex all set the cut-off for making 'low salt' claims at ≤120 mg sodium per 100 g food. Standard 1.2.8 mandates inclusion of sodium as well as potassium content details in nutrition information panels where a content claim is made in respect of salt or sodium. Canada and United States criteria are based on reference amount (and per labelled serving in Canada) with specific criteria for meals and main dishes (≤140 mg or less per 100 g). United Kingdom criteria are the same as the Code and Codex criteria for 'very low salt/sodium' claims.

15.4.2 Issues Raised By Submitters

There was no opposition by submitters for the permission of 'low salt/sodium' claims. Nearly all the submitters supported the criterion that was proposed at Initial Assessment for low salt/sodium claims Instead, the use of the CoPoNC criteria or a criterion of <100 mg per 100 g meal were recommended. Also recommended was that in addition to the proposed criterion, there are disqualifying criteria for energy, fat, sugar and fibre.

15.4.3 Assessment And Rationale

The need for claims in relation to salt/sodium is based on dietary guidelines in Australia and New Zealand that recommend a reduction in dietary sodium intake. It is proposed that the existing criterion of ≤120 mg per 100 g in the Code for 'low salt' or 'low sodium' claims be retained as this is the current standard, it is consistent with Codex criteria and was supported by nearly all submitters. The addition of the criterion based on per 100 mL for liquid food will ensure consistency with other nutrition content claims. Further rationale for the unit of measure is provided in Attachment 5, Chapter 2. The requirement to indicate the potassium content in the nutrition information panel if a salt/sodium claim is made, is consistent with the current requirement in clause 17 of Standard 1.2.8.

15.5 'Very Low (In) Salt/Sodium'

15.5.1 Relevant International Approaches

CoPoNC, the European Union proposal and Codex have criteria for 'very low salt/sodium' claims (≤40 mg per 100 g). This is equivalent to the value at which the United Kingdom defines a 'low salt' claim and the value for 'low salt' meals and main dishes in the United States. United States criteria for 'very low' are ≤35 mg sodium per 100 g meal.

15.5.2 Issues Raised By Submitters

Although the majority of submitters agreed that this claim should be permitted, there was a small number who did not support permission for this claim.

Of those that did support permission for this claim and that answered the question relating to criteria, the majority of submitters agreed that there should not be any provisions. However some submitters suggested that there should be provision for making a 'very low salt/sodium' claim and it was suggested that the criteria could be as per the provision in CoPoNC (<40 mg/100 g of food).

15.5.3 Assessment And Rationale

FSANZ proposes to remove CoPoNC criteria for 'very low (in) sodium/salt' claims for the purpose of achieving consistency with other risk increasing nutrient content claims. The majority of submitters agreed with this approach.

15.6 'Reduced (In) Salt/Sodium' And 'Less Salt/Sodium'

15.6.1 Relevant International Approaches

The minimum percentage reduction required for a 'reduced' claim in CoPoNC, Canada and the United States is 25% as discussed under 'comparative claims'. CoPoNC also stipulates additional conditions (maximum of 600 mg sodium per 100 g food and at least 90 mg less sodium per 100 g compared with reference food). The repealed *New Zealand Food Regulations 1984* criterion is one-third less than the normal counterpart.

15.6.2 Issues Raised By Submitters

Permission to make this claim was supported by almost all submitters. In opposition to this claim, it was considered 'reduced salt' claims are misleading, and if they are to be permitted, an upper limit of sodium, such as 350 mg, should be specified. Some other submitters were also concerned that foods that are still high in sodium would be able to make this claim.

Of those that did support permission for this claim and that answered the question relating to criteria, the majority of submitters agreed with the criterion of a 25% relative difference in the sodium content. A small number of submitters however, did not entirely agree with the preferred criteria. These submitters made recommendations such as retaining the CoPoNC criteria (however it was also noted that the proposed criteria are preferable over CoPoNC criteria), and requiring the identity of the reference food and difference in sodium value to be in an equally noticeable font, adjacent to the comparative claim. It was also recommended that if synonyms are not permitted, the difference in sodium value should not be required to be stated.

15.6.3 Assessment And Rationale

Reduced sodium claims may encourage manufacturers to produce reduced salt products and may assist in the reduction of sodium intake at a population level. The rationale for criteria of a 25% reduction in sodium content is the same as the rationale for other comparative claims (refer to Chapter 3).

15.7 'No Added Salt/Sodium' And 'Unsalted'

CoPoNC, the United Kingdom and Canada permit 'no added salt' claims when a food (and all of its ingredients) contains no added sodium compound or no added salt during processing. In Canada, if potassium has been added to the food, the amount must be declared. The United States, the European Union proposal and Codex have no provisions for this claim.

15.7.1 Consumer Research

FSANZ's qualitative consumer research (2003a) found that 'no added sodium/salt' claims were looked for on chips, baked beans and canned vegetables. Respondents were familiar with the claim, though they did not look for it as often as 'no added sugar' claims. They were much less sceptical of the claim compared to most of the other eight content claims examined in the study and therefore used the nutrition information panel less frequently to verify it. They unequivocally understood it to mean the product had only 'natural' salt, with nothing added.

While they also understood that a 'no added' product did not imply that the product had no salt, there was an underlying feeling that the product would be 'low' in salt. Participants were uncertain as to whether the 'no added' claim referred to the food itself, such as corn in 'no added salt' canned corn, or whether it also included canning and packing agents such as brine. Reactions to disclaimers were mixed. 'Inquirers' and those with special health needs felt that disclaimers that made reference to the nutrition information panel or to the presence of 'natural salt' were unnecessary as they used the nutrition information panel as needed. Others, however, strongly felt that the disclaimer 'contains natural salt/sugar' should appear with 'no added' claims because it removed the ambiguity by clarifying whether the product was free of salt.

FSANZ tested the use of a disclosure statement, 'See nutrition information for fat content' on the front of a box of muesli bars that also contained a 'source of dietary fibre' content claim (FSANZ, 2005). There was a non significant increase in respondents' understanding of the amount of fat in the product when the disclosure statement was present compared to a control, but about a half of all respondents were incorrect in their judgement. Also some consumers seemed to misconstrue the intent of the statement as about a third of respondents thought that 'the manufacturer is trying to highlight the fat favourably'.

15.7.2 Issues Raised By Submitters

Nearly all submitters supported the use of this claim and the proposed criteria in the Initial Assessment Report. Concern was, however, expressed regarding the use of a 'no added salt/sodium' claim and that such claims might infer that there is no salt/sodium present, whereas the product may be intrinsically high in salt/sodium. Alternative recommendations for criteria were that they be set such as zero or less than 1 mg sodium per 100 g.

It was however recommended by some industry submitters that the criterion be simplified to 'the food and ingredients of that food contain no added sodium compound' for consistency with the other salt/sodium claims.

Clarification was requested on 'no added salt' claims when salt substitutes, commonly classed under the additive class name 'mineral salts', are in the ingredient list, in regards to consumer confusion.

There were a number of submitters who supported the use of additional criteria for 'no added salt/sodium' claims to address the issue of manufacturers making the claim on products that are not low in sodium, however some submitters (mainly industry) were opposed to the use of this additional criteria.

Of the supporting submitters there was almost an equal number who supported a disclosure statement as those who supported the food meeting a 'low in salt' criterion. Some submitters preferred that the additional criteria are a combination of both of these approaches.

Comments made regarding the usefulness of a disclosure statement included that this approach is consistent with 'no added sugar' claims; and this approach should help prevent consumer confusion and misunderstanding by translating the sodium issue via the 'salt' message.

However, the only comments made regarding the usefulness of a 'low in salt' criterion also referred to consumers. These comments were that this approach is more consumer-friendly and would be less likely to mislead consumers.

Some of the reasons provided by submitters for not supporting additional criteria for 'no added salt/sodium' claims were that:

- consumers find this claim useful and they do not think it implies salt free;
- these claims are useful when 'reduced' or low salt' claims cannot be made, but manufacturers wish to distinguish their product from others; an additional criterion for 'low salt/sodium' would disadvantage manufacturers and consumers;
- there is insufficient evidence to justify a 'low in salt' criterion;
- consumers know to consult the nutrition information panel if they require clarification, and it would not be necessary to draw attention to this panel.

Some submitters noted that they agreed with the current requirements in subclause 17(2) of Standard 1.2.8 in the Code to declare the potassium content of the food in the nutrition information panel when claims in respect of salt or sodium content are made.

15.7.3 Assessment And Rationale

Retention of 'no added sodium/salt' and 'unsalted' claims has consistency with national dietary guidelines, with CoPoNC, the United Kingdom and Canadian regulations and was supported by nearly all submitters to the Initial Assessment Report. FSANZ considers that the criteria proposed at Initial Assessment Report should be retained, given the strong support by submitters. This includes retention of the 'unsalted' criterion, as high salted ingredients such as pickled herrings, ham and dill pickles should not be added to products that contain a 'no added salt/sodium' claim.

FSANZ's considers that there is a need for an additional criterion to address the issue of manufacturers making the claim on products that are not low in sodium, for the same reasons as given for 'no added sugar' claims; namely that the consumer research outlined above indicates that shoppers do not use the nutrition information panel frequently for 'no added sodium/salt' claims and that there is potential for shoppers to be misled. The preferred approach is to add a disclosure statement that draws the consumer's attention to the presence of naturally occurring salt/sodium.

This provides consistency with the approach for 'no added sugar(s)' claims and provides minimum regulation compared to the setting of an upper sodium/salt limit.

15.8 'Salt Free'

15.8.1 Issues Raised By Submitters

Although the majority of submitters supported that these claims be permitted, there were some who indicated that they did not support their permission.

The majority of submitters who answered the question relating to criteria also supported that there be no provisions for 'salt free' claims, but there were a few submitters who did not agree with this. Of these, some submitters (mainly industry) stated that specific provisions should be made, such as those currently in CoPoNC. Some submitters recommended the addition of a notation as to conformity with fair trade legislation to the criteria for 'salt free' claims.

15.8.2 Assessment And Rationale

The rationale for FSANZ not specifying criteria for 'salt free' claims is the same for other 'free' claims (refer to Chapter 2).

Chapter 16: Gluten Claims

16.1 Preferred Approach At Draft Assessment

FSANZ proposes the following claims and criteria for gluten.

Claim	Preferred criteria (and conditions)
Gluten free	No detectable gluten; and no oats or their products; or no cereals containing gluten that have been malted, or their products.
Low (in) gluten	No more than 20 mg gluten per 100 g of the food.

16.2 Policy Context

Specific criteria for gluten are listed in Standard 1.2.8 in the Code. These claims are regulated on the basis that consumption of foods containing gluten may have adverse health consequences in individuals suffering from coeliac disease and dermatitis herpetiformis.

16.3 Proposal P264

Proposal P264 –Review of Gluten Claims with Specific Reference to Oats and Malt was raised to consider the requirement to retain the specific prohibition on gluten free and low gluten claims on foods containing oats and/or malt. Proposal P264 was finalised in October 2004. As a result of this Proposal, the criteria for gluten free and low gluten claims have been revised as follows:

- Gluten free – no detectable gluten; and no oats or their products; or no cereals containing gluten that have been malted, or their products.
- Low gluten – no more than 20 mg gluten per 100 g of the food.

16.4 Preferred Approach At Initial Assessment

At Initial Assessment FSANZ proposed that the criteria for 'gluten free' and 'low gluten' claims be defined after the ministerial review.

Submitters were asked whether they agreed that these gluten claims should be permitted.

16.5 Gluten Free And Low Gluten

The Current Codex Standard for Gluten-free Foods defines a gluten-free food as:

- consisting of or containing as ingredients such cereals as wheat, triticale, rye, barley or oats or their constituents which have been rendered 'gluten free'; or
- a food in which any ingredients normally present containing 'gluten' have been substituted by other ingredients not containing 'gluten'.

Codex states that for the purpose of the standard, 'gluten free' means that the total nitrogen content of the gluten-containing cereal grains used in the product do not exceed 0.05 g per 100 g of these grains on a dry matter basis.

Codex stipulates that gluten free foods substituting important basic foods like flour or bread, must supply approximately the same amount of vitamins and minerals as the original foods they replace.

The Canadian Food and Drug Regulations prohibit the labelling, packaging, sale or advertising of a food as gluten free unless the food does not contain wheat, including spelt and kamut, or oats, barley, rye or triticale or any part thereof.

16.5.1 Issues Raised By Submitters

Almost all the submitters agreed that gluten claims in general should be permitted, mainly for the reason that they provide essential information regarding appropriate food choices for individuals with coeliac disease. It was also noted by some submitters that gluten claims have been in the marketplace for many years and removal of these claims would disadvantage both consumers and manufacturers.

It was considered that it was not appropriate to include claims regarding allergens in a standard for nutrition, health and related claims. A preference for claims relating to gluten and lactose to be included in a Standard dealing with advisory statements as they are only of interest to individuals with food intolerances or allergies was also expressed.

Some submitters noted that they would await the outcome of the Ministerial Review of Proposal P264 before commenting on the preferred criteria for gluten claims.

It was noted that there is a significant body of evidence that people with coeliac disease are able to tolerate gluten in very small amounts, as in the 'low gluten' standard.

Consistency with international standards was also recommended and it was noted that FSANZ has undertaken to review gluten free claims following finalisation of the Codex Standard.

The Australian Consumer and Competition Commission re-iterated that the criterion of 'no detectable …' satisfies their position with regard to 'free' claims.

A number of submitters commented on the issue of 'free' claims generally, including 'gluten free', noting that:

- 'tree' claims should be permitted when the amount present is physiologically, clinically and nutritionally no different to food containing 'zero' amounts of the substance in question;

- the criteria need to align with levels that are physiologically relevant. 'Not detectable' is not a realistic measure as many techniques are too sensitive and unnecessarily restrict consumer choice by eliminating suitable foods;

- as methods of detection become more sensitive, some products may be disqualified from the marketplace that were previously able to be labelled as 'free' and were acceptable to the relevant population group. Apart from the impact on consumers, there is also an impact on manufacturers who may be required to change their labels to remove claims that are no longer compliant;

- industry and enforcement agencies need clarity and certainty with regard to a threshold that is appropriate from a health and safety perspective for consumers, rather than operating in an environment where the ground rules are being changed due to advances in testing analysis; and

- analytical methods for 'gluten free' claims should be defined in the Standard.

16.5.2 Assessment And Rationale

FSANZ considers that gluten claims should continue to be regulated in the Code as they provide essential information to consumers, specifically those with coeliac disease and dermatitis herpetiformis, regarding appropriate food choices. Submitter comments support this view. It is also proposed that content claims made in relation to gluten should be included with the standard for nutrition, health and related claims, as manufacturers need to be aware that they must comply with the conditions for general level claims. Also, for consistency, gluten content claims should be kept in the same standard that governs health claims that can be made in relation to gluten.

As a result of the Ministerial Council review of Proposal P264, there were no changes to the existing criteria of 'no detectable gluten' and 'no more than 20 mg gluten per 100 g of the food', for 'gluten free' and 'low gluten' claims respectively, as these criteria were not specifically under consideration as part of the review. The only changes made were in relation to oats and malt in the criteria for 'gluten free' and 'low gluten' claims.

FSANZ acknowledges the potential difficulties associated with the 'no detectable' criteria for 'gluten free' claims, as identified by some submitters. However, specifying a threshold level of gluten to be permitted in gluten free foods is contrary to the Australian Competition and Consumer Commission's position that 'free' means 'nil', and therefore to specify a level is potentially misleading. Furthermore, the Australian Competition and Consumer Commission has reiterated that the criterion 'no detectable gluten' supports their position.

Therefore, FSANZ considers that the criteria for gluten free and low gluten claims, as amended from Proposal P264, should be retained.

FSANZ does not propose to specify analytical methods for the determination of 'gluten free' foods for the reasons discussed in Attachment 5, Chapter 2, Section 2.8.

Chapter 17: Lactose Claims

17.1 Preferred Approach At Draft Assessment

Claim	Preferred criteria (and conditions)
Lactose free	No detectable lactose. The nutrition information panel indicates the lactose and galactose content.
Low lactose	FSANZ proposes to increase the criteria for 'low lactose' such that foods must contain no more than 2.0 g lactose per 100 g of the food. The nutrition information panel indicates the lactose and galactose content.
Reduced lactose	FSANZ considers that claims to the effect that a food is 'lactose reduced' should not be made

17.2 Introduction

Lactose claims are regulated on the basis that consumption of foods containing lactose may have adverse health consequences in certain individuals, particularly those suffering from lactose intolerance.

17.3 Relevant International Approaches

Specific criteria for lactose claims are listed in the Code. In the United Kingdom, the Food Standards Agency recommends that in order to make a 'reduced lactose' claim, the product should contain at least 25% less lactose than normal milk. Some products can contain as much as 95% less.

17.4 Preferred Approach At Initial Assessment

At Initial Assessment, FSANZ proposed the following claims and criteria for lactose:

- Lactose free[#]: no detectable lactose.
- Low lactose[#]: ≤0.3g of lactose per 100 g of the food.
- Lactose reduced[#]: The comparison should be based on a relative difference of at least 25% of the nutrient content. The identity of the reference food and the percent, fraction or amount of difference in energy value or nutrient content should be indicated adjacent to the comparative claim.

  [#] Where a claim is made in relation to the lactose content of a food, particulars of the lactose and galactose content of the food must be provided in the nutrition information panel.

Submitters were asked whether they agreed that these lactose claims should be permitted and whether they agreed with FSANZ's preferred criteria.

17.5 Issues Raised By Submitters

Of the submitters that answered the questions relating to lactose claims almost all supported permission for lactose claims in general, the main reason being that they provide essential information for individuals with lactose intolerance regarding appropriate food choices. It was also noted that lactose claims have been in the marketplace for many years and removal of these claims would disadvantage both consumers and manufacturers.

Whilst agreeing that lactose claims should be permitted within the Code, some submitters expressed a preference for these claims to be included in a Standard dealing with advisory statements as they are only of interest to individuals with food intolerances or allergies.

In opposition to permission for lactose claims the issue was raised that they created confusion and paranoia among the majority of people who wrongly perceive that they are lactose intolerant.

17.6 Assessment And Rationale

It is recommended that lactose claims be permitted for public health reasons, as individuals with lactose intolerance need to be able to identify foods containing lactose. It is also proposed that content claims made in relation to lactose should be included with the standard for nutrition, health and related claims, as manufacturers need to be aware that they must comply with the conditions for general level claims. Also, for consistency, lactose content claims should be kept in the same standard that governs health claims that can be made in relation to lactose.

17.7 'Low Lactose'

17.7.1 Issues Raised By Submitters

Virtually all submitters agreed with FSANZ's preferred criteria for 'low lactose' claims. The Manufactured Food Database commented that the criterion for low lactose claims (≤0.3 g/100 g) is meaningless and is too low for individuals with lactose intolerance. They advised that there is significant evidence that individuals with lactose intolerance are able to tolerate foods containing 6 g lactose or less/serving food and therefore recommended a level of 3 g lactose/100 g food as being appropriate.

17.7.2 Assessment And Rationale

Although the majority of submitters supported the criteria provided in Standard 1.2.8, FSANZ proposes to increase the criteria.

The level of lactose intolerance differs between individuals because of differing levels of lactase deficiency. Factors such as the type of dairy product consumed, whether lactose is consumed with a meal or not and the spread of lactose over a day also effect the intolerance. There is evidence, however, that demonstrates that most people with lactose intolerance can tolerate higher doses than 0.3 g per 100 g (Suarez *et al*. (1995, 1997; Hertzler, 1996). For instance Hertzler *et al.* (1996) found that no significant increase in symptoms occurred with a dose of up to 6 g lactose in the 13 subjects in their double blind randomised trial, although partial lactose maldigestion was indicated.

The Dietitians Association of Australia website states that 'most people with lactose intolerance can tolerate half a cup of milk at one time'. This translates to a value of 2.25 g lactose per 100 g.

Increasing the criteria for 'low' claims to 2.0 g lactose per 100 g will provide people with lactose intolerance greater food choices and should not pose a problem for the small number of people who have galactosaemia, which is intolerance to both lactose and galactose, as they are managed by a lactose free/ milk free diet. Education is, however, required so that the individuals with greater sensitivity are not confused. Care also needs to be taken when eating several foods on an occasion to ensure that the tolerated level has not been exceeded.

FSANZ has consulted both the New Zealand Dietetic Association and Dietitians Association of Australia on the issue of 'low lactose' claims. The Dietitians Association of Australia do not support the criteria, as they believe it will create more confusion in the market place, and will be of little use to the more sensitive individuals. They stated that lactose intolerance is a serious health issue for a significant number of Australians and New Zealanders, is dose-dependent and there is no data on the proportion of people that would be affected by a change in the criteria for 'low'. They therefore recommended a prohibition on 'low lactose' claims and retention of the 'reduced lactose' claim, which includes the criterion to state the percentage reduction.

In contrast, the New Zealand Dietetic Association agrees with the proposed increase in the criteria to 2.0 g lactose per 100 g. They argue that lactose intolerance is not an allergy and while the symptoms of intolerance are dependent on the dose, there is no indication from studies that a significant increase in symptoms occurs with a 2 g dose of lactose. They were unaware of any contrary evidence regarding more sensitive individuals, other than the previously noted galactosaemia issue. They did not support the 'reduced lactose' claim as they consider it to be ill understood by the consumer. They also noted that the dual gluten standard has caused much confusion and anxiety for those with coeliac disease.

While contentious, FSANZ proposes to increase the criteria for 'low lactose' such that foods must contain no more than 2.0 g lactose per 100 g for the reasons discussed above.

17.8 'Lactose Reduced'

17.8.1 Issues Raised By Submitters

A small number of submitters did not support permission for this claim. It was believed that 'lactose reduced' claims can cause confusion, with potential adverse effects when at-risk individuals consume these foods as products may still contain a significant amount of lactose.

There were no submitters who specifically opposed the criteria for 'lactose reduced' claims. In support of the proposed criteria it was noted that they are consistent with other 'reduced' claims and ensure that the degree of reduction is significant.

17.8.2 Assessment And Rationale

An increase in the criteria for 'low lactose' has meant that there is little need for a 'reduced lactose' claim. Also, 'reduced by X%' claims, as prescribed in Standard 1.2.8 requires all individuals with lactose intolerance to examine the nutrition information panel to verify that a product has been sufficiently reduced to provide a tolerable absolute amount. Although contentious, FSANZ considers that claims to the effect that a food is 'lactose reduced' should not be made, as they may not necessarily be 'safe' for people with lactose intolerance. This approach should minimise consumer confusion, thereby reducing adverse health effects. It is also provides consistency with gluten claims.

17.9 'Lactose Free'

There is potential inconsistency between the 'no detectable' criteria for 'lactose free' and no provisions being given for other 'free' claims apart from gluten. FSANZ and considers there is justification for the inconsistency on the basis of public health and safety.

17.9.1 Issues Raised By Submitters

The majority of submitters agreed with FSANZ's proposed criterion for 'lactose free' claims, however some made recommendations regarding the criterion. These recommendations related to setting the criterion at a specific value or specifying the method of analysis for detection of lactose.

A number of submitters commented on the issue of 'free' claims generally, including 'lactose free', noting that:

- 'free' claims should be permitted when the amount present is physiologically, clinically and nutritionally no different to food containing 'zero' amounts of the substance in question;

- the criteria need to align with levels that are physiologically relevant. 'Not detectable' is not a realistic measure as many techniques are too sensitive and unnecessarily restrict consumer choice by eliminating suitable foods;

- as methods of detection become more sensitive, some products may be disqualified from the marketplace that were previously able to be labelled as ' free' and were acceptable to the relevant population group. Apart from the impact on consumers, there is also an impact on manufacturers who may be required to change their labels to remove claims that are no longer compliant;

- industry and enforcement agencies need clarity and certainty with regard to a threshold that is appropriate from a health and safety perspective for consumers, rather than operating in an environment where the ground rules are being changed due to advances in testing analysis; and

- analytical methods for 'lactose free' claims should be defined in the Standard.

The Australian Competition and Consumer Commission re-iterated that the criterion of 'no detectable …' satisfies their position with regard to 'free' claims.

A submitter considered that 'lactose free' and 'gluten free' claims should be covered by Trade Practices law for consistency with other 'free' claims.

17.9.2 Assessment And Rationale

FSANZ acknowledges the potential difficulties associated with the 'no detectable' criteria for 'lactose free' claims, as identified by submitters. However, specifying a threshold level of lactose to be permitted in lactose free foods is contrary to the Australian Competition and Consumer Commission's position that 'free' means 'nil', and therefore to specify a level is potentially misleading. Furthermore, the Australian Competition and Consumer Commission has reiterated that the criterion of 'no detectable lactose' supports their position. Therefore, FSANZ considers that the criteria for lactose free claims should be retained.

FSANZ does not propose to specify analytical methods for the determination of 'lactose free' foods for the reasons discussed in Attachment 5, Chapter 2, Section 2.8.

Chapter 18: Wholegrain Claims

18.1 Proposed Approach At Draft Assessment

At Draft Assessment FSANZ proposes the following claims and criteria for wholegrain:

Claim	Preferred criteria (and conditions)
Source	≥ 8 g wholegrain per serve
Good source	≥ 15 g wholegrain per serve

18.2 Policy Context

Wholegrain foods have been promoted over their refined counterparts by dietary guidelines and other authoritative advice for many years because of the increased nutrient content of wholegrain foods particularly for dietary fibre, vitamins and minerals. For instance the Dietary Guidelines for Australian Adults recommend that adults 'eat plenty of breads and cereals (including breads, rice, past and noodles, preferably wholegrain' (NHMRC, 2003). Over the last ten years, a growing body of evidence has supported a link between intake of wholegrain foods and a reduction in the risk of developing certain chronic illnesses. For a scientific assessment of the literature associated with the consumption of grain-based foods, see Application A464 – Definition of Wholegrain. In summary the Application A464 Final Assessment Report states that:

> 'The scientific evidence strongly supports the suggestion that wholegrain-based foods, even with as little as 25% wholegrain and its milled products, protects against the development of type 2 diabetes and improves glycaemic control'.

18.3 Definition Of Wholegrain

The definition of 'wholegrain' has recently been amended in Standard 2.1.1 of the Code to 'the intact grain or the de-hulled, ground, milled, cracked or flaked grain where the constituents – endosperm, germ and bran – are present in such proportions that represent the typical ratio of those fractions occurring in the whole cereal, and includes wholemeal'.

This change to the definition was requested by the cereal processing industry because the previous definition was very restrictive in terms of cereal products that could qualify as wholegrain foods and it impeded the promotion of wholegrain-based foods that is based on an encompassing term and simple concept. Only limited commercial products such as brown rice and unpearled barley could qualify as unmilled cereal foods, whereas other products generally thought of as wholegrain such as wheat flakes or rolled oats did not.

The definition of 'wholemeal' in the cereals standard has not changed, as there would have been no clear delineation between wholegrain and wholemeal foods if the proposed variation had been approved. The market for wholemeal bread, muffins and other cereal-based foods is well established and industry or consumer interests are well served by maintaining the established and familiar identity of such products.

18.4 Relevant International Approaches

No country other than the USA or Codex has developed criteria for wholegrain claims. In the USA, the proposed claims for wholegrains (21 CFR 101.9X of the Code of Fed Regulations) are:

- 'made with': ≥ 8 g wholegrain per serve;
- 'good source', 'contains' or 'provides': 8g to 15 g of wholegrain per serve;
- 'high', 'rich in', 'excellent source': ≥ 16 g wholegrain per serve.

The proposed definition for wholegrain in the USA is similar in intent to the Code: 'a substance that includes all edible parts of the grain including, the bran, germ and endosperm. When used as a component of a food, all three edible parts of the grain must be present in the same proportion either naturally or through technological processes. Food ingredients that may be considered wholegrains are amaranth, barley, buckwheat, bulgur, corn, oats, rice, rye and wheat'.

In terms of enforcement procedures, the US Food and Drug Administration will determine the amount of wholegrain in a product declaring the claims by multiplying the fibre content of the food ingredient that comprises the wholegrain component of the product with the amount of wholegrain associated with the claim declared on the label or in the labelling. Where the product contains more than one food ingredient that comprises the wholegrain component of the product, Food and Drug Administration uses 11.1 g fibre per 100 g as the representative fibre content of the wholegrain blend.

18.5 Issues Raised By Submitters

Although FSANZ did not specifically raise the issue of wholegrain claims in the Initial Assessment Report, several submitters made comment. Campbell Arnott's Asia Pacific, Sanitarium Health Food Comp and Go Grains all requested that wholegrain claims be included in Proposal P293. In particular Go Grains noted that there is benefit in broadening the range of nutrition, health and related claims to include claims in relation to wholegrain content of foods, based on the substantial evidence from large international scientific studies that support the view that people who eat wholegrain foods can have significantly lower risks of heart disease, type 2 diabetes and some cancers compared to those who do not.

They also stated that consumer research studies indicate that people have considerable difficulty identifying grain foods and a wholegrain claim on food labels would make the situation easier for shoppers, thereby assisting them in making wholegrain choices. Guidance would also be provided to food manufacturers by creating a level playing field for meaningful wholegrain claims on product labels.

Go Grains proposed that a 'source of wholegrains' claim should contain 20% or more wholegrain ingredients in order to include mixed grain breads and some wholemeal breads. It was pointed out that the high moisture content in bread (approximately 40% compared to 2-3% in breakfast cereals) means that most breads can not meet more stringent criteria such as 'more than 50% wholegrains', despite the fact that they have the potential to make a significant contribution to total daily wholegrain intake due to their multiple occasions of use. As wholemeal and mixed grain breads currently account for around 35% of all bread eaten in Australia, Go Grains believe there is clearly an opportunity to encourage healthy eating by increasing consumption in these bread categories via wholegrain claims.

Go Grains also proposed that a 'good source' should contain at least 50% of wholegrain ingredients. Such a criterion would include some breakfast cereals, some wholemeal breads and crispbreads.

18.6 Assessment And Rationale

Given that national dietary guidelines encourage the consumption of wholegrains, it is recommended that claims in relation to wholegrains be regulated. Specific criteria for 'source' and 'good source' claims will create a level playing field for industry and avoid a reliance on fair trading laws.

FSANZ considers that per serve is an appropriate unit of measure, as it will provide consistency with other risk reducing nutrition content claims (e.g. vitamins and minerals, protein and fibre) and is consistent with the approach adopted by the USA. A 30 g serve of brown bread should qualify for a 'source of wholegrain' claim if the criterion is 8 g or more per serve as approximately 55% of the product will be flour, of which half is typically wholemeal flour. Wholegrain bread and breakfast cereals should qualify for 'good source' claim if the criterion is set at 15 g or more per serve. It should be noted though that such an approach is advantageous to products that contain small amounts of wholegrain but which are eaten in large amounts. Also it does not fully take into consideration the equity issue for breads and cereals, where the former is high in moisture content, while the latter is low in moisture content and water can be replaced by sugar.

Chapter 19: Lean/Extra Lean Claims

19.1 Proposed Approach At Draft Assessment

Claim	Preferred criteria (and conditions)
Lean	FSANZ proposes not to set criteria for the use of the claims 'lean' and 'extra lean'.

19.2 Relevant International Approaches'

Canada and the United States have requirements for 'lean' and 'extra lean' while in Australia and New Zealand, Clause 5, Standard 2.2.1 – Meat and Meat Products of the Code regulates mandatory fat declaration, expressed in g/100 g, where an express or implied reference is made to the fat content of minced meat. In addition, the United States defines implied claims as: has a petition system whereby specific additional claims may be considered.

19.3 Label Monitoring

The University of Wollongong (Williams *et al*., 2003) demonstrated that in 2001, there were 0.5% of products across a wide range of product categories (4401 products in total) carrying skim/slim/trim/lean claims.

19.4 Issues Raised By Submitters

At Initial Assessment, FSANZ asked submitters whether 'lean' and 'extra lean' claims should be defined, and if so, what criteria should apply.

Although a number of submitters preferred that criteria be developed for the terms 'lean' and 'extra lean' there were more submitters who did not support this. Some submitters felt that these terms should not be permitted unless they were defined, as there is potential for consumers to be misled.

The main recommendations from submitters for specific criteria for 'lean' and 'extra lean', were that the food should meet the criteria for the 'reduced fat' or 'low fat' nutrition content claim. According to Meat and Livestock Australia, the fat content of 'lean' meat on their nutrient composition data is generally less than 10 g/100 g.

Meat and Livestock Australia recommended that specifications for using these terms as per requirements in the USA and Canada for both muscle meat and mincemeat will help to ensure a standard description across retailers and improve consumer understanding. They commented that Standard 2.2.1 does not ensure consistency in use of terms such as 'lean' or 'extra lean'.

Reasons provided by submitters for not supporting the definition of 'lean' and 'extra lean' claims included that their present regulation on a case-by-case basis is sufficient, they are just synonyms for other claims that are already defined, and there has been no market failure.

19.5 Assessment And Rationale

FSANZ proposes not to set criteria for the use of the claims 'lean' and 'extra lean'. The rationale for this, as mentioned by some submitters, is that there is no known market failure that requires regulation. Also, if criteria were developed for these specific implied claims, this would raise issues with the use of similar words such as 'trim', 'skinny' etc, which are also presently used on food labels but which do not have criteria for their use.

Bibliography

Andrews, J.C., Burton, S. and Netemeyer, R.G. (2000) Are some comparative nutrition claims misleading? The role of nutrition knowledge, ad claim type and disclosure conditions. *J. Advertising* **29**(3): 29-42.

Australian Bureau of Statistics (1995) *National Nutrition Survey. Nutrient Intakes and Physical Measurements*. Commonwealth of Australia.

Burton, S., Andrews, J.C., Netemeyer, R.G. (2000) Nutrition ad claims and disclosures: interaction and mediation effects for consumer evaluations of the brand and the ad. *Marketing Letters* **11**(3): 235-247.

Choice (2005) *Low-Carb - but highly processed*. August 2005, p. 20-23.

Crowe, T.C., La Fontaine, H.A., Gibbons, C.J., Cameron-Smith, D., Swinburn, B.A. (2004). Energy density of foods and beverages in the Australian food supply: influence of macronutrients and comparison to dietary intake. *Euro J. Clin. Nutr.* **58**: 1485-1491.

CSIRO (2000) *High grains diet helps lower cancer risk. Media release.* www.csiro.au/index. Accessed on 13 October 2005.

European Cancer Prevention Organisation Consensus Panel on Cereals and Cancer (1998) Consensus statement on cereals, fibre and colorectal and breast cancers. *Eur. J. Cancer. Prev*. **7**(suppl. 2): S1-S2.

EFSA (2004). Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a requires from the Commission related to the presence of trans fatty acids in food and the effect on human health of the consumption of trans fatty acids. European Food Safety Authority.

Foster, G.D., Wyatt, H.R., Hill, J.O., McGuckin, B.G., Carrie Brill, E.M., Selma Mohammed, B., Szapary, P.O., Rader, D.J., Joel S. Edman J.S., Samuel Klein, S.(2003). A multicenter, randomized, controlled trial of a low-carbohydrate diet for obesity. *New England J. Med.* **348**:2082-2090.

FSANZ (2001) *Food labelling issues: qualitative research with consumers*. Evaluation Report Series No. 3. Food Standards Australia New Zealand, Canberra, ACT.

FSANZ (2003a) *Food labelling issues: qualitative consumer study on nutrient content claims*. Evaluation Report Series No. 5. Food Standards Australia New Zealand, Canberra, ACT.

FSANZ (2003b) *Food labelling issues: quantitative research with consumers.* Evaluation Report Series No. 4. Food Standards Australia New Zealand, Canberra, ACT.

FSANZ (in press) *Research on consumers' perceptions and use of nutrition, heath and related claims on packaged foods and associated advertising material.* Food Standards Australia New Zealand, Canberra, ACT.

FSANZ (unpublished) O*n-going Food Label Monitoring Survey in Australia and New Zealand*. Report on the Re-assessment of 2003 Labels for Nutrition, Health and Related Claims. Food Standards Australia New Zealand, Canberra, ACT.

FTC (1998). *Generic Copy Test of Food Health Claims in Advertising*. Federal Trade Commission, Washington, DC.

Hertzler, S.R., Huynh, B.L., Savaiano, D.A. (1996). How much lactose is low lactose? *J. Am. Diet. Assoc.* **96**(3):243-246.

Hooper L., Thompson R.L., Harrison R.A., Summerbell C.D., Moore H., Worthington H.V., Durrington P.N., Ness A.R., Capps N.E., Davey Smith G., Riemersma R.A., Ebrahim S.B.J. (2005). *Omega 3 fatty acids for prevention and treatment of cardiovascular disease* (Cochrane Review). In: The Cochrane Library, Issue 2. Oxford, update 1, August 2004.

Jensen, M.K., Koh-Banerjee, P., Hu, F.B., Franz, M., Sampson, L., Gronbaek, M., Rimm, E.B. (2004) Intakes of whole grains, bran and germ and the risk of coronary heart disease in men. *Am. J. Clin. Nutr*. **80**:1492

Kris-Etherton P.M., Harris W.S., Appel L.J. (2003). American Heart Association. Nutrition Committee: Fish consumption, fish oil, omega-3 fatty acids, and cardiovascular disease. *Circulation* **106**: 2747-2757.

Kris-Etherton, P.M. (1999). Monounsaturated fatty acids and risk of cardiovascular disease. *Circulation* **100**: 1253-1258.

La Fontaine, H.A., Crowe, T.C., Swinburn, B.A. and Gibbons, C.J. (2004) Two important exceptions to the relationship between energy density and fat content: foods with reduced-fat claims and high-fat vegetable-based dishes. *Public Health Nutr.*, **7**: 563-568.

Lake, R. (1995). Trans fatty acids: estimated intake. A report for the Ministry of Health/Public Health Commission. Institute of Environmental Science and Research Limited CRI., Wellington.

Miller, D.L. Castellanos, V.H., Shide, D.J., Peters, J.C., Rolls, B.J. (1998). Effect of fat-free potato chips with and without nutrition labels on fat and energy intakes. *Am. J. Clin. Nutr.* **68**:282-290.

Ministry of Health (1996) *Food and Nutrition Guidelines for Healthy Older People*: *A Background Paper.* Ministry of Health, Wellington.

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

NDA (2004) Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the presence of *trans* fatty acids in foods and the effect of human health on of the consumption of *trans*-fatty acids. *EFSA Journal* **81**: 1-49.

NHF (1997) *Dietary Fibre.* http://www.heartfoundation.com.au/downloads/dietary fibre.htm. Accessed on 13 October 2005.

NHF (1999) A review of the relationship between dietary fat and cardiovascular disease. *Aust. J. Nutr. Diet* **56**(4 Suppl): S5-S22.

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

NHMRC and Ministry of Health (2005) D*raft Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*. Commonwealth of Australia and New Zealand Government.

Noakes, M., Nestel, P. (1994). Trans fatty acids in the Australian Diet. *Food Australia* **46**:124-129.

Nutrition Taskforce (1991) *Food for Health: Report of the Nutrition Taskforce.* Department of Health, Wellington.

Porrini, M., Crovetti, R., Riso, P., Santangelo, A., Testolin, G. (1995). Effects of physical and chemical characteristics of food on specific and general satiety. *Physiol. and Behav.* **57**: 461-468.

Public Health Commission (1995) *Food and Nutrition Guidelines for Healthy Pregnant Women: A Background Paper*. Public Health Commission, Wellington, New Zealand.

Rolls, B. and Barnett R.A. (2003) *The Volumetrics Weight Control Plan.* Harper Collins, Sydney.

Russell D.G., Parnell W.R. and Wilson N.C. (1999) *NZ Food: NZ People. Key results of the 1997 National Nutrition Survey.* Ministry of Health, Wellington.

Shide, D.J. Rolls, B.J. (1995) Information about the fat content of preloads influences energy intake in healthy women. *J. Am. Diet. Assoc.* **95**:993-998.

Sigman-Grant, M. (1997). Can you have your low fat cake and eat it too? The role of fat-modified products. *J. Am. Diet. Assoc.* **97**(spl):S76-S81.

Stauffer C.E., (1996) *Fats and Oils*. Egan Press, St Paul, Minnesota, USA.

Stanley, J. (2004). Trans fatty acids, plasma lipid levels, and risk of developing cardiovascular disease. A Statement for Health Care Professionals from the American Heart Foundation.

Stubbs, J., Ferres, S., Horgan, G. (2000) Energy density of foods: effects on energy intake. *Critical Rev. in Food Sci. Nutr*. **40**(6):481-515.

Suarez, F.L., Savaiano, D., Levitt, M.D. (1995) A comparison of symptoms after the consumption of milk or lactose-hydrolyzed milk by people with self-reported severe lactose intolerance. *New England J. Med*. **333**:1-4.

Suarez. F.L., Savaiano, D., Arbisis, P., Levitt, M.D. (1997) Tolerance to the daily ingestions of two cups of milk by individuals claiming lactose intolerance. *Am. J. Clin. Nutr*. **65**:1502-1506.

Thomson, C.D., Colls, A.J. (1998). Twenty-Four Hour Urinary Sodium Excretion in Seven Hundred Residents of Otago and Waikato. Report prepared for the Ministry of Health. Dunedin: Department of Human Nutrition, University of Otago.

Truswell, A.S., Dreosti, I.E., English, R.M., Rutishauser, I.H.E. and Palmer, N. (1990) *Recommended Nutrient Intakes: Australian Papers*. Mosman: Australian Professional Publications.

UK Department of Health (1998) *Nutritional aspects of the development of cancer: report of the working group on diet and cancer of the Committee on Medical Aspects of Food and Nutrition Policy.* The Stationery Office, Norwich, UK

USDA (2005) *Dietary Guidelines for Americans. Part D. Science base, Sect.4, Fats*. http://www.health.gov/dietaryguidelines/dga2005/report/HTML/D4_Fats.htm. Accessed on 19/10/2005.

Weggemans, R., Rudrum, M., Trautwein, E. (2004). Intake of ruminant versus industrial trans fatty acids and risk of coronary heart disease – what is the evidence? *Euro. J. Lipid Sci Technol* **106**: 390-307.

Westerterp-Plantenga, M.S. (2004). Modulatory factors in the effect of energy density on energy intake. *Brit. J. Nutr*. **92**(Suppl. 1): S35-S39.

Williams, P., Yeatman, H. and Zakrzewski, S. (2003). Nutrition and related claims used on packaged Australian foods – implications for regulation. *Asia Pacific J. Clin. Nutr* **12**(2): 138-150.

World Cancer Research Fund & American Institute for Cancer Research (1997) *Food, nutrition and the prevention of cancer: a global perspective.* American Institute for Cancer Research, Washington

Appendix To Part 1

International Comparison Of Content And Related Claims

USA definitions

Reference amount - refers to the reference amount customarily consumed (Code of Federal Regulations)

Small reference amount - refers to reference amount of 30 g or less or 2 tablespoons or less (Code of Federal Regulations)

Reference Food:

'Reduced' and *'Added'* (or *'Fortified'* and *'Enriched*')
1. An established regular product or average representative product, and
2. Similar food.

'More' and *'Less'* (or *'Fewer'*)
1. An established regular product or average representative product: and
2. A dissimilar food in the same product category, which may be generally substituted, for the labelled food (e.g., potato chips for pretzels) or a similar food.

'Light' or *'Lite'* claims
1. A food representative of the type of food bearing the claim (e.g., average value of top three brands or representative value from valid data base);
2. Similar food (e.g., potato chips for potato chips); and
3. Not low-calorie and low fat (except light-sodium foods which must be low-calorie and low-fat).

Canadian definitions

Food group – means one of the four following categories of foods:

- milk products and milk product alternatives such as fortified plant-based beverages;
- meat, poultry and fish, and alternatives such as legumes, eggs, tofu and peanut butter;
- bread and grain products; and
- vegetables and fruit.

Similar reference food – means a food of the same type as the food to which it is compared and that has not been processed, formulated, reformulated or otherwise modified in a manner that increases or decreases either the energy value or the amount of a nutrient that is the subject of the comparison, i.e. whole milk is a similar reference food for partly skimmed milk.

Transition period for the new Canadian requirements

Transition period for the new Canadian Nutrition Facts Table of the Food and Drug Regulations ends on 12 December 2005 for most businesses (3-year transition period) and 12 December 2007 for small businesses (5-year transition period).

However, if claims are made in relation to the following: 100% fat free, % fat free, free of *trans* fatty acids, reduced in *trans* fatty acids, lower in *trans* fatty acids, source of omega-3 or omega-6 polyunsaturated fatty acids, the label must comply fully with the new requirements.

The EU Proposal

The EU Proposal for a regulation of the European Parliament and of the Council on nutrition and health claims made on foods is currently held up by the European Parliament's Environment Committee. The Committee decided against voting on the Proposal because there were too many areas of disagreement. The first reading on the Proposal by the Council is still pending.

ENERGY/CALORIES

LOW CALORIE/ ENERGY/JOULE	**FOOD COMPOSITION CRITERIA**
CoPoNC	Regulated by Standard R2 of Volume 1 of the Code
Volume 1	Standard R2 specifies the maximum energy that may be contained in prescribed reference quantities of a range of foods if they are described by one of these terms. If the food is not listed in Standard R2, then clause A1 (8) of the Food Standards Code prohibits these terms being used to describe the food
New Zealand Food Regulations 1984	Contains at least 1/3 less energy compared with normal counterpart; and must be statement of comparison with named normal counterpart; and for food specified in table to subclause (1) of regulation 241, < 70 kJ energy per reference quantity specified; and for all other foods, < 170 kJ energy per serving, and a) Solid foods: energy density < 170 kJ/100 g b) Liquid foods: energy density < 80 kJ/100 mL
The Code Standard 1.2.8, Subclause 14(1)	Solid or semi-solid foods: average energy content is ≤ 170 kJ per 100 g Beverages or other liquid foods: average energy content is ≤ 80 kJ per 100 mL
Canada *New requirements:* Food and Drug Regulations B.01.513, item 2	*Old requirements (still current):* ≥ 50% reduced in calories compared to the same food not calorie-reduced; and ≤ 15 Kcal/ average serving and ≤ 30 Kcal/ reasonable daily intake *New requirements:* ≤ 40 Calories or 167 kJ per reference amount and per labelled serving and ≤ 40 Calories per 50 g food if reference amount is ≤ 30 g or 30 mL (for prepackaged meal, ≤ 120 Cal or 500 kJ less per 100 g)
US 21 CFR 101.60(b) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	≤ 40 cal per reference amount (and per 50 g if reference amount is small) Meals and main dishes: ≤ 120 cal per 100 g
EU Proposal 2003/0165(COD)	< 40 kcal (170 kJ) per 100 g and < 20 kcal (80 kJ) per 100 ml
UK Nutrition claims in food labelling and advertising guidance notes & Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidance notes refers to FLR for conditions on energy. FLR – energy value of food ≤ 167 kJ (40 kcal) per 100 g or 100 ml (unless food is an intense sweetener or contains an intense sweetener); energy value of normal serving of the food ≤ 167 kJ (40 kcal)
Codex Guidelines for Use of Nutrition and Health Claims	≤ 40 kcal (170 kJ) per 100 g (solids) or ≤ 20 kcal (80 kJ) per 100 ml (liquids)

REDUCED ENERGY/ CALORIE/ JOULES LOWER IN ENERGY/ CALORIES/ JOULES	**FOOD COMPOSITION CRITERIA**
CoPoNC & Less energy & Fewer calories/joules	≤ 75% of the energy of the same quantity of reference food; and food must contain at least 170 kJ less energy per 100 g of food, or 80 kJ less per 100 g liquid food, compared with the same quantity of reference food; and must be statement of comparison with reference food
New Zealand Food Regulations 1984	Contains at least 1/3 less energy compared with normal counterparts; and must be statement of comparison with named normal counterpart
Canada *New requirements:* Food and Drug Regulations B.01.513, item 3 & 4 (Lower in energy refers to reference food of same food group rather than similar reference food)	*Old requirements (still current):* ≥ 50% reduced in calories compared to the same food not calorie-reduced *New requirements:* ≥ 25% less energy per reference amount of food than reference amount of similar reference food (per 100 g, than 100 g similar reference food if prepackaged meal) and similar reference food does not meet food composition conditions of 'low' in energy
US 21CFR 101.60(b) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	At least 25% fewer calories per reference amount than an appropriate reference food Reference food may not be 'low calorie'
EU Proposal 2003/0165(COD)	Energy value must be reduced by at least 30% and there must be an indication of the characteristic(s) which make(s) the food reduced in total energy value.
UK Nutrition claims in food labelling and advertising guidance notes & Food Labelling Regulations (FLR) 1996, schedule 6, part II	At least 25% reduction of energy contained in the food by comparison with the normal product
CALORIE FREE	**FOOD COMPOSITION CRITERIA**
Canada *New requirements:* Food and Drug Regulations B.01.513, item 1	*New requirements:* < 5 Calories or 21 kJ per reference amount and per labelled serving
US 21 CFR 101.60(b) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	< 5 cal per reference amount and per labelled serving
EU Proposal 2003/0165(COD) Energy free	< 4 kcal (17 kJ) per 100 ml
Codex Guidelines for Use of Nutrition and Health Claims	≤ 4 kcal per 100 ml (liquids)

LESS CALORIES	**FOOD COMPOSITION CRITERIA**
Canada *New requirements:* Food and Drug Regulations B.01.513, item 4	*Old requirements (still current):* ≥ 25% less calories and ≥ 30 fewer calories per serving than appropriate reference food *New requirements:* As for reduced calorie/energy above
US 21 CFR 101.60(b) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	As 'reduced'. Although using the term 'fewer' rather than 'less' is suggested.
SOURCE OF ENERGY/ CALORIES	**FOOD COMPOSITION CRITERIA**
Canada *New requirements:* Food and Drug Regulations B.01.513, item 5	*New requirements:* ≥ 100 Cal or 420 kJ per reference amount and per labelled serving
MORE ENERGY/ CALORIES	**FOOD COMPOSITION CRITERIA**
Canada *New requirements:* Food and Drug Regulations B.01.513, item 6	*New requirements:* ≥ 25% more energy, totalling ≥ 100 cal or 420 kJ more per reference amount of food than the reference amount of the reference food of same food group or similar reference food (Per 100 g, than 100 g of the reference food of same food group or similar reference food, if prepackaged meal)

PROTEIN

LOW PROTEIN	**FOOD COMPOSITION CRITERIA**
New Zealand Food Regulations 1984	Contains at least 1/3 less protein compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and < 5% of energy of food derived from protein
Canada *New requirements:* Food and Drug Regulations B.01.513, item 7	*New requirements:* food must contain ≤ 1g protein per 100 g of food
SOURCE OF PROTEIN	**FOOD COMPOSITION CRITERIA**
Volume 1	At least 12% of the energy value of the food is derived from protein; and the amount of food stated as a serve in the nutrition information panel contains at least 5 g of protein
Codex	Not less than 10% of nutrient recommended value (NRV) per 100 g (solids), 5% of NRV per 100 mL (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving

Canada *New requirements:* Food and Drug Regulations B.01.513, item 8 & High protein	*New requirements:* Food must have a protein rating[2] of ≥ 20 per reasonable daily intake or per 30 g of breakfast cereal with 125 mL of milk
EU Proposal 2003/0165(COD)	At least 12% of the energy value of the food is provided by protein
UK Nutrition claims in food labelling and advertising guidance notes & Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidelines refer to FLR FLR – quantity of the food that can reasonably be expected to be consumed in one day ≥ 12 g protein and ≥ 12% of energy value of the food must be provided by protein
<u>HIGH</u> PROTEIN	**FOOD COMPOSITION CRITERIA**
New Zealand Food Regulations 1984	Contains at least 1/3 more protein compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and > 15 g protein per serving
Canada *New requirements:* Food and Drug Regulations B.01.513, item 8 & Source of protein	*New requirements:* same food composition conditions as 'source of protein'
US A Food Labeling Guide – Appendix B	≥ 10 g per reference amount for meals or main dishes
EU Proposal 2003/0165(COD)	At least 20% of the energy value of the food is provided by protein
Codex	Two times the value for 'source of protein'
VERY HIGH PROTEIN/ EXCELLENT SOURCE OF PROTEIN	**FOOD COMPOSITION CRITERIA**
Canada *New requirements:* Food and Drug Regulations B.01.513, item 9	*New requirements:* Protein rating ≥ 40 per reasonable daily intake or per 30 g of breakfast cereal with 125 mL of milk
UK Nutrition claims in food labelling and advertising guidance notes & Food Labelling Regulations (FLR) 1996, schedule 6, part II (inc. rich source)	Guidelines refer to FLR FLR – quantity of the food that can reasonably be expected to be consumed in one day ≥ 12 g protein and ≥ 20% of energy value of the food must be provided by protein

[2] The protein rating of a food is based on the protein content in a Reasonable Daily Intake of that food. It is calculated by multiplying the **quantity** of protein present in the food by the **quality** of the protein, which is the protein efficiency ratio (PER) of the food.

MORE PROTEIN	**FOOD COMPOSITION CRITERIA**
Canada *New requirements:* Food and Drug Regulations B.01.513, item 10	*New requirements:* Protein rating ≥ 20 per reasonable daily intake (or 30 g of breakfast cereal with 125 mL of milk) and ≥ 25% increase in protein totaling at least 7 g or more, per reasonable daily intake than reference food of same food group or similar reference food
US A Food Labeling Guide – Appendix B	≥ 5 per reference amount (that is, 10% of DRV[3] per reference amount). Quantitative comparison of the amount of the nutrient in the product per labelled serving with that in reference food must be declared on information panel.

TOTAL FAT

LOW-FAT	**FOOD COMPOSITION CRITERIA**
CoPoNC	≤ 3 g total fat/ 100 g food or ≤1.5 g total fat per 100 g liquid food
New Zealand Food Regulations 1984	Contains at least 1/3 less fat compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and <10% of energy of food derived from fat
Canada New requirements: Food and Drug Regulations B.01.513, item 12	*Old requirements (still current):* ≤ 3 g fat per serving and ≤ 15% fat on dry basis *New requirements:* ≤ 3 g fat per reference amount and per serving of stated size and ≤ 3 g fat per 50 g if reference amount is ≤30 g or 30 mL or if food is a pre-packaged meal ≤ 3 g fat per 100 g and ≤ 30% energy from fat.
US 21 CFR 101.62(b) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	≤ 3 g per reference amount (and per 50 g if reference amount is small) Meals and main dishes: ≤ 3 g per 100 g and ≤ 30% of calories from fat
EU Proposal 2003/0165(COD)	≤ 3 g fat per 100 g or ≤1.5 g fat per 100 ml (or ≤ 1.8 g of fat per 100 ml semi-skimmed milk)
UK Nutrition claims in food labelling and advertising guidance notes	≤ 3 g per 100 g (solids) or per 100 ml (liquids)
Codex Guidelines for Use of Nutrition and Health Claims	≤ 3 g per 100 g (solids); ≤ 1.5 g per 100 ml (liquids)
REDUCED/LESS FAT	**FOOD COMPOSITION CRITERIA**
CoPoNC & Lower fat	≤ 75% of total fat content of the same quantity of reference food; and must be reduction of at least 3 g fat per 100 g food, or 1.5 g fat per 100 g liquid food, compared with same quantity of reference food; and must be a statement of comparison with reference food
New Zealand Food Regulations 1984	Contains at least 1/3 less fat compared with normal counterpart; and must have a statement of comparison with named normal counterpart

[3] DRV = Daily Reference Value for protein is 50 g, in 21 CFR 101.9(c) of the Code of Federal Regulations and A Food Labeling Guide – Reference values for Nutrition Labeling.

Canada *New requirements:* Food and Drug Regulations B.01.513, item 13 & Lower in fat	*Old requirements (still current)*: ≥ 25% less fat and ≥ 1.5 g less fat per serving than appropriate reference food and no increase in energy from reference food *New requirements:* ≥ 25% less fat per reference amount than reference amount of similar reference food and reference food not 'low fat'
US 21 CFR 101.62(b) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	At least 25% less saturated fat per reference amount than an appropriate reference food Reference food may not be 'low fat'
UK Food Standards Agency Fact Sheet	Should only be used with foods that contain less than ¾ of the amount of fat compared to the standard product.
X% FAT FREE	**FOOD COMPOSITION CRITERIA**
CoPoNC	Meet requirements for 'low fat' and must carry statement of actual total fat content (expressed as a percentage of food) in close proximity to claim
New Zealand Food Regulations 1984	Must meet requirements for 'low fat'
Canada *New requirements:* Food and Drug Regulations B.01.513, item 16	*Old requirements (no longer current for this claim)*: As for reduced/less fat claim *New requirements*: Meets food composition conditions for 'low fat' 100% fat free – meets food composition requirements for 'fat free' and < 0.5 g fat per 100 g and contains no added fat
US 21 CRF 101.62(b) of Code of Federal Regulations & A Food Labelling Guide – Appendix A	Must meet requirements for 'low fat' 100% fat free – must be 'fat free'
EU Proposal 2003/0165(COD)	Claims expressed as X% fat-free shall be prohibited
UK Nutrition claims in food labelling and advertising guidance notes	Should not be made
FAT FREE	**FOOD COMPOSITION CRITERIA**
CoPoNC	≤ 0.15 g total fat per 100 g food
Canada *New requirements:* Food and Drug Regulations B.01.513, item 11	*New requirements:* < 0.5 g fat per reference amount and per labelled serving or if a prepackaged meal < 0.5g fat per serving of stated size
US 21 CFR 101.62(b) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	< 0.5 g per reference amount and per labelled serving (meals and main meals: < 0.5 g per labelled serving)
EU Proposal 2003/0165(COD)	≤ 0.5 g fat per 100 g or 100 ml

UK Nutrition claims in food labelling and advertising guidance notes	≤ 0.15 g per 100 g or 100 ml
Codex Guidelines for Use of Nutrition and Health Claims	≤ 0.5 g per 100 g (solids) or 100 ml (liquids)
NO ADDED FAT	**FOOD COMPOSITION CRITERIA**
Canada *New requirements:* Food and Drug Regulations B.01.513, item 17	*New requirements:* Food or ingredients contain no added fats and oils or added butter or ghee. The similar reference food contains added fats or oils or added butter or ghee.

LEAN

LEAN	**FOOD COMPOSITION CRITERIA**
US A Food Labeling Guide – Appendix B	Seafood or game meat and must contain < 10 g total fat, ≤ 4.5 g saturated fat and < 95 mg cholesterol per reference amount and per 100 g (for meals and main, meets criteria per 100 g and per labelled serving)
Canada *New requirements:* Food and Drug Regulations B.01.513, item 46	*New requirements:* Food is meat or poultry that has not been ground, marine or fresh water animals or a product of any of these and ≥ 10 % less fat. (No criteria when related to prepackaged meals for use in weight-reduction or weight-management diets (B.01.502 (2))
EXTRA LEAN	**FOOD COMPOSITION CRITERIA**
US A Food Labeling Guide – Appendix B	Seafood or game meat and must contain < 5 g total fat, < 2 g saturated fat and < 95 mg cholesterol per reference amount and per 100 g (for meals and main, meets criteria per 100 g and per labelled serving)
Canada *New requirements:* Food and Drug Regulations B.01.513, item 47	*New requirements:* Food is meat or poultry that has not been ground, marine or fresh water animals or a product of any of these and ≥ 7.5 % less fat.

SATURATED FAT

LOW SATURATED FAT	**FOOD COMPOSITION CRITERIA**
CoPoNC	Must comply with 'low fat' claim; and Food must contain ≤ 1.5 g saturated fatty acids per 100 g of food or ≤ 0.75 g of saturated fatty acids per 100 g liquid food
New Zealand Food Regulations 1984	Contains at least 1/3 less saturated fat compared with normal counterpart; and must have a statement of comparison with named normal counterpart
Canada *New requirements:* Food and Drug Regulations B.01.513, item 19	*Current:* ≤ 2 g saturated fatty acids per serving and ≤ 15% energy from saturated fatty acids *New requirements:* ≤ 2 g saturated and trans fatty acids combined per reference amount and per labelled serving (per 100 g in the case of prepackaged meals) and ≤ 15% energy from saturated and trans fatty acids combined per reference amount and per labelled serving

US 21 CFR 101.62(c) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	≤ 1 g per reference amount and ≤ 15 % of calories from saturated fat. Meals and main dishes: ≤ 1 g per 100 g and < 10 % of calories from saturated fat Note: next to all saturated fat claims, must declare amount of cholesterol if ≥ 2 mg per reference amount; and the amount of total fat if > 3 g per reference amount (or ≥ 0.5 g total fat for 'saturated fat free')
EU Proposal 2003/0165(COD)	≤ 1.5 g of saturates per 100 g for solids or ≤ 0.75 g of saturates per 100 ml for liquids and saturated fat must not provide more than 10% of energy for both liquids and solids.
UK Nutrition claims in food labelling and advertising guidance notes	≤ 1.5 g per 100 g for solids or per 100 ml for liquids and should not make up more than 10% of the total energy of product for both liquid and solids.
Codex Guidelines for Use of Nutrition and Health Claims	≤ 1.5 g per 100 g (solids) ≤ 0.75 g per 100 ml (liquids) and 10% of energy Trans fatty acids should be taken into account where applicable
REDUCED/LESS SATURATED FAT	**FOOD COMPOSITION CRITERIA**
CoPoNC & Lower saturated fat	≤ 75% saturated fatty acid content of same quantity of reference food; and must be reduction in saturated fatty acid content of at least 2 g per 100 g food compared with same quantity reference food (or 1 g saturated fatty acids per 100 g of liquid food); and either fatty acid portion of food must contain ≤ 20 % of saturated fatty acids, and must contain ≥ 40% in total of *cis*-mono-unsaturated fatty acids and *cis*-poly fatty acids; or ≤ 15% of total energy in food derived from saturated fatty acids; and must be a statement of comparison with reference food
New Zealand Food Regulations 1984	Contains at least 1/3 less saturated fatty acid compared with named normal counterpart; and must have a statement of comparison with named normal counterpart (Clause 3 of Regulation 13C specifies the conditions which apply to 'reduced' claims. With the exception of Clause 3(c) which refers to energy claims, no other nutrients are specified)
Canada New requirements: Food and Drug Regulations Reduced B.01.513, item 20 Lower/less/fewer B.01.513, item 21	*Old requirements (still current)*: ≥ 25% less saturated fatty acids and ≥ 1 g less saturated fatty acids per serving than appropriate reference food and no increase in energy from reference food *New requirements:* ≥ 25% less saturated fatty acids per reference amount than reference food (or per 100 g for prepackaged meal) and no increase in content of trans fatty acids and reference food not 'low' in saturated fatty acids *New requirements:* ≥ 25% less saturated fatty acids per reference amount than reference food (or per 100 g for prepackaged meal) and no content of trans fatty acids is not higher and reference food not 'low' in saturated fatty acids
US 21 CFR 101.62(c) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	≥ 25% less saturated fat per reference amount than an appropriate reference food; reference food may not be 'low saturated fat' Note: next to all saturated fat claims, must declare amount of cholesterol if ≥ 2 mg per reference amount; and the amount of total fat if > 3 g per reference amount (or ≥ 0.5 g total fat for 'saturated fat free')
SATURATED FAT FREE	**FOOD COMPOSITION CRITERIA**
Canada New requirements: Food and Drug Regulations B.01.513, item 18	*New requirements*: < 0.2 g saturated fatty acids and < 0.2 g trans fatty acids per reference amount and per labelled serving (or per serving of stated size for prepackaged meal)

US 21 CFR 101.62(c) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	< 0.5 g saturated fat and < 0.5 g trans fatty acids per reference amount and per labelled serving (meals and main meals: < 0.5 g saturated fat and < 0.5 g trans fatty acids per labelled serving) Note: next to all saturated fat claims, must declare amount of cholesterol if ≥ 2 mg per reference amount; and the amount of total fat if > 3 g per reference amount (or ≥ 0.5 g total fat for 'saturated fat free')
EU Proposal 2003/0165(COD)	≤ 0.1 g saturated fat per 100 g or 100 ml
UK Nutrition claims in food labelling and advertising guidance notes	≤ 0.1 g per 100 g or 100 ml
Codex Guidelines for Use of Nutrition and Health Claims	≤ 0.1 g per 100 g (solids), ≤ 0.1 per 100 ml (liquids)

TRANS FAT

***TRANS* FAT FREE**	**FOOD COMPOSITION CRITERIA**
Canada *New requirements:* Food and Drug Regulations B.01.513, item 22	*New requirements*: < 0.2 g *trans* fatty acids per reference amount and per labelled serving (or per serving of stated size if prepackaged meal) and meets food composition conditions of 'low in saturated fat'
REDUCED/ LOWER TRANS FAT	**FOOD COMPOSITION CRITERIA**
Canada *New requirements:* Food and Drug Regulations B.01.513, item 22	*New requirements:* ≥ 25% less *trans* fatty acids per reference amount than reference food (per 100 g, than 100 g of similar reference food for prepackaged meal), no increase in content of saturated fatty acids and reference food not 'low' in saturated fatty acids
New Zealand Food Regulations 1984	Contains at least 1/3 less *trans* fatty acids compared with normal counterpart; and must have a statement of comparison with named normal counterpart (Clause 3 of Regulation 13C specifies the conditions that apply to 'reduced' claims. With the exception of Clause 3(c), which refers to energy claims, no other nutrients are specified.)

POLYUNSATURATED FAT

POLY UNSATURATED FATTY ACIDS CLAIMS	**FOOD COMPOSITION CRITERIA**
New Zealand Food Regulations 1984	Contains at least 1/3 more polyunsaturated fatty acids compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and ≥ 40% of fat is polyunsaturated and ≤ 20% of fat is saturated and ≥ 50% of energy is derived from fat
The Code Standard 1.2.8, Subclause 12(1)	Total of saturated fatty acids and trans fatty acids ≤ 28% of total fatty acid content of food; and polyunsaturated fatty acids ≥ 40% of total fatty acid content of food

MONOUNSATURATED FAT

MONO UNSATURATED FATTY ACIDS CLAIMS	**FOOD COMPOSITION CRITERIA**
New Zealand Food Regulations 1984	Contains at least 1/3 more polyunsaturated fatty acids compared with normal counterpart; and must have a statement of comparison with named normal counterpart
The Code Standard 1.2.8, Subclause 12(1)	Total of saturated fatty acids and trans fatty acids ≤ 28% of total fatty acid content of food; and monounsaturated fatty acids ≥ 40% of total fatty acid content of food

OMEGA-3 POLYUNSATURATES

SOURCE OF/CONTAINS OMEGA-3 POLY UNSATURATED FATTY ACIDS	**FOOD COMPOSITION CRITERIA**
The Code Omega-3 fatty acid claims Standard 1.2.8, Subclause 13(2) & 13(3)	Other than fish and fish products, the total of saturated fatty acids and trans fatty acids < 28% of total fatty acid content of food; or Food contains ≤ 5 g saturated fatty acids and trans fatty acids per 100 g of food; and Food contains ≥ 200 mg alpha-linolenic acid per serving; or Food contains ≥ 30 mg total eicosapentaenoic acid and docosahexaenoic acid per serving
Canada *New requirements:* Food and Drug Regulations B.01.513, item 25	*New requirements*: ≥ 0.3 g omega-3 polyunsaturates per reference amount and per labelled serving (or per 100 g if food is prepackaged meal)
GOOD SOURCE OF OMEGA-3 FATTY ACIDS	**FOOD COMPOSITION CRITERIA**
The Code Standard 1.2.8, Subclause 13(4)	Other than for fish & fish products that have no added saturated fatty acids, the total of saturated fatty acids and trans fatty acids < 28% of total fatty acid content of food; or Food contains ≤ 5 g saturated fatty acids and trans fatty acids per 100 g of food; and food contains ≥ 60 mg total eicosapentaenoic acid and docosahexaenoic acid per serving

OMEGA 6-POLYUNSATURATES

SOURCE OF/CONTAINS OMEGA-6 POLY-UNSATURATED FATTY ACIDS	**FOOD COMPOSITION CRITERIA**
The Code Polyunsaturated Fatty Acid claims Standard 1.2.8, Subclause 13(6)	Total of saturated fatty acids and trans fatty acids of food ≤ 28% of total fatty acid content of food; and Omega-6 polyunsaturated fatty acids ≥ 40% of total fatty acid content of food
Canada *New requirements:* Food and Drug Regulations B.01.513, item 26	*New requirements:* ≥ 2 g omega-6 polyunsaturates per reference amount and per labelled serving (or per 100 g if food is a prepackaged meal)

OMEGA-9 POLYUNSATURATES

OMEGA-9 POLY UNSATURATED FATTY ACIDS CLAIMS I.E. SOURCE OF/CONTAINS	**FOOD COMPOSITION CRITERIA**
The Code Standard 1.2.8, Subclause 13(6)	Total of saturated fatty acids and trans fatty acids of food ≤ 28% of total fatty acid content of food; and Omega-9 polyunsaturated fatty acids ≥ 40% of total fatty acid content of food

CHOLESTEROL

LOW CHOLESTEROL	**FOOD COMPOSITION CRITERIA**
CoPoNC	≤ 20 mg cholesterol per 100 g food; and food must either meet conditions for 'low fat' claim or fatty acid component of food must contain ≤ 20% saturated fatty acids and ≥ 40% of *cis*-poly or of *cis*-mono fatty acids
New Zealand Food Regulations 1984	Contains at least 1/3 less cholesterol compared with normal counterpart; and must have a statement of comparison with named normal counterpart; and < 20 mg cholesterol per specified serving of food
Canada *New requirements:* Food and Drug Regulations B.01.513, item 28	*Old requirements (still current):* ≤ 20 mg cholesterol per 100 g and per serving, and ≤ 2 g saturated fatty acids per serving, and 15% energy from saturated fatty acids *New requirements:* ≤ 20 mg cholesterol per reference amount and per labelled serving and per 50 g food if reference amount is ≤ 30 g or 30 mL (per 100 g if food is a prepackaged meal) and food meets food composition criteria for 'low' in saturates
US 21 CFR 101.62(d) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	Food must contain ≤ 20 mg per reference amount (and per 50 g of food if reference amount is small) (meals and main meals: ≤ 20 mg/100 g) Cholesterol claims only allowed when food contains ≤ 2 g saturated fat per reference amount Further qualifying/disqualifying conditions apply where the food qualifies by special processing and total fat > 13g per reference and labelled serving.
UK Nutrition claims in food labelling and advertising guidance notes & Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidance notes suggest that cholesterol claims should not be made. However, FLR states for presence or absence claims the food must be ≤ 0.005% of cholesterol, with exception that a claim can only be made if the claim relates to the removal of cholesterol from, or its reduction in, the food – as part of an indication of the true nature of the food, as part of an indication of the treatment of the food, within the list of ingredients, or as a footnote in respect of a prescribed nutrition labelling.
Codex Guidelines for Use of Nutrition and Health Claims	≤ 0.02 g per 100 g (solids); ≤ 0.01 g per 100 ml (liquids) and, < 1.5 g saturated fat per 100 g (solids), < 0.75 g saturated fat (liquids) and < 10% energy from saturated fat Trans fatty acids should be taken into account where applicable

REDUCED/LESS CHOLESTEROL	**FOOD COMPOSITION CRITERIA**
CoPoNC & Lower cholesterol	Must meet conditions for 'low cholesterol' claim and must carry statement of comparison with reference food; and food must either meet conditions for a 'low fat' claim, or the fatty acid component of the food must contain ≤ 20% saturated fatty acids and ≥ 40% *cis*-poly or of *cis*-mono fatty acids
New Zealand Food Regulations 1984	Contains at least 1/3 less cholesterol compared with normal counterpart; and must have a statement of comparison with named normal counterpart (Clause 3 of Regulation 13C specifies the conditions that apply to 'reduced' claims. With the exception of Clause 3(c), which refers to energy claims, no other nutrients are specified.)
Canada *New requirements:* Food and Drug Regulations B.01.513, item 29 & Lower Cholesterol (but refers to same food group rather than similar food) B.01.513, item 30	*Old requirements (still current)*: ≥ 25% less cholesterol and saturated fatty acids per serving, ≤ 20 mg less cholesterol and ≤ 1 g less saturated fatty acids per serving than appropriate reference food, and no increases from reference food *New requirements*: ≥ 25% less cholesterol per reference amount than reference food (per 100 g than 100 g of similar food if food is a prepackaged meal) and food meets food composition criteria of 'low' in saturates and similar reference food does not meet food composition criteria of 'low' in cholesterol
US 21 CFR 101.62(d) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	Food must contain ≥ 25% less cholesterol per reference amount than an appropriate reference food. Reference food may not be low cholesterol Cholesterol claims only allowed when food contains ≤ 2 g saturated fat per reference amount
UK Nutrition claims in food labelling and advertising guidance notes & Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidance notes suggest that cholesterol claims should not be made. However, FLR states cholesterol must be ≤ 0.005% of food **or** claim can only be made as part of an indication of the true nature of the food, as part of an indication of the treatment of the food, within the list of ingredients or as a footnote in respect of prescribed nutrition labelling.
CHOLESTEROL FREE	**FOOD COMPOSITION CRITERIA**
CoPoNC	≤ 3 mg cholesterol per 100 g food; and the food must either meet the conditions for 'low fat' claim or the fatty acid component of the food must contain ≤ 20% saturated fatty acids and ≥ 40% of *cis*-poly or of *cis*-mono fatty acids
Canada *New requirements:* Food and Drug Regulations B.01.513, item 27	*Old requirements (still current)*: N/A *New requirements:* < 2 mg cholesterol per reference amount and per labelled serving (or per serving of stated size if food is a prepackaged meal) and food meets the food composition criteria of 'low' saturates
US 21 CFR 101.62(d) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	< 2 mg per reference amount and per labelled serving (meals and main meals: < 2 mg per labeled serve) No ingredient containing cholesterol Further qualifying/disqualifying conditions apply where the food qualifies by special processing and total fat > 13g per reference and labelled serving.

UK Nutrition claims in food labelling and advertising guidance notes & Food Labelling Regulations (FLR) 1996, schedule 6, part II	Guidance notes suggest that cholesterol claims should not be made. However, FLR states cholesterol must be ≤ 0.005% of food **or** if claim is a removal of cholesterol claim can only be made as part of an indication of the true nature of the food, as part of an indication of the treatment of the food, within the list of ingredients or as a footnote in respect of prescribed nutrition labelling.
Codex Guidelines for Use of Nutrition and Health Claims	≤ 0.005 g per 100 g (solids), ≤ 0.005 g per 100 ml (liquids) and, < 1.5 g saturated fat per 100 g (solids), < 0.75 g saturated fat (liquids) and < 10% energy from saturated fat Trans fatty acids should be taken into account where applicable

SUGARS

LOW SUGAR	**FOOD COMPOSITION CRITERIA**
CoPoNC	≤ 5 g total sugars per 100 g of the food, or ≤ 2.5 g total sugars per 100 g liquid food
New Zealand Food Regulations 1984	Contains at least 1/3 less sugar compared with normal counterpart; and must be statement of comparison with counterpart; and < 5% of energy of food derived from sugars
Canada	*Old requirements (still current):* ≤ 2 g sugars per serving and ≤ 10% sugars on a dry basis
US 21 CFR 101.60(c) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	Not defined. No basis for recommended intake
EU Proposal 2003/0165(COD)	≤ 5 g total sugars per 100 g or 100 ml
UK Nutrition claims in food labelling and advertising guidance notes	≤ 5 g per 100 g or 100 ml
REDUCED/ LESS SUGAR	**FOOD COMPOSITION CRITERIA**
CoPoNC & Lower Sugar	≤ 75% of the total sugars content of the same quantity of the reference food; and must be a reduction of at least 5 g total sugars per 100 g food, or 2.5 g total sugars per 100 g liquid food, compared with the same quantity of the reference food; and must be a statement of comparison with reference food
New Zealand Food Regulations 1984	Contains at least 1/3 less sugar compared with normal counterpart; and must have a statement of comparison with named normal counterpart (Clause 3 of Regulation 13C specifies the conditions that apply to 'reduced' claims. With the exception of Clause 3(c), which refers to energy claims, no other nutrients are specified.)

Canada *New requirements:* Food and Drug Regulations B.01.513, item 38 & Lower in sugars (but refers to same food group rather than similar food) B.01.513, item 39	*Old requirements (still current):* ≥ 25% less sugars and ≥ 5 g less sugars per serving than appropriate reference food, and no energy increase from reference food *New requirements:* ≥ 25% less sugars and totalling ≥ 5g less per reference amount than reference amount of similar reference food (or per 100 g, than 100 g of a similar reference food, if the food is a prepackaged meal)
US 21 CFR 101.60(c) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	≥ 25% less sugars per reference amount than an appropriate reference food (May not be used on dietary supplements of vitamins and minerals)
EU Proposal 2003/0165(COD)	Reduction in the sugar content is at least 30% compared to a similar product
SUGAR FREE	**FOOD COMPOSITION CRITERIA**
CoPoNC	Food must contain ≤ 0.2 g sugars per 100 g food, or ≤ 0.1 g of sugars per 100 g liquid food
New Zealand Food Regulations 1984	Claim allowed if food does not contain sugars; or sugar alcohol
Canada *New requirements:* Food and Drug Regulations B.01.513, item 38	*New requirements:* < 0.5 g sugars per reference amount and per labelled serving and with the exception of chewing gum, meets food composition criteria for 'free' of energy
US 21 CFR 101.60(c) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	< 0.5 g sugars per reference amount and per labelled serving Disclose calorie profile (e.g. 'low calorie') (Meals and main meals: < 0.5 g sugars/labelled serve)
EU Proposal 2003/0165(COD)	≤ 0.5 g per 100 g or 100 ml
UK Nutrition claims in food labelling and advertising guidance notes	≤ 0.2 g per 100 g or 100 ml
Codex Guidelines for Use of Nutrition and Health Claims	≤ 0.5 g per 100 g (solids), ≤ 0.5 g per 100 ml (liquids)
NO ADDED SUGAR (S)	**FOOD COMPOSITION CRITERIA**
CoPoNC	Regulated by clause A1 (10) of Volume 1 of the Code
Volume 1	A1 (10) prohibits the claim unless the food contains no added sugar or related products as defined in Standard K1; no added honey as defined in Standard K2; and no added malt, malt extract or maltose
New Zealand Food Regulations 1984	Claim allowed if food does not contain added carbohydrate sweetener; or added sugar alcohol (> 1%) as an ingredient in that food

Canada *New requirements:* Food and Drug Regulations B.01.513, item 40	*New requirements:* No added sugars or other ingredients containing added sugars or ingredients that contain sugars that functionally substitute for added sugars and the sugar content not increased through other means e.g. use of enzymes except where functional effect is not to increase sugar content of food and; Similar reference food must have added sugars
US 21 CFR 101.60(c) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	Claim allowed if no sugar or sugar-containing ingredient is added during processing. State if food is not 'low' or 'reduced calorie'
EU Proposal 2003/0165(COD)	Claim allowed if the product does not contain any added mono- or disaccharides or any other food used for its sweetening purposes.
UK Nutrition claims in food labelling and advertising guidance notes	No sugars or foods composed mainly of sugars added to the food or to any of its ingredients
UNSWEETENED	**FOOD COMPOSITION CRITERIA**
CoPoNC	Regulated by clause A1 (10A) of Food Standards Code
Volume 1	Clause A1 (10A) prohibits the claim unless the product contains: no added sugars as defined in Standard K1, no added honey as defined in Standard K2, malt, malt extract or maltose, no added artificial sweetening substance as defined in Standard A8; and no added sorbitol, mannitol, glycerol, xylitol, maltitol, maltitol syrup, isomalt or lactitol
New Zealand Food Regulations 1984	Claim allowed if food does not contain added carbohydrate sweetener; or added sugar alcohol (> 1%) as ingredient; or any artificial sweetener as ingredient
US 21 CFR 101.60(c) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	The terms 'unsweetened' and 'no added sweeteners' remain as factual statements
Canada *New requirements:* Food and Drug Regulations B.01.509	*New requirements:* meet food composition requirements for 'no added sugars' and the food does not contain a sweetener
UK Nutrition claims in food labelling and advertising guidance notes	No sugars or foods composed mainly of sugars added to the food or to any of its ingredients except in accordance with provision of Condensed Milk and Dried Milk Regulation 1977 (as amended)

FIBRE

CoPoNC	Claims relating to fibre are discouraged on foods with significant fat content. Conditions apply where ≥ 30% energy is derived from fat.
SOURCE OF FIBRE **CONTAINS FIBRE**	**FOOD COMPOSITION CRITERIA**
CoPoNC	≥ 1.5 g dietary fibre per serving of food Main dish or meal type products: ≥ 2 g dietary fibre per 100 g meal

Canada *New requirements:* Food and Drug Regulations B.01.513, item 41	*Old requirements (still current):* ≥ 2 g dietary fibre per serving *New requirements:* ≥ 2 g dietary fibre per reference amount and per labelled serving when a specific fibre source is not mentioned, or ≥ 2 g of each named dietary fibre per reference amount and per labelled serving when a specific fibre source is mentioned Prepackaged meals and main dish entrees: Must contain at least one ingredient that meets food composition criteria for 'source of dietary fibre'
EU Proposal 2003/0165(COD)	≥ 3 g of fibre per 100 g or ≥ 1.5 g of fibre per 100 kcal
UK Nutrition claims in food labelling and advertising guidance notes	Either 3 g per 100 g or 100 ml; or ≥ 3 g in the reasonable expected daily intake of food
Codex Draft table of conditions for nutrient contents (Part B) Dietary Fibre	≥ 3 g per 100 g or ≥ 1.5 g per 100 kcal or per serving Liquid foods: ≥ 1.5 g per 100 ml (Serving size to be determined at national level)
HIGH FIBRE/ GOOD SOURCE OF FIBRE	**FOOD COMPOSITION CRITERIA**
CoPoNC	≥ 3 g dietary fibre per serving of the food Main dish or meal type products: ≥ 4 g dietary fibre per 100 g meal
New Zealand Food Regulations 1984	Contains at least 1/3 more fibre compared with normal counterparts; and must have a statement of comparison with named normal counterpart; and > 4g dietary fibre per specified serving of food
Canada *New requirements:* Food and Drug Regulations B.01.513, item 42	*Old requirements (still current):* ≥ 4 g dietary fibre per serving *New requirements:* ≥ 4 g fibre per reference amount and per labelled serving when a specific fibre source is not mentioned, or ≥ 4 g of each named dietary fibre per reference amount and per labelled serving when a specific fibre source is mentioned Prepackaged meals and main dish entrees: Must contain at least one ingredient that meets criteria for 'high source of fibre'
US A Food Labeling Guide – Appendix B	≥ 5 g per reference amount (high fibre) 2.5 g to 4.75 g per reference amount (good source – only to be used for meals or main dishes)
EU Proposal 2003/0165(COD). Only refers to high fibre	≥ 6 g of fibre per 100 g or ≥ 3 g of fibre per 100 kcal
UK Nutrition claims in food labelling and advertising guidance notes	Either ≥ 6 g per 100 g or 100 ml or ≥ 6 g in the reasonable expected daily intake of the foods
Codex Draft table of conditions for nutrient contents (Part B) Dietary Fibre	≥ 6 g per 100 g or ≥ 3 g per 100 kcal or per serving Liquid foods: ≥ 3 g per 100 ml (Serving size to be determined at national level)
VERY HIGH FIBRE EXCELLENT SOURCE OF FIBRE	**FOOD COMPOSITION CRITERIA**

CoPoNC	≥ 6 g dietary fibre per serving of food Main dish or meal type products: ≥ 6 g dietary fibre per 100 g of the meal
Canada *New requirements:* Food and Drug Regulations B.01.513, item 43	*Old requirements (still current):* ≥ 6 g dietary fibre per serving *New requirements:* ≥ 6 g fibre per reference amount and per labelled serving when a specific fibre source is not mentioned, or ≥ 6 g of each named dietary fibre per reference amount and per labelled serving when a specific fibre source is mentioned Prepackaged meals and main dish entrees: Must contain at least one ingredient that meets criteria for 'very high' in dietary fibre
INCREASED FIBRE **FIBRE ENRICHED** **HIGHER FIBRE**	**FOOD COMPOSITION CRITERIA**
CoPoNC	≥ 3 g dietary fibre per serving of food; and claims may only be applied to foods which contain, prior to enrichment with dietary fibre, at least 1.5 g of dietary fibre per serving; and must have a statement of comparison with reference food; the reference food must be a similar food made from the same ingredients but without enrichment with dietary fibre
Canada *New requirements:* Food and Drug Regulations B.01.513, item 44 Refers only to more/higher fibre	*New requirements:*≥ 2 g fibre per reference amount and per labelled serving when a specific fibre source is not mentioned or ≥ 2 g of each named dietary fibre per reference amount and per labelled serving when a specific fibre source is mentioned and ≥ 25% increase in fibre totalling ≥ 1 g fibre when a specific fibre source is not mentioned, or ≥ 25% increase in the named fibre, totalling ≥ 1 g fibre when a specific fibre source is mentioned. Also prepackaged meal requirements.
EU Proposal 2003/0165(COD)	Product must meet conditions of 'source of' and the increase in content is at least 30% compared to a similar product
UK Nutrition claims in food labelling and advertising guidance notes	≥ 25% more than a similar food for which no claim is made and ≥ 3 g in either the reasonable daily intake of a food for which this is lower than 100 g or 100 ml or in 100 g or 100 ml
FIBRE ADDED	**FOOD COMPOSITION CRITERIA**
CoPoNC	Food must meet conditions for 'high fibre' claim; and must be statement of comparison with reference food
US A Food Labeling Guide – Appendix B	≥ 2.5 g more per serving than reference food (that is, 10% of DRV[4] per reference amount). Quantitative comparison of the amount of the nutrient in the product per labelled serving with that in reference food must be declared on information panel.

SALT AND SODIUM

LOW SALT/ SODIUM **LIGHT IN SALT/ SODIUM**	**FOOD COMPOSITION CRITERIA**
CoPoNC	Regulated by Standard R8 of the Code
Volume 1	Standard R8 states that food must not contain > 120 mg sodium per 100 g or not > 50% of the sodium content of the normal counterpart food, whichever is less

[4] DRV = Daily Reference Value for fibre is 25 g, in 21 CFR 101.9(c) of the Code of Federal Regulations and A Food Labeling Guide – Reference values for Nutrition Labeling.

New Zealand Food Regulations 1984	Contains at least 1/3 less sodium compared with normal counterpart; and must have a statement of comparison with counterpart; and < 120 mg sodium per 100 g when ready for consumption
The Code Standard 1.2.8, Subclause 17(1)	≤ 120 mg sodium per 100 g Particulars relating to both the sodium and potassium content of food must be provided in accordance with 5(1) (+ other conditions)
Canada *New requirements:* Food and Drug Regulations B.01.513, item 32 only refers to low salt/ sodium	*Old requirements (still current)*: Only for foods for special dietary use: ≤ 50% of sodium that would be present if the food were not a low sodium food and ≤ 40 mg sodium/ 100 g (except ≤ 50 mg/ 100 g for cheddar cheese, and ≤ 80 mg/ 100 g for meat, poultry and fish); and except for salt substitutes, contains no added salts of sodium *New requirements:* ≤ 140 mg sodium per reference amount and per labelled serving and per 50 g if reference amount is ≤ 30 g or 30 mL (or per 100 g if food is a prepackaged meal)
US 21 CFR 101.61 of Code of Federal Regulations & A Food Labeling Guide – Appendix A	≤ 140 mg per reference amount (and per 50 g if reference amount is small) meals and main dishes: ≤ 140 mg per 100 g (+ conditions)
EU Proposal 2003/0165(COD) refers only to low salt/ sodium	≤ 0.12g sodium per 100 g or 100 ml
UK Nutrition claims in food labelling and advertising guidance notes	≤ 40 mg sodium per 100 g or 100 ml
Codex Guidelines for Use of Nutrition and Health Claims (Only refers to Low Sodium)	≤ 0.12 g per 100 g
VERY LOW SALT/ SODIUM	**FOOD COMPOSITION CRITERIA**
CoPoNC	≤ 40 mg sodium per 100 g of food
US 21 CFR 101.61 of Code of Federal Regulations & A Food Labeling Guide – Appendix A	≤ 35 mg per reference amount (and per 50 g if reference amount is small) (Meals and main meals: ≤ 35 mg/100 g)
EU Proposal 2003/0165(COD)	≤ 0.04 g of sodium per 100 g or 100 ml
Codex Guidelines for Use of Nutrition and Health Claims	≤ 0.04 g per 100 g
REDUCED SALT/ SODIUM LESS SALT/SODIUM	**FOOD COMPOSITION CRITERIA**

CoPoNC does not include 'Less Salt/Sodium'	≤ 75% of sodium content of same quantity of the reference food; and food must contain at least 90 mg less sodium per 100 g of food than same quantity of reference food; and food must contain >≤ 600 mg sodium per 100 g food; and must be a statement of comparison with reference food
New Zealand Food Regulations 1984	Contains ≤ 1/3 sodium or salt compared with normal counterpart; and must have a statement of comparison of the amount of sodium with named normal counterpart
Canada *New requirements:* Food and Drug Regulations B.01.513, item 33 & Lower in Sodium (but refers to same food group rather than similar food) B.01.513, item 34	*Old requirements (still current):* Compared to reference food it must have: ≥ 25% less sodium; and ≥ 100 mg less sodium/ serving *New requirements:* ≥ 25% less sodium per reference amount than reference amount of similar food (per 100 g of a similar food, if food is a prepackaged meal) and similar reference food does not meet food composition criteria for 'low' in sodium
US 21 CFR 101.61 of Code of Federal Regulations & A Food Labeling Guide – Appendix A	At least 25% less sodium per reference amount than an appropriate reference food Reference food. May not be 'low sodium'
EU Proposal 2003/0165(COD)	Reduction in the content is at least 30% compared to a similar product, except micronutrients where a 10% difference in the reference values as set in Council Directive 90/496/EEC shall be accepted
UK Food Standards Agency Fact Sheet	Law doesn't say how much less salt or sodium a 'reduced salt' product should contain, it is recommended that it should be at least 25% less than a standard product.
SALT/ SODIUM <u>FREE</u> <u>NO</u> SALT/SODIUM	**FOOD COMPOSITION CRITERIA**
CoPoNC	≤ 5 mg sodium per 100 g of food, or ≤ 2.5 mg sodium per 100 g liquid food
Canada *New requirements:* Food and Drug Regulations B.01.513, item 31	*Old requirements (still current):* ≤ 5 mg sodium/ 100 g food *New requirements:* <5 mg sodium per reference amount and per labelled serving (per serving of stated size if food is a prepackaged meal)
US 21 CFR 101.61 of Code of Federal Regulations & A Food Labeling Guide – Appendix A	< 5 mg per reference amount and per labeled serving (Meals and main meals: <5 mg/labeled serving)
EU Proposal 2003/0165(COD)	≤ 0.005 g of sodium per 100 g
UK Nutrition claims in food labelling and advertising guidance notes	≤ 5 mg sodium per 100 g or 100 ml
Codex Guidelines for Use of Nutrition and Health Claims	(Only refers to salt/sodium free) ≤ 0.005 g per 100 g
<u>NO ADDED</u> SALT/ SODIUM & UNSALTED	**FOOD COMPOSITION CRITERIA**

CoPoNC	Regulated by clause A1 (24) of the *Food Standards Code*
Volume 1	Clause A1 (24) states that the food and its ingredients must contain no added salt, no added sodium compound and must be unsalted
Canada *New requirements:* Food and Drug Regulations B.01.513, item 35	*Old requirements (still current):* No salt (NaCl) or other salts of sodium have been added directly to the food; and no ingredient or component contributes a significant amount of sodium to the food *New requirements:* No added salt or other sodium salts or ingredients that contain sodium that functionally substitutes for added salt. The similar reference food does not meet the food composition criteria for 'low' in sodium.
UK Nutrition claims in food labelling and advertising guidance notes	No salt or sodium shall have been added to the food or to any of its ingredients
LIGHTLY SALTED	**FOOD COMPOSITION CRITERIA**
CoPoNC	≤ 75% of sodium content of same quantity of the reference food; and food must contain at least 90 mg less sodium per 100 g of food than same quantity of reference food; and food must contain ≤ 600 mg sodium per 100 g food; and must be a statement of comparison with reference food
Canada *New requirements:* Food and Drug Regulations B.01.513, item 36	*New requirements:* ≥ 50% less added sodium than added to similar reference food and similar reference food does not meet compositional criteria for 'low sodium' food
US 21 CFR 101.61 of Code of Federal Regulations & A Food Labeling Guide – Appendix A	Food must have 50% less sodium than normally added to reference food

GLUTEN

CONTAINS GLUTEN/ HIGH IN GLUTEN	**FOOD COMPOSITION CRITERIA**
The Code Standard 1.2.8, Subclause 16(4)	may be made without any criteria been met
LOW GLUTEN	**FOOD COMPOSITION CRITERIA**
The Code Standard 1.2.8, Subclause 16(3)	cannot be made unless the food contains no more than 20 mg gluten per 100 g of the food; and oats or malt (this is subject to amendment pending the outcome of P264, i.e. the removal of oats or malt)
GLUTEN FREE	**FOOD COMPOSITION CRITERIA**
The Code Standard 1.2.8, Subclause 16(2)	Cannot be made unless the food contains no detectable gluten; and oats or malt (This is subject to minor amendment pending the outcome of P264)

Codex Guidelines for Gluten Free Foods	Gluten free food shall be based on: (a) Total nitrogen content of the gluten-containing cereal grains used in the product ≤ 0.05g per 100 g of these grains on a dry matter basis; or (b) Ingredients which do not contain gluten in substitution for the ingredients containing gluten which are normally used in food of that kind (c) Any mixture of two or more ingredients as in a. and b.

LACTOSE

LOW LACTOSE	**FOOD COMPOSITION CRITERIA**
The Code, Standard 1.2.8, Subclause 15(1)	≤ 0.3g lactose per 100 g
LACTOSE FREE	**FOOD COMPOSITION CRITERIA**
The Code Standard 1.2.8, Subclause 15(2)	Cannot be made unless the food contains no detectable lactose
Canada *New requirements:* B.01.502 (2)	Cannot be made unless the food contains no detectable lactose
REDUCED LACTOSE	**FOOD COMPOSITION CRITERIA**
The Code Standard 1.2.8, Subclause 15(3)	Must be accompanied by a declaration of the proportion by which the lactose content of the food has been reduced
UK Food Standards Agency – Fact Sheet	There are no rules to say how much less lactose a 'reduced lactose' milk must contain, it is recommended that it should be at least 25% less than normal milk, but some products can contain as much as 95% less lactose

DIET

DIET	**FOOD COMPOSITION CRITERIA**
CoPoNC	Must comply with Standard R2 of Vol. 1 or: Energy content of food must contain ≤ 60% of the energy content of the same quantity of reference food; and food must contain at least 170 kJ less energy per 100 g of food, or 80 kJ less per 100 g liquid food, compared with the same quantity of reference food; and must be statement of comparison with reference food
Volume 1	Must comply with Standard R2 of Volume 1 of the Food Standards Code - Low joule foods
The Code Standard 1.2.8, clause 14	Must comply with Clause 14 of Standard 1.2.8 – Low Joule Claims (i.e. is a claim to the effect that a food is low joule).
LIGHT OR LITE	**FOOD COMPOSITION CRITERIA**
CoPoNC	'Light' characteristic of food to be stated on label. If claim refers to nutrient or energy, food must comply with conditions for corresponding 'reduced' or 'low' claim
New Zealand Food Regulations 1984	Permitted only if food is: Meal replacement for weight reduction or weight maintenance diet; or conforms with regulation 241 – low energy foods; or conforms with regulations 13b and 13c – low energy and reduced energy claims

Canada *New requirements:* Food and Drug Regulations B.01.513, item 45	*New requirements:* Food must meet food composition conditions for 'reduced' in energy or fat: Not allowed with respect to nutrients other than fat and energy
US 21 CFR 101.60(b) of Code of Federal Regulations & A Food Labeling Guide – Appendix A	If ≥ 50% of calories are from fat, fat must be reduced by ≥ 50% per reference amount If < 50% of calories are from fat, fat must be reduced by ≥ 50% or calories reduced at least 1/3 per reference amount Generally % reduction for both fat and calories must be stated For meal or main dish: Must meet definition for 'low calorie' or 'low fat' and labelled to indicate which definition is met
EU Proposal 2003/0165(COD)	Must meet the requirements for 'reduced' and be accompanied by an indication of the characteristic(s) which make the food 'light' or 'lite'
UK Food Standards Agency Fact Sheet	There are no requirements that need to be met for 'light' or 'lite' claims. It is recommended that manufacturers explain exactly what their claim means.
Codex Guidelines for Use of Nutrition and Health Claims	Follow the same criteria as for 'reduced'

GENERAL

X% FREE (OTHER THAN FAT)	**FOOD COMPOSITION CRITERIA**
CoPoNC	Not permitted
MODIFIED	**FOOD COMPOSITION CRITERIA**
US A Food Labeling Guide – Appendix B	May be used in statement of identity that bears a relative claim (e.g. 'Modified Fat Cheese Cake, contains 35% less fat than our Regular Cheese Cake')
REDUCED (NAME OF NUTRIENT)	**FOOD COMPOSITION CRITERIA**
EU Proposal 2003/0165(COD)	Reduction in the content is at least 30% compared to a similar product, except micronutrients where a 10% difference in the reference values as set in Council Directive 90/496/EEC shall be accepted
INCREASED (NAME OF NUTRIENT)	**FOOD COMPOSITION CRITERIA**
EU Proposal 2003/0165(COD)	Product must meet conditions of 'source of' and the increase in content is at least 30% compared to a similar product

Part 2: General Level Health Claims

Chapter 1: General Level Health Claims Excluded From Disqualifying Criteria

1.1 Summary of Proposed Approach At Draft Assessment

- Generic disqualifying criteria will not apply to general level health claims referring to gluten or lactose.
- Generic disqualifying criteria will not apply to general level health claims on foods for infants.
- For the time being general level health claims in relation to vitamins and minerals will not be subject to generic disqualifying criteria but will be required to meet the claimable food criterion.

1.2 Background

FSANZ has drawn on stakeholder views regarding the regulation of general level health claims, consumer research, and approaches to regulation in other countries. As a result of this assessment, generic disqualifying criteria for general level health claims have been proposed by FSANZ at draft assessment (Attachment 5, Chapter 3, Section 3.1). Foods are not permitted to carry a claim unless they contain less than or equal to 325 mg of sodium, 4 g of saturated fat or 16 g of total sugar in a serve of food. However, there are some proposed exceptions to application of generic disqualifying criteria to general level health claims: gluten and lactose claims, claims placed on foods for infants, and claims in regards to vitamins and minerals.

1.3 Gluten And Lactose

FSANZ proposes that the generic disqualifying criteria will not apply to general level health claims that refer to gluten and lactose. This is because consumers who rely on these products should be able to choose from a full range of suitable products (based on the need to avoid undesirable reactions to chemical sensitivities), rather than being restricted to choosing from only those that meet nutritional criteria based on different and additional objectives (i.e. the 'healthy' diet). It is therefore important that messages about foods meeting the related qualifying criteria as currently specified in Standard 1.2.8 (i.e. 'low lactose', 'lactose free' or 'lactose reduced' and 'gluten free' or 'low gluten') are not restricted by the generic disqualifying criteria applicable to other general level health claims .

However, other conditions around general level health claim use would still need to be met including that the general level health claim would need to be scientifically substantiated and meet any wording conditions for health claims.

A specific exclusion from the application of generic disqualifying criteria to general level health claims in relation to gluten and lactose will be included in Standard 1.2.7.

1.4 Foods For Infants

Standard 2.9.2 – Food for Infants, provides for the compositional (including nutritional) and labelling requirements of food intended and/or represented for use as foods for infants. Clause 8 of Standard 2.9.2 provides for the regulation of claims in relation to vitamins and minerals however these relate primarily to content claims. However, there are no specific provisions in Standard 2.9.2 restricting the use of general level health claims (or function claims as they have been referred to historically). Whilst such claims are currently permitted, FSANZ is now proposing a regulatory framework around the use of general level health claims including that foods must not exceed maximum established levels of risk increasing nutrients (generic disqualifying criteria), consistent with healthy eating guidelines. These requirements will sit in Standard 1.2.7

FSANZ considers that it is not necessary to apply the generic disqualifying criteria where general level health claims are made in relation to infant foods because of compositional requirements for infant foods that are specified in Clause 2 of Standard 2.9.2. In particular, these compositional requirements take into account sugars and salt, two of the three risk increasing nutrients for generic disqualifying criteria. In addition, the Dietary Guidelines for Children and Adolescents in Australia (NHMRC 2003) specify that low fat diets are not suitable for infants and therefore imposing a saturated fat disqualifier around the use of general level health claims may not be appropriate.

A specific exclusion from the application of generic disqualifying criteria to general level health claims made in relation to foods for infants will be included in Standard 1.2.7.

1.5 Vitamins And Minerals

General level health claims in relation to vitamins and minerals will adopt the current qualifying criteria for content claims. As a minimum requirement, general level health claims will have to meet Clause 6 currently specified in Standard 1.3.2, however this Clause is being amended to be on a per serve basis rather than per reference quantity[5].

This current clause allows a claim to be made in relation to the presence of a vitamin or mineral in a food if:

- the vitamin or mineral is listed in column 1 of the schedule to Standard 1.1.1; and
- the food is a **claimable food;** and
- a reference quantity of the food contains at least 10% of the Recommended Dietary Intake or Estimated Safe and Adequate Daily Dietary Intake, for that vitamin or mineral.
  'Claimable food' is defined as a food that consists of at least 90% by weight of
- primary foods[6] or food lists in the Table to clause 3 of Standard 1.3.2, or

  a. a mixture of primary foods; and/or

[5] Note that claim requirements in 1.3.2 will be removed and included in Standard 1.2.7 so that the remaining Standard 1.3.2 only covers permissions for the additions of vitamins and minerals to foods. This brings it into line with other standards within Part 1.3 of the Code, which deals with substances added to foods, rather than labelling requirements.

[6] **Primary Food** means fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish.

b. water; and/or
c. foods listed in the Table to clause 3 of standard 1.3.2 excluding butter, cream and cream products, edible oils, edible oil spreads and margarines.

At the time of developing the concept of 'claimable foods', FSANZ devised the above definition to act as a criterion that ensured claims made in relation to vitamins and minerals were placed only on foods consistent with healthy eating guidelines. Therefore the 'claimable food' criterion is acting in a similar way to the generic disqualifying criteria that have been developed for general level health claims. The question arises as to whether it is necessary for the generic disqualifying criteria to be applied to general level health claims made in relation to vitamins and minerals when there is already a criterion in place that serves a similar purpose.

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

A specific exclusion from the application of generic disqualifying criteria to general level health claims in relation to vitamin and minerals that are required to meet the 'claimable food' criterion, will be included in Standard 1.2.7.

Chapter 2: Ineligibility For General Level Claims

2.1 Summary of Proposed Approach At Draft Assessment

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

2.2 Background

The Policy Guideline states, *consideration should be given during the FSANZ standard development process for including the criteria for making each level of claim and any parameters (for example, qualifying and disqualifying criteria, or exclusions for certain categories of food, such as alcohol and baby foods) should be specifically stated in the standard*.

Attachment 5, Chapter 2 and 3 discuss the approaches to applying qualifying and disqualifying criteria to both nutrition content claims and general level health claims so that these claims are only permitted on foods that meet certain compositional requirements. Qualifying and disqualifying criteria around the use of high level claims will also be considered on a case-by-case basis given that high level claims have to be pre-market assessed and approved (see Attachment 5, Chapter 5 regarding pre-approved high level claims). Foods proposed as vehicles for high level claims will be required to meet the qualifying criteria established on the basis of evidence and the distribution of nutrient sources in the food supply, as well as the generic disqualifying criteria for general level health claims (unless case-by-case exceptions are granted).

Moving to the new regulatory paradigm for nutrition, health and related claims, FSANZ has also considered the appropriateness of prohibiting certain levels of claims (i.e. nutrition content claims, general level health claims and high level claims) on particular categories of foods, largely guided by the examples of 'alcohol' and 'baby foods' provided in the Policy Guideline.

2.3 Current Requirements And Prohibitions On The Use Of Claims

Currently, alcohol labelling is regulated under Standard 2.7.1 - Labelling of Alcoholic Beverages and Food Containing Alcohol. Under clause 4, an alcoholic beverage can be represented as a 'low alcohol' beverage if it contains no more than 1.15% alcohol by volume. Representations regarding the use of the words 'non-intoxicating' and 'non-alcoholic' are referenced in clauses 5 and 6, respectively. There are no provisions in the Code in relation to 'light'/'lite' claims on alcohol or 'reduced alcohol' claims.

Under Standard 2.7.1, alcoholic beverages must state the % alcohol by volume and also the number of standard drinks (equal to 10 grams of ethanol) per package. This provides consumers with information within the public context of responsible consumption of alcohol.

There are provisions in CoPoNC governing the use of the term 'light' or 'lite'. Under CoPoNC, the term may be used to refer to the nutrient or energy content of the food, or to some other characteristic of the food. In relation to alcoholic beverages, the term 'light' is often used to represent beer that has a reduced or low alcohol content. The use of this term in relation to alcohol content is not defined by regulation or industry code of practice. There is an 'understanding' within industry on the application of this term to beer, which differs between Australia and New Zealand. In Australia, 'light' beers are generally below 3% vol/vol and in New Zealand they are less than 2.5% vol/vol. This reflects the higher alcohol content of most beers in Australia compared to New Zealand.

FSANZ is also aware that claims in relation to the energy/calorie content of alcoholic beverages are being made, for example, 'reduced energy' or 'low energy' beer. Such claims are subject to the general requirements in CoPoNC, and in clause 14, Standard 1.2.8, respectively.

In Australia and New Zealand, specific labelling requirements for foods for infants, including vitamin and mineral claims, are regulated under Standard 2.9.2 - Foods for Infants. Standard 2.9.1 regulates infant formula products and includes a list of prohibited representations (clause 20). There are no standards regarding claims for products to 'young children'.

The Transitional Standard for Health Claims (1.1A.2) prohibits health claims on foods standardised in:

- Part 2.7 of the Code (alcoholic beverages);
- foods standardised in 2.9.1 (infant formula), 2.9.2 (foods for infants), 2.9.3 (formulated meal replacements), 2.9.4 (formulated supplementary sports foods); and
- soft cheeses and pâté.

It is important to note that 'health claim' in the context of the transitional standard is the equivalent to high level claims classification under the new regulatory paradigm.

2.4 Relevant Issues Raised In Submissions

At Initial Assessment, FSANZ sought advice on whether any foods should be prohibited from making nutrition content claims. A small number of submitters supported that no foods should be prohibited from making claims, other than those already stipulated as prohibited by certain Standards in the Code. Other submitters, mostly representing industry, stated that no foods at all should be prohibited from making a content claim. Some of these submitters added that a nutrition content claim should be able to be made on any food as long as the claim is truthful, and complies with substantiation requirements and any qualifying criteria.

A number of submitters recommended that specific foods should be prohibited from making nutrition content claims, including:

- alcohol;
- infant formula and infant food; and
- confectionery and soft drinks.

Other submitters were opposed to prohibiting alcohol from making nutrition content claims, in particular, 'low/reduced alcohol' ('lite') and 'reduced energy'. It was noted that 'light' and 'mid-strength' are well established terms used to describe beers with a lower alcohol content than regular beer and that these products assist in promoting responsible alcohol consumption. It was also pointed out that many reduced alcohol beers have the word 'lite' or 'light' in their brand names and submitters were therefore concerned about any potential prohibition on content claims in relation to alcohol. In addition, some submitters noted that a range of 'reduced energy' beers is currently marketed in both Australia and overseas, and the prohibition of such claims would have a negative impact.

Regarding the term 'baby food' as used in the Policy Guideline, it was suggested that this was probably meant to refer to infant formula or relate only to the use of high level claims.

One submitter opposed infant foods and infant formulas being banned from making claims, as nutrition information on these foods is very important given the well-established nutrient deficiencies in New Zealand and Australia. Some submitters agreed to the current provisions in Standards 2.9.1 – Infant Formula Products, 2.9.2 – Food for Infants, 2.9.3 –Formulated meal Replacements and 2.9.4 –Formulated Supplementary Foods, but were concerned about precluding 'baby foods' from making content claims.

2.5 Assessment And Rationale

2.5.1 Alcoholic Beverages And Food Containing Alcohol

The requirements for low alcohol, non-alcoholic and non-intoxicating claims are included under Standard 2.7.1 Labelling of Alcoholic Beverages and Food Containing Alcohol. Under this Standard, a statement of the alcohol content is required on the label if the food contains more than 1.15% alcohol by volume and on alcoholic beverages containing at least 0.5% alcohol by volume. Claims about energy/calorie content are also currently being made in relation to alcoholic beverages and submissions representing the alcoholic beverages industry have indicated that there should not be a prohibition on making such claims under the new regulatory framework.

FSANZ considers that content claims in relation to alcohol content and energy should continue to be permitted as there is no evidence of market failure. These claims, particularly 'low alcohol' and 'light/lite' claims, have been established for some time, and serve a useful purpose in promoting responsible alcohol consumption.

The criteria for 'low alcohol' claims are currently contained in Standard 2.7.1 of the Code and will be retained. This claim applies specifically to alcoholic beverages. FSANZ also considers that 'reduced alcohol' claims should continue to be permitted on the basis of providing additional choices for individuals who may wish to moderate their alcohol consumption. 'Reduced alcohol' beers are commonly termed 'mid-strength' beers in the market. The market place is effectively self-regulating and therefore FSANZ doesn't intend to prescribe criteria for 'reduced alcohol' claims.

FSANZ is also recommending that 'low energy' and 'reduced energy' claims continue to be permitted in relation to alcoholic beverages and foods containing alcohol. As noted by submitters, these claims are currently being made on beers in both Australia and overseas. Similar to 'low energy' and 'reduced energy' claims for non-alcoholic foods, these claims serve a purpose in providing an additional choice for consumers of alcohol who are seeking a lower energy alternative. The proposed general criteria for making 'low energy' and 'reduced energy' claims in Chapter 6 of Part 1 of this attachment will apply in relation to alcoholic beverages and foods containing alcohol.

FSANZ believes that 'light/lite' claims in relation to alcohol are justifiable because they are well-established terms and are commonly associated with lower alcohol beverages. However, it is considered that the use of the term 'light/lite' should only be used to refer to energy or alcohol content because there is no justification for making claims in relation to other nutrients. The criteria and conditions that FSANZ is recommending in relation to the use of 'light/lite' claims for energy are consistent with the general recommendations for making 'light/lite' claims in Chapter 5 of Part 1 of this Attachment. Industry usage of the lite/light term for alcohol content relates to at least a 33% reduction in alcohol.

Since this is a greater reduction than that required under 'reduced' claims, a move to achieve consistency by requiring beers to only meet 'reduced' criteria (25% reduction) in order to carry a 'light/lite alcohol' claim would potentially mislead consumers and lead to confusion within the market place, which is effectively self-regulating. Furthermore, the additional labelling requirements for alcohol (% alcohol by volume and number of standard drinks per package) provide an effective mechanism for representing alcohol-containing beverages and, consistent with minimal regulation, no further prescription in labelling is required. Therefore it is proposed that the use of 'light/lite' claims in relation to alcohol content on alcohol products in terms of 'reduced' criteria, will not be prescribed in the Code.

FSANZ is proposing that the following criteria and conditions apply to making content claims in relation to alcoholic beverages and food containing alcohol. These are also listed in Appendix 5.2 of Attachment 5.

Claim	**Preferred criteria (and conditions)**
Low alcohol (as per Std 2.7.1 clause 4)	The alcoholic beverage must contain no more than 1.15% alcohol by volume.
Low calorie, low joule, low energy	The food containing alcohol or the alcoholic beverage must meet the conditions for a nutrition content claim in relation to low energy, as outlined in Chapter 6 of Part 1 of this attachment.
Reduced calorie, reduced joule, reduced energy	The food containing alcohol or the alcoholic beverage must meet the conditions for a nutrition content claim in relation to reduced energy, as outlined in Chapter 6 of Part 1 of this Attachment.
Light or Lite	The claim can only be made in respect of alcohol or energy content. The characteristic that makes the food 'light/lite' must be stated adjacent to the claim. For energy claims, the food must comply with the criteria and conditions for making a 'reduced energy' claim as above.

Whilst there is research to suggest that light-to-moderate alcohol consumption may have some health benefits, there is also a large body of evidence highlighting the myriad of problems associated with alcohol misuse. The consultation paper on the National Alcohol Strategy for 2005-2009 (Anon., 2005) also suggests that regulatory approaches, including effective controls on advertising, can reduce the detrimental effects associated with alcohol consumption in the community.

Given social issues regarding the abuse of alcoholic beverages, FSANZ considers that claims that attribute a health benefit are not appropriate on foods regulated in Part 2.7 of the Code and therefore a prohibition on the use of general level health claims and high level claims is warranted and will be reflected as such in Standard 1.2.7.

2.5.2 Infant Formula

Currently representations made in relation to the nutritional composition of infant formula are prohibited unless expressly permitted in Standard 2.9.1. Given that nutrition content claims may act against policies to promote breast-feeding, FSANZ considers there is no justification to relax the current requirements of Standard 2.9.1.

As nutrition content claims on infant formula will be prohibited unless expressly permitted, and there is no international or policy support for the use of health claims on infant formula, it also follows that a prohibition on the use of general level health claims and high level claims is appropriate. As such, Standard 1.2.7 will include a provision that general level health claims and high level claims must not be made in relation to infant formula products as standardised under Standard 2.9.1.

2.5.3 Other Foods

In a small number of cases, nutrition content claims or health claims are permitted under pre-existing provisions of the Code. In particular, Standard 2.9.3 – Formulated Meal Replacements and Standard 2.9.4 – Formulated Supplementary Sports Foods permit some health claims to be made in relation to foods regulated under those Standards.

Standard 1.2.7 will be drafted to include a general prohibition on the use of claims in relation to these foods but will allow the current permissions in Standard 2.9.3 and 2.9.4 to continue to operate.

Some submitters also recommended that specific foods, such as confectionary and soft drink, be prohibited from making any claims. FSANZ has developed a framework that consists of qualifying and disqualifying criteria as regulatory controls to ensure that claims appear only on foods consistent with national nutrition and dietary guidelines. Therefore, it is proposed that it is not necessary to specifically prohibit claims on such foods.

Chapter 3: Biologically Active Substance Claims

3.1 Summary of Proposed Approach At Draft Assessment

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

3.2 Background

Currently many nutrition content claims and health claims are based on a scientific consensus on well-established diet-health relationships. In the context of the general level health claims framework this may manifest in a claim based on a particular dietary intake of a nutrient achieving a health effect that can be substantiated by using a pre-approved nutrient function statement, or from authoritative sources (see Attachment 8, Substantiation Framework).

A different type of claim is based on the biological activity of substances (biologically active substances) that are not recognised by the Code as nutrients, achieving a health effect through biological activity of some kind. Such claims may relate to a positive contribution to health, improvement of a function, or modification, or preservation of health.

Currently, there are no well-established intake-health relationships, and substantiation of such claims is more complex because pre-approved function statements or authoritative sources are not available. Similarly, content claims about biologically active substances differ from content claims about nutrients, because they are not currently underpinned by recommended intakes or nutritional guidelines.

3.3 Current Regulations In Australia And Relevant International Approaches

The *Australia New Zealand Food Standards Code* defines a *biologically active substance* as a substance, other than a nutrient, with which health effects are associated (Standard 1.2.8). There are currently no criteria in relation to making nutrition claims with respect to biologically active substances, however there is a requirement under Standard 1.2.8 to declare the name and average quantity of the biologically active substance in the nutrition information panel.

The policy relating to the addition of substances other than vitamins and minerals is currently under development by the Food Regulation Standing Committee (see Section 11.4). FSANZ is already considering the issue of addition of substances other than vitamins and minerals to food, as was requested by some submitters, in particular in submissions from government and public health professionals. In this context there is a clear separation between regulating the safe use of a substance, which is the subject of Standards 1.4.4, 1.5.1, and 1.3.4, and the regulation of claims, which may be made in relation to the use of biologically active substances, which will be regulated by Standard 1.2.7.

Criteria for nutrients are based on officially recognised health reference standards, such as Recommended Dietary Intake for vitamins and minerals. At present, there are no such standards for biologically active substances, and no country has yet set criteria for content claims. Canada does permit quantitative claims for these substances (for example, '14 mg of lycopene per 50 g serving') but biological role claims (equivalent to general level health claims) are not permitted (Canadian Food Inspection Agency, 2003). In the USA, the Food and Drug Administration does not permit nutrition content claims for biologically active substances that state that the food is a good source of that substance, because they do not have a recommended intake. However, a labelling statement made to the effect that a food provides a stated amount of a biologically active substance per serving ('X mg of substance Y per serving') is permitted (Institute of Food Technologists, 2005).

3.4 Relevant Issues Raised In Submissions

There was general support by the majority of submitters to allow nutrition content claims, general level health claims and high level claims in relation to biologically active substances.

Submitters were asked to provide a list of the most common claims in relation to biologically active substances, and examples such as lycopene, antioxidants, phytosterols, and probiotics were provided. The following substances were cited by submitters as biologically active substances for which claims are currently being made:

sulphides and thiols	**carotenoids**	**vitamins**
allium sulphur compounds	lycopene, lutein, zeaxanthin, beta carotene	vitamins C & E

flavonoids
catechins, anthocyanidins, rutin, anthocyanins, quercetin

glucosinolates, indoles, isothiocyanates

co-vitamins, co-enzymes
choline, ubiquinone

herbs
echinacea, St John's Wort, chamomile, peppermint

whole foods
lemon, cranberry, alfalfa, wholegrain

fatty acids
omega-3 fatty acids

anti-nutrients
phytic acid

phytoestrogens
isoflavones, lignans

phytosterols

proteins
phaseolamin

fibre, carbohydrates
resistant starch, psyllium

minerals
silica

tannins
proanthocyanidins

prebiotics
fructo-oligosaccharides

probiotics
live cultures, acidophilus

miscellaneous
caffeine
citric acid
creatine

In the Initial Assessment Report, submitters were asked what criteria they have applied to claims based on biologically active substances and what evidence there is to support these claims. Three submitters provided criteria.

The first submitter reported that they have benchmark data for criteria for antioxidant claims and note that antioxidant activity will need to be considered in addition to antioxidant content.

The second submitter reported that their teams search the literature for daily intake levels of phytoestrogens, antioxidants and lycopene that are proven to have a benefit, then use the following criteria:

- 'source'/'contains' claim – 10% of this level per serve;
- 'good source'/'rich' claim – 25% of this level per serve.

If a daily amount is not proven, e.g. total antioxidants, they compare the product with other foods that contain the substance to make a judgement.

The final submitter that responded to the query used the following criteria for lycopene claims:

- 'source' claim - 25% of suggested daily intake (5-7 mg) per serving;
- 'good source'/'high'/'rich' – 100% of the suggested daily intake (5-7 mg) per serving.

Submitters were also asked whether criteria should be set for making claims based on biologically active substances, and the majority were in favour of this. However, there were a small number of industry submitters opposed to setting criteria, mainly because this process would be difficult, and substantiation and the declaration in the nutrition information panel would mean this was unnecessary. A few submitters suggested there should be criteria for quantitative claims only.

A number of submitters noted the onus should be on the manufacturer to substantiate the claim, and that the amount of the substance must be listed in the nutrition information panel. Some industry submitters noted that biologically active substances do not have recommended daily intakes or reference values, as is the case for nutrients that have established Recommended Dietary Intakes. This must be taken into account when establishing criteria and conditions. Two industry submitters also noted that the criteria for content claims would not be appropriate for setting criteria for whole food claims

Many submissions supported the setting of criteria for biological active substance claims, and some public health and government submitters recommended this should be done in conjunction with the development of the standard on the addition of vitamins, minerals, and other biologically active substances to food. There were at least five submitters that did not support the setting of criteria. This was mainly for the reason that the substantiation process should mean that criteria are not necessary (this was implied by other submitters).

Some submitters commented on the interface between foods, food type dietary supplements, and therapeutic products. It was also noted that therapeutic claims are required to deliver a relevant dosage, so they considered that foods should also meet these requirements, except where the whole food is relevant in its own right (e.g. tomatoes, not lycopene). Other submitters recommended that reference to the substance should only be made if it was normally found in a food, i.e. claims under this standard should not be able to be made for foods fortified with a biologically active substance where it was not naturally present.

Other relevant issues raised by submitters were that:

- a list of reference values would be needed to ensure that content claims were not made when the amount of biologically active substance delivered was not clinically significant;
- there is limited knowledge of the efficacy of biologically active substances outside their effect within whole food;
- the bioavailability as opposed to the content of the substance would need to be considered. Evidence of the bioavailability would be needed to determine an efficacious quantity of a substance that needed to be added to a food;
- there was concern around the issue of establishing a process for measuring biologically active substances and identifying levels that were effective;
- consumers see any claim for the presence of a biologically active substance as a (implied) health claim;
- there is a danger that if content claims are allowed without health related claims, the content of biologically active substances could be declared without the need to hold evidence that such fortification is of any real dietary benefit.

3.5 Assessment And Rationale

While some submitters wanted a prohibition on claims on all biologically active substances that did not naturally occur in food, most submissions acknowledged the presence of such claims in the market place.

Not all the examples that submitters considered to be biologically active substances are captured by the definition given in Standard 1.2.8[7], for example, substances such as vitamins, minerals and fatty acids would not be biologically active substances by this definition.

3.5.1 Rationale For Labelling Conditions For Biologically Active Substances

It is difficult to argue that content claims stating the presence of a biologically active substance should be prohibited. Such claims do not imply any efficacy or benefit beyond the presence of the biologically active substance ('presence' claims). Allowing such claims is consistent with the Policy Guidelines, which require regulations to be cost effective, and not more trade restrictive than necessary.

It is important to ensure that consumers are not misled by a content claim, and can purchase a food that actually contains a stated amount of the claimed substance. To ensure this, the amount of biologically active substance present in the food must be substantiated and stated on the nutrition information panel.

At present, there are no officially recognised reference values for biologically active substances. Should such values become available in the future, the proposed standard could potentially be amended to accommodate this. Until then, claims that a food is a 'good source' ('high in', 'rich in', and synonyms thereof) imply the existence of recommended intakes. 'Good source' claims in regards to a substance without a reference value are deceiving because there is no way for the consumers to either verify or assess such a claim, or choose between comparable foods based on such claims. Therefore, if a manufacturer wants to make a content claim about the presence of a biologically active substance in a food, only a claim that does not characterise the level of the substance in that food is appropriate.

Biologically active substance content claims that use comparison statements are only meaningful if the amount of the substance that provides the health effect has been substantiated. This is not the case for biologically active substance content claims. Therefore, comparison statements are not appropriate for biologically active substance content claims.

There is also the possibility that a content claim could mislead consumers by implying that a substance that is naturally present in a food is unique to the particular brand containing the food. Therefore, the wording of the claim needs to make clear that the claim refers to the whole class of similar food not to the particular food making the claim.

A requirement for additional information in the form of a percentage Daily Intake (%DI) of energy for biologically active substance content claims is consistent with the approach taken regarding other content claims (refer to Attachment 5, Chapter 2, Section 2.6). It allows the consumer to compare foods that contain biologically active substances based on energy content. However, the % DI for the biologically active substances is not required as there are no agreed reference values for biologically active substances.

[7] **Biologically active substance** means a substance, other than a nutrient, with which health effects are associated.

3.5.2 Rationale For Substantiation For Biologically Active Substances

As outlined in the General Level Claims Substantiation Framework, the only substantiation requirement for content claims is determination of the level of the component in the food. This is sufficient to ensure that the consumer purchase a food that contains the stated amount of the biologically active substance. Once the level of the biologically active substance in question has been determined, it is necessary to compare this to any compositional permissions stipulated in the Code or related materials.

3.5.3 Rationale For Regulating General Level Health Claims For Biologically Active Substances

Manufacturers should be able to make a claim to the effect that a biologically active substance provides a specific health effect, as long as the statement is not misleading in any way. Allowing such claims is consistent with the Policy Guidelines, which require regulations to be cost effective, not more trade restrictive than necessary, and to allow innovation.

General level health claims based on biologically active substance differ from similar claims made for nutrients. Claims based on biologically active substances are not supported by Recommended Dietary Intakes, nutrition guidelines, or scientific consensus. Claims based on biologically active substances are also less familiar to consumers than similar claims based on nutrients. Therefore, there is a rationale for providing additional information to consumers. This is consistent with the policy guideline, which requires the Standard to enable the responsible use of scientifically valid health and related claims.

3.5.4 Rationale For Labelling Conditions For Regulating General Level Health Claims For Biologically Active Substances

The rationale for restricting the use of 'good source' and comparative claims, stating the amount of substance present in the nutrition information panel, making it clear that the claim refers to the whole class of similar foods, and including the % DI of energy in the nutrition information panel, have been discussed in the section on content claims. Like other general level health claims, biologically active substance general level health claims are based on related content claims.

In the absence of Recommended Dietary Intakes for biologically active substances, general level health claims for biologically active substances must state the daily amount of the substance that provides the claimed health effect in the context of a healthy diet including a variety of foods, e.g. 'When consumed as part of a healthy diet containing a variety of foods, oligofructose can contribute to intestinal health. The suggested consumption of oligofructose is 5 g a day'.

Some industry submitters currently base their health claims for biologically active substances on suggested daily intakes, and because substantiation of general level health claims based on biologically active substances will require the establishment of suggested intakes, it would be appropriate for industry to disclose these values as part of making a claim.

Stating, as part of the general level health claim, the amount of substance necessary to achieve the desired health effect together with the content information provided in the nutrition information panel will give consumers the additional information to choose a product that suits their needs. This approach accommodates the current lack of Recommended Dietary Intakes for biologically active substances and aims to provide appropriate labelling for general level health claims based on biologically active substances.

3.5.5 Rationale For Criteria For Regulating General Level Health Claims For Biologically Active Substances

To provide consistency across the regulatory framework, any generic disqualifying criteria that apply to general level health claims based on saturated fat, sodium and total sugars will also apply to general level health claims based on biologically active substances (refer to Attachment 5, Chapter 3, Section 3.6).

It is important that consumers are not deceived by general level health claims on foods that contain insufficient levels of the biologically active substance to actually achieve the health effect. At this point in time these substances do not have officially recommended reference intakes. Criteria as applied to 'source' and 'good source' content claims for nutrients, i.e., based on a percentage of an officially recognised nutrient reference value, are therefore not similarly applicable to content claims for biologically active substances.

However, in order to ensure that a meaningful amount of the biologically active substance underpins the claim, the qualifying criterion of '10%' of prescribed 'per day reference intake' per serve that is applied to vitamin and mineral content claims, will also apply to claims around biologically active substances. That is, 10% of a self nominated 'per day intake' of the substantiated efficacious 'per day' amount will need to be present in the food. It is recognised that the 'per day' amount may differ according to the claim, and because it will be self nominated, potentially between products. However this information will be required on the label and thus transparent to consumers.

Furthermore, FSANZ recommends at Draft Assessment that a claim can be made to the effect that a food only 'contains' or is a 'source of' a biologically active substance and should not characterise the level of the substance in that food as being in greater amounts, such as, 'good source', or 'rich in'. The amount of that substance per serving is to be stated in the nutrition information panel.

This approach is consistent with the regulation of nutrient claims, and aims to give consumers confidence in the validity of general level health claims based on biologically active substances. It is also in the interest of manufacturers that general level health claims relating to biologically active substance are only placed on products that can deliver the promised health effect.

3.5.6 Rationale For Substantiation For General Level Health Claims For Biologically Active Substances

As for other general level health claims, the evidence for the substantiation of the claim is to be held by manufacturers. This is consistent with the approach suggested by many submissions and with the general approach taken for substantiation of general level health claims (refer to Attachment 8).

Currently, there are no suitable biologically active substance function statements on the pre-approved list of nutrient function statements (refer to Attachment 8). Furthermore, substantiation based on authoritative, generally-accepted information sources outlined by the substantiation framework for general level claims (refer to Attachment 8) are currently unlikely to provide enough appropriate evidence for substantiation of general level health claims based on biologically active substances.

To make general level health claims for biologically active substances credible, substantiation of such claims must be rigorous and determine with confidence that the evidence shows consistent associations that are likely to stand the test of time. This requires a structured approach, evidence of suitable quality, and a required intake that is achievable in the context of a relevant healthy diet. Substantiation of general level health claims for biologically active substances can be achieved by carrying out a comprehensive review of the available evidence, or based on existing reviews of the evidence conducted by authoritative bodies (refer to Attachment 8).

The substantiation process must identify the amount of a biologically active substance required per day in order to achieve the health effect. Consideration also 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.

In determining a reasonable amount of a food or component that should be present in a serve of a food, it is necessary to take into account a number of factors. These include the distribution of the food or component in foods, any specific target group needs the existing requirements of the Code, and any safety issues that may be associated with particular levels (refer to Attachment 8).

3.5.7 High Level Claims For Biologically Active Substances

FSANZ proposes pre-market assessment for high level claims. This approach is adequate for the regulation of high level claims based on biologically active substances. This is consistent with the majority of submissions, which supported appropriate criteria for biologically active substances. It is also consisted with the Policy Guidelines, which require a process of substantiation that aligns the level of evidence with the level of claims.

3.6 Proposed Approach At Draft Assessment

FSANZ recommendations for the regulation of content claims, general level health claims and high level claims for biologically active substances are given below.

The recommendations have been summarised in Figure 6.1.

The recommendations aim to strike a balance between the established presence of such claims in the market place, public health and safety, the consumer's ability to make an informed choice, health benefits from claims and the ability of industry to market innovative food products. Due regard has been given to submissions, the Policy Guideline, expert advice, the literature on biologically active substances, regulation in other jurisdictions, and the wider context of the role and responsibilities of FSANZ when developing standards.

3.6.1 Content Claims For Biologically Active Substances

- The presence of biologically active substances in a food can only be claimed in the form of a 'presence' type ('contains', 'with' and synonyms thereof) content claim.
- The amount present within the food must be stated in the nutrition information panel.
- Claims that imply that a food is a 'good source' ('high in', 'rich in', and synonyms thereof) of a biologically active substance are not permitted.
- Comparison statements are not permitted.
- Content 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.
- A content claim for a biologically active substance triggers the requirement to include the %DI of energy supplied by a serving of the food in the nutrition information panel.

3.6.2 Substantiation of content claims

- The only substantiation requirement for content claims is determination of the level of the component in the food.

3.6.3 General Level Health Claims For Biologically Active Substances

- Claims that imply that a food is a 'good source' or equivalent, or comparison statements such as 'reduced' or 'increased' are not permitted for general level health claims based on biologically active substances.
- Amount present within the food must be stated in the nutrition information panel as specified in standard 1.2.8.
- 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.
- 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.
- A general level health claim for a biologically active substance triggers the requirement to include the %DI of energy supplied by a serving of the food in the nutrition information panel.

3.6.4 Criteria for general level health claims

- Any generic disqualifying criteria that apply to general level health claims will also apply in relation to claims based on biologically active substances.
- Ten per cent (on a per serve basis) of the amount of the substance that provides the claimed health effect in the context of a healthy diet including a variety of foods needs to be present in the food to allow a general level health claim.

3.6.5 Substantiation of general level health claims

- Substantiation of general level health claims based on biologically active substances has to occur as outlined by the Substantiation Framework for General Level Claims.
- In determining a reasonable amount of a food or component that should be present in a serve of a food, it is necessary to take into the following into account: Distribution of the food or component in foods, any specific target group needs, existing requirements of the Code, and safety issues that may be associated with particular levels.

3.6.6 High Level Claims For Biologically Active Substances

- High level claims based on biologically active substances are treated as all other such claims.

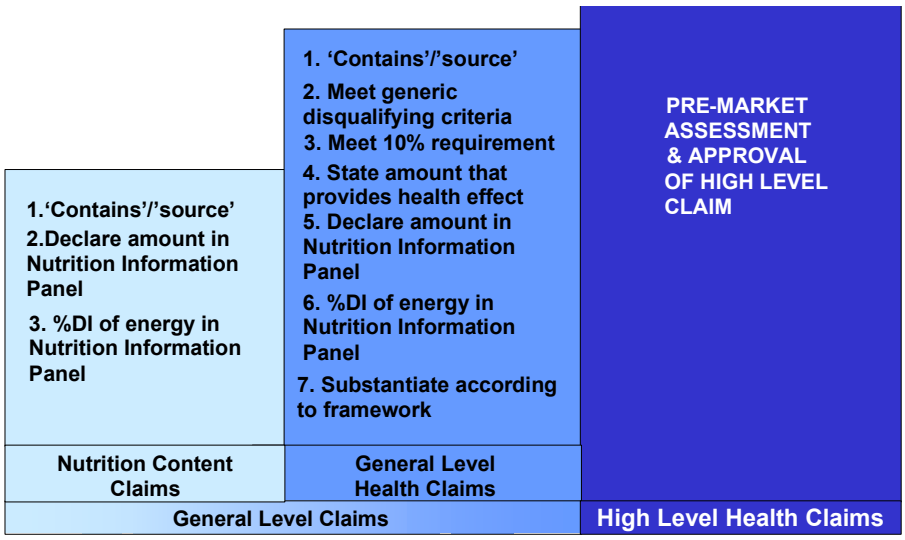

Figure 6.1: Requirements for content claims, general level health claims, and high level health claims based on biologically active substances

Chapter 4: Dietary Interaction Claims

4.1 Summary of Proposed Approach At Draft Assessment

- Synergist or antagonist claims must contain reference to the component and to the target substance.
- Qualifying and disqualifying criteria relate to the synergist or antagonist.
- The target substance does not have to be present in the food but must be able to be consumed in the normal diet at levels sufficient to have the desired health effect.

4.2 Background

Currently many health claims, including nutrition content claims, are based on a scientific consensus of well-established diet-health relationships. In the context of the health claims framework, this is often seen in claims based on the direct effect a particular dietary intake of a nutrient achieving a substantiated health effect.

Dietary interaction claims are claims based on the effect of a nutrient or substance on a target substance or nutrient (this may be a synergistic or antagonistic type of action). The health effect then arises as a result of the target substance or nutrient.

Dietary interactions may occur in the intestinal lumen and during utilisation or storage of nutrients. A large number of such dietary interactions have been described in the literature (Caballero, 1998). Many publications in this area focus on nutritional deficiencies caused by the antagonistic action of food components. The conditions reported to contribute to nutritional deficiencies from dietary interactions include: diets high in non-refined foods, drug-nutrient interactions and inadequate food intake in vulnerable populations.

Deficiencies due to dietary interactions are unlikely to be a concern in a healthy diet consisting of a variety of foods. However, Dietary Interaction Claims that promise a desired health effect by increasing the ability of a food component such as a nutrient to be readily absorbed, distributed and utilised in the body (Elwood, 1992) (bioavailability) or activity of nutrients or other substances are becoming common. In a recent comparison of market trends with nutrition science underpinning formulations, 'enhancing biological availability' was included in the top category (Tapsell, 2005).

Like other claims, Dietary Interaction Claims may relate to a positive contribution to health, improvement of a function, or modification, or preservation of health. As for biologically active substances, there are no well-established criteria, at least for the part of the claim that describes the dietary interaction. However, the part of the claim linking the secondary substance or nutrient to the health effect may be a well-established dietary intake-health effect relationship. Substantiation and regulation of Dietary Interaction Claims is complex because the health effect becomes removed from the ingredient to which the claim refers and may be achieved through a substance or food not present in the food carrying the claim.

FSANZ is establishing a regulatory framework in relation to health claims. Consideration of Dietary Interaction Claims is required to determine whether such claims need to be regulated differently to other health claims. This is to ensure that the framework allows for a wide range of innovative claims. This approach is consisted with the Policy Guidelines, which encourages the responsible use of scientifically valid nutrient, health and related claims, promotes innovation and requests FSANZ to be responsive to future trends and developments.

4.3 Definitions And Example Claims

A Dietary Interaction Claim has three parts: *Synergist*/*Antagonist*, specific *target substance,* and specific *health effect.*

There are two types of Dietary Interaction Claims. Firstly, claims that that the presence, or increased presence, of a substance or nutrient affects the bioavailability or activity of a target substance to achieve a health effect (*synergism claims*). Secondly, claims that the absence, or reduced presence, of a substance in a food affects the bioavailability or activity of a target substance to achieve a health effect (*antagonism claims*). The general structure of both types of claims, together with examples is presented in the box below.

(1) Synergism Claims
Increased level of ***Synergists*** present (including *source*, *good source*, or *increased content,* as appropriate) in a food enhance the bioavailability or activity of a specific ***target substance*** to achieve a ***health effect***
OR decrease the bioavailability or activity of a specific ***target substance*** to achieve a ***health effect***

Example:
[This food] is an excellent source of Vitamin C. A healthy diet high in Vitamin C increases the availability of iron from a diet including iron rich foods. Iron contributes to normal blood formation.

(2) Antagonism claim
Decreased level of ***Antagonists*** present (including *free, low, reduced,* as appropriate) in a food enhances the bioavailability or activity of a specific ***target substance*** to achieve a ***health effect*** OR decrease the bioavailability or activity of a specific ***target substance*** to achieve a ***health effect.***

Example:
[This food] is low in phytates (X% reduced, less than y g per serve). Consuming foods with phytate content reduced by at least Z% as part of a healthy diet increases the availability of zinc. Zinc contributes to the normal structure of skin.

4.4 Current Regulations

In the United Kingdom, the Joint Health Claims Initiative has released the Code of Practise on Health Claims of Food (JHCI, 1995), which considers claims based on synergistic benefits to be acceptable. However, the benefit from the health claim must be entirely derived from the food, and not from consuming the food with other foods, even if this is the intended mode of consumption. In Europe, foods that carry claims based on dietary interactions are classified as functional foods (Ashwell, 2002). In the USA, synergistic effects have been discussed in the context of isolating the health effects of specific foods (Institute of Food Technologists, 2005), but no particular reference is made to health claims based on the synergistic or antagonistic effects of foods.

In Australia, Dietary Interaction Claims are currently not considered in the Code. However, any part of a Dietary Interaction Claim is subject to the relevant sections of the Code, e.g. Standards 1.2.8, 1.3.2, and 1.5.1.

Furthermore, any regulatory arrangements in regard to general level claims and high level health claims apply to all elements of a Dietary Interaction Claim, including special considerations such as the regulation of biologically active substances.

4.5 Assessment And Rationale

4.5.1 Rationale For Pre-Requisite Conditions

Unlike other claims, Dietary Interaction Claims rely on a food or substance other than the one against which a health claim is made to deliver the health effect.

To prevent misleading claims, the full chain of evidence has to be presented to the consumer so that a clear connection can be made. Therefore, all three elements of the claim must be specified, i.e. the synergist/ antagonist, the target substance and the health outcome.

4.5.2 Rationale For Substantiation

All three elements of a Dietary Interaction Claim must be substantiated at the appropriate level (refer to Attachment 8) i.e. the effect of the synergist on the target substance and the effect of the target substance on the health effect. The first element involves substantiating the effect of the synergist on the specified target, e.g. 'substance x increases the availability or iron' and not 'substance x increases nutrient absorption'. The substantiation of the second element links the health effect to the target substance e.g. 'substance x increases the availability of iron. Iron contributes to normal blood formation',

There is a risk that the health effects promised by Dietary Interaction Claims may depend on a diet not ordinarily eaten by most consumers, or on unreasonable changes in consumption patterns, i.e. a synergist that increases the bioavailability of a target substance only present in a food that is not part of the normal healthy diet, or that relies on a diet unusual in some other respect. The substantiation therefore also needs to demonstrate that the health effect is achievable in the context of a normal healthy diet.

4.5.3 Rationale For Criteria

To be consistent with other claims, appropriate qualifying and disqualifying criteria and conditions should be applied to Dietary Interaction claims. Therefore, the generic disqualifying criteria and conditions that apply to all other general level health claims also apply to Dietary Interaction Claims, and high level claims based on dietary interactions will have to undergo pre-approval.

All general level health claims are underpinned by content claims. This should also be the case for Dietary Interaction Claims. To be consistent, the criteria and conditions applied to ordinary content claims should also be applied to Dietary Interaction Claims. Therefore, all qualifying and disqualifying criteria and conditions that apply to nutritional content claims apply to the synergist/antagonist, i.e. the property of the food that carries the Dietary Interaction Claim.

Dietary Interaction Claims are based on a content claim in regard to the synergist/antagonist. The presence of the target is not relevant in this context, because the target may not be present in the delivery vehicle. The synergist/antagonist may act on a target substance supplied from a variety of foods, i.e. the delivery vehicle for a prebiotic may not contain calcium, but may increase the bioavailability of calcium from dairy products that can be reasonably expected to form part of a healthy diet.

Allowing a claim, even if a target is not present in the delivery vehicle, allows for a range of innovative claims. However, there is a danger that the health effect promised by such claims may depend on a diet other than a healthy diet consisting of a wide variety of food. It therefore needs to be specified that the target has to be present in sufficient amounts in the healthy diet, and that the health effect triggered by the action of the target is obtainable by following a healthy diet and eating a wide variety of foods.

4.5.4 Rationale For Wording Conditions

To give the consumer appropriate information all three elements of the claim must be specified in the wording of the claim. To be consistent with other claims, the total dietary context must be included in the claim.

Generally, 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 the property of the food; or the property of the food and the specific health effect on the front of the package, so long as there is a statement that directs the consumer to the general level health claim which must be stated in it's entirety elsewhere on the package of food (refer to Attachment 5, Chapter 4, Section 4.8).

In the case of Dietary Interaction claims there is an additional element (the target) linking the property of the food (synergist/antagonist) with the health effect. Theoretically, the property of the food could be split from the rest of the claim. However, this would lead to claims that could be confusing to consumers. To avoid this, the claim may be split such that the property and target substance are presented together, without the health effect, but must then refer to the complete claim elsewhere on the label. For example, on the front of the pack the wording may be: *Contains selenium, which strengthens the activity of Vitamin E* and elsewhere on the pack: *Contains selenium, which strengthens the activity of Vitamin E when consumed as part of a healthy diet rich in Vitamin E.*

All other wording conditions apply to Dietary Interaction Claims in the same way as for other claims.

4.6 Proposed Approach At Draft Assessment

FSANZ recommends the following approach at draft assessment to the regulatory management of dietary interaction claims:

4.6.1 Pre-Requisite Conditions

- In order to qualify these claims need to meet the pre-requisite conditions required by the framework.
- In this context:

    a. the synergist/antagonist is the 'property' of a dietary interaction claim;
    b. the 'health effect' is the effect arising from the target substance; and
    c. all links in the chain need to be substantiated.

4.6.2 Substantiation

- To prevent misleading claims the full chain of evidence has to be presented to the consumer so a clear connection can be made and all links in the chain need to be substantiated.
- The substantiation needs to demonstrate that the health effect is achievable in the context of a normal healthy diet.

4.6.3 Criteria

- All qualifying and disqualifying criteria that apply to nutritional content claims apply to the synergist/antagonist.
- The generic disqualifying criteria for general level health claims apply.
- The target substance does not have to be contained in the delivery vehicle, but has to be present in sufficient amounts in the ordinary diet, and the health effect must be obtainable through ordinary consumption patterns.
- High level claims will be required to undergo pre-approval similarly to other high level claims.

4.6.4 Wording Conditions

- All three elements of the claim must be specified i.e. the synergist/ antagonist, the target substance and the health outcome.
- The claim may be split such that the property and target substance are presented together, without the health effect, but must then refer to the complete claim elsewhere on the label.
- The total dietary context must be included in the claim.

Chapter 5: Life Stage Claims

5.1 Summary of Proposed Approach At Draft Assessment

- Life stage claims will not be considered as a separate category of claim but will be regulated as other general level or high level health claims.

5.2 Background

The Policy Guideline does not specifically refer to 'life stage' claims.

FSANZ is aware of the potential for claims to refer to a life stage such as menopause or pregnancy. At Initial Assessment, FSANZ envisaged that claims that refer to 'normal' life stages such as pregnancy and menopause would be treated as general level claims, given that it was not the intent that 'normal' life stages should be captured by the definition of 'serious disease'. FSANZ therefore asked submitters to comment on whether there are there any unintended impacts of regulating claims that refer to 'normal' life stages as general level claims.

5.3 Relevant Issues Raised In Submissions

Of the respondents to this question, some submitters indicated that they were not aware of any unintended impacts of regulating normal life stage claims as general level health claims, with some also commenting that claims should be accurate, substantiated and not be presented as a disease state or condition. It was also noted that life stage claims should be permitted as these types of claims simply target a product to a particular population group to provide nutritional benefits.

Some submitters raised concerns regarding the applicability of health claims to different life stages. For example, nutrients targeted towards one population group may not be appropriate for other groups. Others stated that life stage claims have the potential for 'medicalisation' of the food supply, resulting in a range of products to 'treat' symptoms of normal physiological changes.

Several submitters commented that life stage claims could be classified as either a general level health claim or high level claim depending on the nature of the claim, rather than being based on the life stage itself. For example, in relation to menopause, hot flushes could be considered as non-serious, while osteoporosis would be considered as a serious disease.

Several submitters sought clarification on the types of claims and conditions that could be considered as normal life stage claims.

Two submitters recommended a prohibition on life stage claims or that life stage claims should be pre-approved as high level claims.

5.4 Assessment And Rationale

Life stage claims can be considered in a continuum of claims ranging from those that refer to different life stages, such as puberty, menopause and old age and associated symptoms, through to serious diseases associated with different life stages. For example, puberty can be associated with minor skin conditions through to severe acne, while old age can be associated with conditions such as hair loss through to serious diseases such as age-related macular degeneration.

FSANZ therefore considers that the life stage itself should not determine whether a claim is classified as a high level claim or a general level health claim, but that classification of a claim that refers to a life stage should be based on whether the claim refers to a biomarker or serious disease (the draft definitions of biomarker and serious disease are discussed in Attachment 9). This approach is consistent with the Policy Guideline, which differentiates between high level claims and general level health claims on this basis, and is also supported by submitters' comments. It is not considered appropriate to treat all life stage claims as high level claims, given that life stage claims could potentially refer to a broad spectrum of conditions ranging from non-serious to serious diseases.

Claims that refer to a life stage will be required to comply with all conditions for making a general level health claim or high level claim, as appropriate (refer to Attachment 5, Chapters 3, 4 and 5) For example, where the health effect relates to a specific population group, the general level health claim will be required to state the specific population group to which the health effect relates. FSANZ considers that these conditions, together with the prohibition on making therapeutic claims will address submitters' specific concerns regarding life stage claims.

5.5 Proposed Approach At Draft Assessment

FSANZ has identified the following recommendation at draft assessment in relation to life stage claims:

- life stage claims will not be considered as a separate category of claim but will be regulated in accordance with the Claims Classification Framework;
- claims that refer to a biomarker or serious disease will be regulated as high level claims while those that do not refer to a biomarker or serious disease will be regulated as general level health claims.

Chapter 6: Weight Management Claims

6.1 Summary of Proposed Approach At Draft Assessment

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

6.2 Background

The Policy Guideline is silent with respect to 'slimming'/weight management claims.

Clause 2, Standard 1.1A.2 Transitional Standard - Health Claims states that the label on or attached to a package containing or an advertisement for food shall not contain a claim or statement that a food is a slimming food or has intrinsic weight reducing properties.

Given this existing prohibition on 'slimming' claims, FSANZ considered it important to raise the issue of 'slimming' claims at Initial Assessment. Specifically, FSANZ sought comments from submitters on how such claims should be regulated and to provide rationale and supporting evidence for their views.

6.3 Relevant Issues Raised In Submissions

The majority of submitters (mainly from industry) considered that 'slimming' claims should be permitted, and regulated as either high level claims or general level claims, as appropriate. Support for slimming claims focused around the following arguments:

- body weight is a physiological condition, therefore a food that claims to assist in weight management would require substantiation and be expressed in the context of an appropriate total diet;
- weight loss is a concern for a large percentage of the population and individuals are seeking clarity about foods that are appropriate for their weight loss goals. In the absence of clarity on food labels, consumers may turn to inappropriate foods or foods having undesirable nutritional profiles for weight loss; and
- 'slimming' claims offer the food industry the opportunity to support government initiatives in tackling obesity, by increasing the availability of 'healthy' foods with less calories and reduced portion sizes.

Some submitters considered that if permitted, 'slimming' claims should be regulated as high level claims as they reference overweight and obesity, which are serious diseases and are biomarkers for other serious diseases such as cardiovascular disease and diabetes.

Other submitters, mainly public health professionals and governments, considered that 'slimming claims' should be prohibited. These submitters commented that no single foods have intrinsic weight reducing properties and that weight loss relates to the overall energy balance of the diet. Therefore, 'slimming' claims have great potential to mislead consumers.

Several submitters recommended that certain conditions be met in order to make a 'slimming' claim. These included:

- claims must be written in terms of the specific role of the product in the context of an appropriate total diet or other appropriate context; and
- information about the contribution of a serving of the food to daily energy requirements should be included.

6.4 Assessment And Rationale

FSANZ's approach to the regulation of weight management claims as either a high level claim or a general level health claim is consistent with the Policy Guideline which differentiates between two levels of claims, high level claims and general level claims, on the basis of whether they refer to a biomarker or a serious disease. In line with the Policy Guideline, FSANZ has developed definitions of biomarker and serious disease (refer to Attachment 9). Obesity is included in the definition of 'serious disease' but overweight is not. Therefore, a claim that refers to obesity will be regulated as a high level claim, while a claim that refers to overweight will be regulated as a general level health claim.

At a minimum, weight management claims will be regulated as general level health claims and, as such, they must be substantiated according to the substantiation framework for general level health claims, and meet all the requirements of a general level health claim, as discussed in Attachment 5, Chapters 3 and 4). The general level health claim requirements, as they relate to weight management claims, are discussed below.

6.4.1 Qualifying Criteria

FSANZ has recommended that the qualifying criteria be consistent with those recommended for a 'low calorie/joule/energy' content claim (refer to Part 1, Chapter 6) namely, less than or equal to 80 kJ per 100 mL of liquid foods, or less than or equal to 170 kJ per 100 g of solid or semi-solid foods. For claims in relation to 'calories' the declaration of energy in the nutrition information panel must be expressed as calories as well as kilojoules.

Given that the overriding factor in weight management is overall energy balance, FSANZ considers that the use of qualifying criteria based on energy content should be used for weight management claims. In this regard, FSANZ is recommending that the 'low joule' criteria be used.

6.4.2 Disqualifying Criteria

FSANZ has recommended that weight management claims be subject to the proposed generic disqualifying criteria for general level health claims, as follows:

- sodium – 325 mg/serve;
- saturated fat – 4 g/serve; and

- total sugars – 16 g/serve.

This approach is consistent with the approach taken to apply generic disqualifying criteria to other general level health claims. The rationale for imposing disqualifying criteria in relation to general level health claims is outlined Attachment 5, Chapter 3, Section 3.6).

6.4.3 Requirement For Inclusion Of Percentage Daily Intake Information

FSANZ has recommended that the percentage daily intake/serve (%DI) for energy and the claimed nutrient(s) must be included in the nutrition information panel when any content claim, general level health claim or high level claim is made (refer to Attachment 5, Chapter 2, Section 2.6). In terms of weight management claims, this means that, at a minimum, the %DI for energy must be included in the nutrition information panel, as energy is the claimed nutrient and is also a mandatory requirement.

The inclusion of %DI information will provide additional information to consumers, allowing them to relate the energy content in a serving of the food to a targeted daily intake. This point was also raised in comments by several submitters.

6.4.4 Wording Conditions

Attachment 5, Chapter 4 outlines the general conditions that are to apply to the wording of general level claims, (with the exception of content claims), together with supporting rationale. These conditions are: that the claim must state the property of the food; and 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 through the consumption of a variety of foods, as appropriate to the type of food and specific health effect claimed. For consistency purposes, these conditions should also apply to weight management claims.

6.5 Proposed Approach At Draft Assessment

FSANZ has identified the following recommendations at draft assessment in relation to weight management claims:

- the term ‘weight management
- claims’ refers to claims that include weight loss and weight maintenance;
- weight management claims will be permitted and regulated in accordance with the Claims Classification Framework;
- claims that refer to a biomarker or serious disease will be regulated as high level claims while those that do not refer to a biomarker or serious disease will be regulated as general level health claims;
- the following criteria and conditions will apply to weight management claims that are regulated as general level health claims:

    a. the food will be required to meet the qualifying criteria of ‘low calorie/joule/energy’;
    b. the food will be required to meet the generic general level health claim disqualifying criteria;
    c. the percentage of the Daily Intake (%DI) of energy that is contributed by one serving of the food;

d. the claim will be required to state the property of the food (i.e. energy), 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; and
e. the claim will be required to state the importance of regular exercise.

Chapter 7: Glycaemic Index And Glycaemic Load Claims

7.1 Summary of Proposed Approach At Draft Assessment

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

7.2 Background

Glycaemic Index (GI) and Glycaemic load (GL) relate to the effect on blood glucose levels in response to carbohydrate in foods, and does not specifically relate to a nutrient or a biologically active substance, nor does it have units of measurement. For these reasons, GI and GL do not easily fit into the health claims classification framework.

7.2.1 Glycaemic Index

The GI is a measure of the blood glucose response to carbohydrate in a food as a percentage of the response to an equal weight of glucose. For foods containing the same amount of carbohydrate, the GI indicates what effect the food will have on an individual's blood glucose levels. Foods with a high GI contain carbohydrates that are quickly digested and absorbed, and low GI foods contain carbohydrates that break down slower.

Recently, significant attention has been paid to GI as a result of its connection with weight control and the effect it has on the body's blood sugar levels. While a low GI food may help control diabetes and the body's sensitivity to insulin, high GI foods are thought to be helpful in quickly replenishing the body's carbohydrate stores after exercise, or when blood glucose levels fall below normal in people with diabetes, especially insulin dependent diabetes.

7.2.2 Glycemic Index Symbol Program

The Glycemic Index Symbol Program is an endorsement program that was launched in Australia by Glycemic Index Limited (a non-profit company, whose members are the University of Sydney, Diabetes Australia and the Juvenile Diabetes Research Foundation) in July 2002. The GI Symbol Program involves the use of a recognised symbol, 'G - Glycemic Index Tested' on licensed food products, the statement of the GI value on food labels, and a consistent explanation of the GI.

To be eligible for the program, foods must not be high in fat, particularly saturated fat, must be moderate in sodium content, must be a source of dietary fibre (where appropriate), and must have a nutritional composition that meets the required nutrient criteria for the relevant food category. Certain foods are excluded, such as high and intermediate GI soft drinks, cordials, syrups, confectionery and sugars. Additionally, the GI of the food must be determined by the Sydney University Glycaemic Index Research Service or other approved laboratory, using the Glycemic Index Symbol Program's standardised *in vivo* procedure.

Their criteria for GI are:

- high GI ≥70;
- medium GI = 56–69; and
- low GI <55.

7.2.3 Proposed Regulation Of GI Endorsement Programs

Attachment 5, Chapter 6 of the Draft Assessment Report outlines FSANZ's approach to the regulation of endorsement programs within the context of Proposal P293. As part of this approach, FSANZ will be pre-approving those current endorsement programs that fit within the definition of 'endorsement' as proposed in the draft standard, and providing the nutrition criteria used by the endorsement program are consistent with Australian and New Zealand nutrition policy principles. FSANZ is recommending that the Glycemic Index Symbol Program be pre-approved within this system.

7.2.4 Standardisation Of Determination Of GI

Standards Australia, a non-government standards development body, is currently developing a Standard for the determination of GI in foods. One of its objectives in standardising the analytical method is to discourage the use of less rigorous methods of testing that may result in unreliable GI values.

7.2.5 Glycaemic Load

GL is a measure of the relative amount that blood glucose levels will change after a serving of a food (Liu et al. 2003; Munro 2004). GL is calculated by multiplying the GI with the amount of carbohydrate in the food, divided by 100. While GI describes the qualitative effect of a food on blood glucose levels, GL also considers the quantity of the carbohydrate available from the food.

GL is divided into three categories with Glycaemic Glucose Equivalents (GGEs) as units (University of Sydney, 2005):

- low 0–10 GGEs;
- medium 11–19 GGEs; and
- high 20 GGEs.

The categories indicate the effect of one serve of food on blood glucose levels. New Zealand Crop and Food Research proposes that GL is only applied to foods that have general nutritional benefits, are low in saturated fat and meet established nutritional guidelines.

At this stage, FSANZ is not aware of any claims being made in relation to the GL of a food, nor to the existence of any endorsement programs in relation to GL.

7.2.6 Comparison Of Relative Values In Foods As Consumed

GI is based on glycaemic carbohydrate only, not on the response of the whole food. Because foods contain differing amounts of carbohydrate, ranking foods by GI will not necessarily rank them according to the effect they have on blood sugars. For example, if the GI of an apricot is 57 and the GI of a banana is 58, it would be assumed that if an individual ate either of these it would result in the same blood glucose response. However, an apricot has only 5 g of available carbohydrate and a banana has 31 g; an apricot weighs approximately 50 g and a banana weighs approximately 130 g. As a result, the banana will raise blood glucose levels six times higher than an apricot will because it contains six times more carbohydrate and is over double the size of the apricot. Therefore, GL effectively communicates the 'actual' blood glucose impact of the food to a consumer, as consumed. For example, the GL of banana is 18 and the GL of an apricot is 3.

In addition, as GI is expressed as a ratio it does not change with food intake. Therefore, a muesli bar has the same GI whether the person eats 50 g of the bar or 150 g, whilst the impact on blood glucose for 150 g of the bar should be three times the impact of 50 g of the bar. GL addresses this aspect by measuring the glycaemic impact of the whole food, rather than just the carbohydrate portion. GL is the weight of glucose that will induce the same glycaemic response as a given weight of food. As GL is not just a ratio, it is responsive to changes in food intake and, as it measures the blood glucose response of the whole food, it can be used to compare foods containing different amounts of carbohydrates.

7.3 Relevant Issues Raised In Submissions

At Initial Assessment, FSANZ sought feedback from submitters on how GI and GL claims should be regulated, including what provisions should apply in relation to the declaration of GI.

There were mixed views from submitters regarding how GI and GL claims should be regulated. A small number of the respondents to this question considered that GI and GL were content claims, whilst the remaining submitters had opposing views. The main reasons provided for not considering GI and GL as content claims revolved around the fact that they are indicators of an effect on the body, rather than just the 'content' of a food.

Several submitters suggested that GI and GL are more appropriately termed nutrition function claims, while others considered that GI and GL should be considered as biomarkers, as they relate to the effect on blood glucose. Two submitters were undecided as to where these types of claims fit into the Claims Classification Framework, and a further two submitters did not consider that GI and GL claims should be captured by the regulatory system for health claims at all.

In terms of qualifying and disqualifying criteria, several submitters recommended that there should be a minimum level of total carbohydrate in the food. It was also noted that the GI Tested Program has established disqualifying criteria for total energy, total and saturated fat and sodium; and qualifying criteria for total carbohydrate (10 g/serve), dietary fibre and calcium in appropriate food categories.

Some submitters commented on the merits of GL versus GI, noting that GL is a more accurate measure of likely blood glucose response than GI as it takes into account serving size and therefore total glycaemic load. Also, it can be readily incorporated into the nutrition information panel. By comparison, others considered that GL is potentially problematic as the average GL of a diet can be lowered by decreasing the amount of total carbohydrate despite still eating high GI foods. This can lead to potential health risks such as type 2 diabetes and other chronic diseases.

Several submitters stated that clarification/definition of testing methodologies for GI or GL is required, with some of these submitters recommending that GI should be tested using methodology in accordance with Standards Australia.

7.4 Assessment And Rationale

The risk management approach outlined in Attachment 5, Chapter 2, Section 2.3 takes account of whether there are specific public health recommendations in relation to the property under consideration and also whether consumers are being misled.

Both the Australian and New Zealand guidelines discuss GI and its place within dietary recommendations. The New Zealand guidelines refer to the value of low GI foods for people with diabetes to enable them to maintain blood glucose within the normal range, but also reference studies showing a beneficial effect in people with hyperlipidemia, and people with and without diabetes. They conclude that the GI of foods needs to be evaluated in conjunction with other dietary constituents and recommendations.

The Australian guidelines state that lower GI diets may possibly be protective against both diabetes and heart disease, and low-GI diets may help with weight control. They recommend achieving a lower GI diet through consumption of slowly digested cereal foods.

Neither of these guidelines, or any international ones, defines the criteria for low GI. Thus, whilst there are public health recommendations in relation to GI, these are insufficient to allow FSANZ to set criteria. Taking into account the risk management model the FSANZ recommendations presented below are therefore based on a need for qualifying criteria for GI/GL.

7.4.1 Statement Of GI And GL Only

A statement of the GI or GL of a food, without a reference to a health claim, is considered as a nutrition content claim. In the absence of any criteria for making GI or GL claims, the GI/GL might be expressed as an index (i.e. a numerical value), a relative descriptor such as ‘reduced’, ‘low’, ‘medium’ or ‘high’, or an index and a descriptor.

At present, there are no nationally recognised reference values for GI or GL. Descriptors such as ‘low’, ‘medium’ or ‘high’ imply that there is an accepted range of GI/GL values, whereby a food is classified as being a ‘low’, ‘medium’ or ‘high’ GI/GL food. The use of these terms is potentially misleading, as consumers are unable to verify or assess such a claim, or choose between comparable foods making such a claim.

While it could be argued that a GI/GL numerical value on its own is not meaningful to consumers, it could be reasonably expected that those individuals who are seeking low GI/GL foods for health reasons would be under the care of health professionals and would be able to ascribe meaning to these values.

FSANZ therefore considers that GI/GL claims should only refer to a numerical value or index and that descriptor terms should not be permitted. This is consistent with the approach recommended for biologically active substances to not permit the use of 'good source', 'high in' or similar terms, where nationally recognised reference values do not exist. Should reference values for GI/GL become available in the future, the Standard could be amended to accommodate the use of descriptor terms.

As GI/GL is not a nutrient or biologically active substance, it is not appropriate that a declaration be made in the nutrition information panel.

A requirement for the declaration of percentage daily intake (%DI) for energy in the nutrition information panel when a GI/GL claim is made is consistent with the approach taken for other nutrition content claims. No further declaration of %DI is required as GI/GL is not a nutrient and therefore does not have agreed reference values.

7.4.2 GI And GL Claims That Are Linked With An Endorsement

As discussed in Attachment 5, Chapter 6, FSANZ has proposed that a separate framework apply to the regulation of endorsements. Under this framework, current endorsement programs that are pre-approved by FSANZ will be exempt from the requirements of the Nutrition, Health and Related Claims Standard. New endorsements, which may also be accompanied by a nutrition content claim or health claim, will need to comply with specific elements of the Claims Classification Framework, as specified in the Standard. This is in addition to complying with the relevant criteria that have been established by the endorsing agency as part of their endorsement program.

Given that a separate regulatory framework has been established for endorsements, FSANZ considers that GI and GL claims that are made in conjunction with an endorsement, be regulated in accordance with the endorsements framework.

7.4.3 GI And GL Claims That Are Not Linked To An Endorsement

FSANZ considers that GI and GL claims that are not linked to an endorsement should continue to be permitted. While there are no specific public health recommendations in relation to the consumption of low, medium or high GI foods, there is some evidence of health benefits associated with a lower GI diet.

GI and GL claims that are not linked to an endorsement can be expressed as a statement of the GI or GL on the label (content claim) or a statement of the GI or GL, which is also coupled with a health claim (general level health claim or high level claim).

7.4.4 Statement Of GI And GL Coupled With A Health Effect

These claims will be regulated as either general level health claims or high level claims, depending on the nature of the claim, that is, whether the claim refers to a biomarker or a serious disease. This approach is consistent with the Policy Guideline, which differentiates between general level health claims and high level claims on this basis.

A general level health claim in relation to GI or GL will be required to comply with the general conditions for making a general level health claim. This approach is deemed necessary for consistency with other general level health claims. As general level health claims are based on content claims, the reference to the property of the food (i.e. GI/GL) can only be made in the form of a numerical value. The rationale for this approach has been discussed previously under content claims.

7.5 Proposed Approach At Draft Assessment

At draft assessment, FSANZ is recommending the following approach to the regulation of GI and GL claims.

- **GI and GL claims that are linked with an endorsement,** as defined in the draft Standard, will be considered in accordance with the conditions relating to the regulation of endorsements. These conditions are outlined in Attachment 5, Chapter 6.
- **GI and GL claims that are not linked with an endorsement,** as defined in the draft Standard**,** will be considered in terms of whether:

    - the claim refers to a GI or GL index only; or
    - the claim refers to a GI or GL index and a health effect.

- **If the claim refers to a GI or GL index only** it will be regulated as a content claim as follows:

    a. the GI or GL can only be claimed in the form of an index (e.g. GI = 35);
    b. descriptor terms such as ‘reduced’, ‘ low’, ‘medium’ or ‘high’ GI or GL will not be permitted;
    c. a declaration of the percentage daily intake (%DI) for energy is required in the nutrition information panel.

- **If the claim refers to a GI or GL index and a health effect**, it will be regulated as either a general level health claim or high level claim, depending on the nature of the claim made. In addition to meeting the regulatory requirements for content claims above, the following conditions will apply to general level health claims:

    a. the food will be required to meet the generic general level health claim disqualifying criteria;
    b. the claim will be required to state the property of the food (i.e. GI or GL), 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;
    c. the claim will need to meet the general level health claim substantiation framework;
    d. high level claims will be subject to pre-market assessment and approval by FSANZ.

Chapter 8: Whole Food Claims

8.1 Summary of Proposed Approach At Draft Assessment

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

8.2 Background

General level health claims in relation to whole foods are an important aspect of the regulatory framework for general level claims that FSANZ needs to address.

The proposed pre-requisites for nutrition and health claims are that they:

1. be substantiated according to the substantiation framework;
2. make reference to a specific 'component' of the food; and
3. other than nutrition content claims, make reference to specific benefit.

Health claims in relation to whole foods do not meet the second claim pre-requisite. There could be substantiated evidence of a health effect of a whole food while there is a lack of evidence on the specific component responsible for the effect. Alternatively, consumption of the whole food could have an effect that is greater than the effect of a single component of that food (food synergy; Jacobs and Steffen, 2003).

To provide more flexibility in making Whole Food general level health claims, the definition of Whole Foods covers foods that consist of at least 90% by weight of primary foods. Under Standard 1.3.2, 'primary food' means fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish. Foods defined as 'primary foods' are consistent with national nutrition guidelines.

8.3 Relevant Issues Raised In Submissions

At initial assessment FSANZ asked what factors would need to be taken in consideration in the regulation of general level health claims in relation to Whole Foods, and introduced the concept that such claims could be limited to where the food is a 'primary food'.

Some submitters provided responses in relation to this particular issue whilst others provided responses that related more to the regulation of general level health claims in general. In addition, some submitters misinterpreted the proposed application of the definition of 'primary foods', assuming that all foods, other than 'primary foods', would not be permitted to make any type of general level claim.

Some submissions from the public health sector considered that general level health claims in relation to whole foods should be permitted on foods that are consistent with the recommendations of national dietary guidelines in Australia and New Zealand. Other submitters suggested that general level health claims relating to whole foods should only be made where the food is a 'primary food' and credible research shows that the food is a good source of a nutrient, or consumption of the food assists with the prevention of disease.

However, most submissions from public health and government discussed the regulation around nutrition health and related claims in general and suggested that certain types of foods be prohibited from making claims, that qualifying criteria in relation to the concentration of nutrients or biologically active substances be developed and that disqualifying criteria relating to levels of saturated fat, sugar and sodium be established.

Some submitters indicated that all claims should be expressed in terms of the specific nutrient or biologically active substance that brings about the claimed benefit (i.e. calcium for strong bones as opposed to milk) and therefore general level health claims in relation to whole foods would not be permitted. It was also emphasised that the regulations need to be simple and realistic and that concepts such as 'claimable foods' becomes overly complicated.

The majority of submissions from industry put forward the view that for all foods, the substantiated benefits should be able to be claimed in relation to the whole food itself, or its ingredients or nutrients contained therein. Some submitters believed that general level health claims in relation to whole foods should not be limited to a pre-determined list such as those defined as 'primary foods'. Others queried the definition of 'primary food' versus processed foods and when one becomes the other and suggested that further guidelines on what constitutes a 'whole food' and 'primary food' are warranted.

8.4 Relevant International Approaches

Canada does not permit biological role claims (equivalent to general level health claims) in relation to food. They can only be made in relation to energy value or nutrients in a food. According to The Canadian Food Inspection Agency (Canadian Food Inspection Agency, 2003) an unacceptable biological role claim is 'Milk helps build strong bones and teeth', whilst the claim 'Milk is an excellent source of calcium which helps build strong bones and teeth' is acceptable. Therefore, the Canadian regulatory framework requires claims to state the specific component of the food as part of a claim.

8.5 Assessment And Rationale

8.5.1 Rationale For Criteria And Conditions

Comments from submitters, the Policy Guideline, and Australian and New Zealand nutrition guidelines, indicate that the consumption of whole foods provides a range of benefits to individual consumers, and to public health. It is therefore desirable that general level health claims based on the consumption of whole foods be possible within the Health Claims Framework.

To allow Whole Food general level health claims within the regulatory framework requires the exemption of such claims from the prerequisite condition that a health claim makes reference to a specific component of the food (refer to Attachment 5, Chapter 1).

However, the prerequisite conditions that require a claim to be substantiated according to the substantiation framework, and to make reference to a specific health effect apply to all general level health claims, including those made in reference to a Whole Food.

The approach to regulating general level health claims of Whole Foods aims to balance the potential health benefits against the potential negative health effects of foods that are inconsistent with national dietary guidelines in Australia and New Zealand, i.e. foods that contain undesirable levels of saturated fat, sodium or energy. This concept is consistent with the Policy Guideline, and was supported by a number of submissions. It also provides a consistent regulatory approach to all general level health claims.

This approach would allow some processed primary foods to carry a Whole Food general level health claim. However, because the generic disqualifying criteria apply, foods with high sodium, saturated fat or sugar content would not be able to make a claim.

The Policy Guideline states that claims must not imply that a healthy diet is reliant on the inclusion of a single food. There is the possibility that a Whole Food claim could mislead consumers by implying that a health effect of a food is unique to the particular brand or type of product. Therefore, limitations are placed around the use of general level health claims in relation to whole foods to prevent these claims being made with regard to specific foods, products or brands. The wording of the claim needs to make clear that the claim refers to the whole class of similar food not to the particular food making the claim. general level health claims in relation to Whole Foods should be worded such that the generic primary food type e.g. ‘apples’ is referred to in the claim rather than specific brand names such as ‘Bloggs apples’.

8.5.2 Rationale For Substantiation

The approach for substantiating general level health claims has described in the substantiation framework for general level claims (refer to the Substantiation Framework at Attachment 8). To ensure the consistency of the substantiation framework, Whole Food general level health claims need to be substantiated using the same options available to claims based on the specific property of the food.

Because general level health claims based on Whole Foods are considered to be a special case they are exempt from some of the requirements applying to other claims. The basis of this exemption is evidence that the health effect is only achievable by the action of the whole food, rather than individual components of that food. While the health effect may well have been substantiated for the whole food, sufficient evidence (refer to the Substantiation Framework at Attachment 8) that the effect is linked to a specific component voids the exemption from the requirement to include a specific property of the food.

8.6 Proposed Approach At Draft Assessment

FSANZ recommends the following approach at draft assessment to the regulatory management of general level health claims in relation to whole foods:

8.6.1 Criteria And Conditions

- General level health claims in relation to Whole Foods do not need to state the specific property of the food.

- General level health claims in relation to Whole Foods must make reference to a specific health effect.
- Whole Foods are foods that consist of at least 90% by weight of primary foods defined in Standard 1.3.2.
- The generic disqualifying criteria and conditions for general level health claims apply to claims on whole foods.
- Claims can only be made in reference to generic food types.

8.6.2 Substantiation

- General level health claims in relation to Whole Foods are to be substantiated according to the substantiation framework for general level claims.
- The evidence supporting the claim must point to the health effects being attributed to the whole food.
- There is no or very little evidence of appropriate quality substantiating the relationship between specific component/s of the Whole Food and the health effect of the claim.

Chapter 9: Dietary Information

9.1 Summary of Proposed Approach At Draft Assessment

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

9.2 Background

Whilst 'dietary information' is not specifically referred to in (or excluded by) the Policy Guideline, all affirmative references to health claims are made in the context of 'the food' or 'component', rather than multiple food groups (as is generally understood by the term 'diet'). However, 'whole of diet' claims are specifically referred to under both the general level and high level claims classification criteria.

The Guideline also defines 'whole of diet' claims, as – 'claims which communicate the appropriate total diet required to achieve the stated benefit'.

The examples provided by the Policy Guideline in reference to 'whole of diet ' are:

A healthy, balanced diet that includes dietary fibre from a number of sources is one that can help reduce your risk of constipation. A healthy diet that may lower risk of certain kinds of cancer is one that is low in fats and include fibre from a number of sources including a variety of fruits and vegetables, and wholegrain and bran cereals.

These claims both include reference to a specific component (i.e. dietary fibre, fats, fibre) and the associated health effect (reduction of risk of constipation, cancer). FSANZ considers that, under the proposed claim pre-requisite conditions, these elements of the claim would capture these examples as health claims.

It is also noted in the Guideline that 'General level claims are those which …describe how a diet, food, or component can…' The example provided in this context is:
Exercise and a diet high in calcium and calcium containing foods like product 'X' may help give you stronger bones.

Again this example makes reference to a specific food property and from this angle would be captured by the proposed health claim pre-requisite conditions.

In accordance with this approach, FSANZ suggests that 'whole of diet' claims which do not contain reference to specific branded foods/properties, should not be considered as health claims.

9.3 Relevant Issues Raised In Submissions

Submitters noted this was a difficult issue that requires clarifying, and it is important that dietary information can be provided by appropriate agencies without contravening the Code, and that definitions or explanatory clarification is required to effectively manage this.

It was generally agreed, that where a claimed benefit (health effect) is expressed in a 'whole of diet claim' this provides guidance as to positioning of the claim within the classification framework, and that the reference to specific benefits differentiates them from more general 'dietary information' – which in itself should be excluded from the claims framework. It was noted that were such claims to include serious disease, this would equate to a high level claim and accordingly, should be treated in the same way as claims about individual foods.

There were some views that whole of diet claims should be restricted to unprocessed foods or only 'appropriate' [not categorically defined] foods, whilst others questioned why this should be the case, i.e., that both processed and unprocessed foods should be eligible, and would be [anyway] subject to further generic criteria and substantiation.

Whilst there was some confusion and inconsistency around the use of the terms 'dietary advice[8]' and 'whole of diet claims', a useful summary of the prevailing views is provided in the comment …… *recommend dietary advice (e.g., the Dietary Guidelines….) should remain outside the Standard and should not be considered a nutrition and health claim. Agree that whole of diet claims are nutrition and health claims, directly related to food product nutrition marketing and promotion, and could also reasonably be made in the context of a holistic dietary approach*. Overlaying this, was the view by others that such claims should refer to specific benefits.

9.4 Assessment And Rationale

- Dietary information is intended to promote national nutrition policy for the broad population - without reliance on specific food products. When provided in the context of the total diet and consistent with national nutrition policies dietary information is considered to be an appropriate and effective education tool.
- Dietary information is generally provided by independent and credible source(s) with no direct financial gain from the sale of specific foods.

[8] Now being referred to as dietary information.

- Dietary information serves a different purpose to nutrition and health claims and hence, should not be captured under this framework. In order to achieve this, dietary information should be:

    a. excluded by virtue of not meeting the criteria for health and nutrition claims; and to ensure clarity, be
    b. specifically excluded from the definition of 'health claim'.

- 'Whole of diet' claims that do not reference a specific and/or branded food and/or property should be interpreted as dietary information as they are generic in nature and do not serve direct financial gain in relation to the sale of food.

To be excluded from the health claims standard, dietary information must first be captured by 'claim' in the Code.

The recommended definition of a 'claim' in Standard 1.1.1 at draft assessment will be very broad, encompassing any voluntary representations made in relation to a food. As such it will capture dietary information.

Term	**Recommended definition in Standard 1.1.1 in the Code**
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.

The standard for nutrition, health and related claims will include a general prohibition on the use of nutrition and health claims including implied claims, unless certain conditions are met. The most basic of these conditions are claim pre-requisite conditions. If a nutrition or health claim meets these pre-requisites, it will then be eligible for further consideration within the context of the standard.

The proposed pre-requisites for nutrition and health claims are, that they:

- be substantiated according to the substantiation framework (excepting nutrition content claims);
- make reference to a specific property of the food; and .
- other than nutrition content claims, make reference to specific health effect.

Dietary information will not meet the second of these requirements.

A clear and comprehensive description of dietary information, and its exclusion, will be required in supporting documentation. Such a description will include the following indications.

Dietary information:

- does not reference a specific branded food or health effect;
- is consistent with national nutrition policies and/or specific medical information; and
- refers to intake of multiple food groups.

9.5 Proposed Approach At Draft Assessment

FSANZ recommends the following approach be taken at Draft Assessment, for the purposes of draft Standard 1.2.7:

- 'dietary information' – means general diet-related information that has broad application to the general population and does not relate a specific health effect to a specific food or property of a food;
- 'whole of diet' claims, which do not reference a specific and/or branded food/property, are dietary information; and should not be considered as a separate category for the purposes of the regulatory framework;
- dietary information should be expressly excluded from the definition of 'health claim',
- dietary information that is presented directly in association with a specific product must be supported by a nutrition or health claim (which will then be subject to the usual framework); and the claim should relate to the dietary information. For example, dietary information around fibre may only be presented on a product, which is making a nutrition or health claim about fibre. The dietary information will then constitute part of the overall claim;
- further explanation around dietary information should be included in an interpretive user guide/ guideline.

Chapter 10 – Meals and Main Dish Products

10.1 Summary of Proposed Approach At Draft Assessment

- A meal / main dish product is defined as a food that contains, per serve, at least 170 g of food and at least two ingredients (including compound ingredients) from at least two different food groups (bread and other cereal products; fruit and/or vegetables; milk and milk products and meat, fish, eggs, nuts, seeds and legumes) of at least 40 g each. Sauces, condiments, coatings, stuffings or garnishes are not considered representative of a food group unless a single ingredient is at least 40 g per serve of the meal/main dish product and falls with the food groups.

- Specific disqualifying criteria for General Level Health Claim apply to meals and main dish products, namely <775 mg sodium, 7 g saturated fatty acids and 31 g total sugars per serve.

- The qualifying criteria will be as for other content claims except in the case of fibre claims where the 'source' claim is 5.5 g per serve and the 'good source' claim criterion is 11 g of dietary fibre per serve.

10.2 Background

Increasingly, foods are being presented in more convenient forms for the consumer including ready-to-serve meals comprising a number of different serves of individual foods. Due to the combination into one package these meals may not qualify for claims under the serve-based model for qualifying and disqualifying criteria, or if the criteria were to be applied to each portion of food within the meal (e.g. chicken, peas, carrots, potato, sauce etc) the whole meal may be disqualified due to one individual food only, which may not be appropriate. Furthermore , because meal type products or main dishes contribute a larger proportion of the

daily intake it may be necessary to ensure that they have sufficient amounts of risk reducing nutrients in order for them to contribute a sufficient level of these nutrients in relation to their contribution to the daily intake. FSANZ therefore consider 'meals' require special consideration, particularly in relation to:

- Disqualifying criteria for General Level Health Claims
- Nutrition content claims that relate to dietary fibre (see Attachment 6: Part 1, Chapter 14).

10.3 Issues raised by submissions

Submitters to the Initial Assessment Report for Proposal P293 did not specifically comment on meals and main dishes, except in the case of claims made in relation to dietary fibre (see Attachment 6: Part, Chapter 14).

10.4 Definitions

10.4.1 Meal type product'

A meal type product is one that makes a major contribution to the total diet and which is intended to be consumed at one time as a meal. This includes formulated meal replacements as defined in Standard 2.9.3 ('a single food or pre-packaged selection of foods that is sold as a replacement for one or more of the daily meals but not as a total diet replacement'). A minimum serving size is necessary for enforcement reasons to assist in delineating a meal type product from other products. The USA has defined this as 10 ounces (283.75 g). In examining Australia's and New Zealand's food composition databases there are some meals which fall short of this, so it is recommended that the minimum serving size be 270 g.

The most appropriate basis for defining what constitutes a meal type product is national nutrition guidelines. FSANZ proposes that a meal product should contain at least three portions of food of a minimum quantity from two or more of the four food groups:

1. Breads and other cereal products
2. Fruits and/or vegetables
3. Milk and milk products
4. Meat, fish, eggs, nuts, seeds and legumes.

Sauces, condiments, coatings, stuffings and garnishes should not be considered as representing a food group, unless a portion of the food is in the four food groups in a minimum required amount.

The required three portions from at least two food groups ensures that a meal is made up of a variety of foods and is therefore consistent with both Australian and New Zealand nutrition guidelines. As three portions of the food must be represented by at least two of the food groups, 15% (or 40 g) seems an appropriate minimum quantity. This provides consistency with the 40 g that is stipulated in the US. The types of foods that might be captured are chicken chow mein, spinach and ricotta lasagne and roast lamb or beef stew with vegetables.

In conclusion then, a meal type product is a food that:

1. has a serving size of at least 270 g;
2. contains not less than three portions of different foods (or combinations of foods) from two or more of the following food groups:

    i) bread and other cereal products;
    ii) fruit and/or vegetables;
    iii) milk and milk products;
    iv) meat (as defined in Standard 2.2), fish, eggs, nuts, seeds and legumes;

3. has a minimum portion size of 40 g; and
4. sauces, condiments, coatings, stuffings and garnishes are not considered representative of any of the food groups unless there is a specific ingredient in the food that is represented in a food group and constitutes 40 g or more.

10.4.2 'Main dish product'

A 'main dish product' is different to a 'meal product' in that it is only part, albeit a significant part, of a meal. FSANZ considers the US definition to be appropriate for Australia and New Zealand. That is, a main dish product is a food that:

1. has a serving size of at least 170 g;
2. contains not less than two portions of different foods (or combinations of foods) from two or more of the following food groups:

    i) bread and other cereal products;
    ii) fruit and/or vegetables;
    iii) milk and milk products;
    iv) meat (as defined in Standard 2.2), fish, eggs, nuts and seeds and legumes;

3. has a minimum portion size of 40 g.
4. sauces, condiments, coatings, stuffings and garnishes should not be considered as representing a food group, unless a specific ingredient of the food is in the four food groups and is a minimum of 40 g.

The types of foods that might be captured in this instance are pies (e.g. chicken and vegetable), nachos dishes, burgers, tacos dishes and chicken cordon bleu.

10.4.3 FSANZ's preferred definition for meals and main dishes

Because FSANZ has determined the same General Level Health Claims disqualifying criteria for meals and main dishes (see below) and the same qualifying criteria for dietary fibre content claims for meals and main dishes (see Attachment 6, Part 1, Chapter 14), FSANZ's preferred approach is to use the definition of main dish products for both meal type products and main dish products.

10.5 Criteria for meals and main dishes

10.5.1 Qualifying criteria

It is only necessary to consider whether specific criteria are required for those nutrients where the criteria for content claims are expressed per serve – fibre, protein and wholegrain. FSANZ does not recommend separate criteria for protein claims because inadequate protein intake is not considered to be of concern in Australia and New Zealand. Also meal type products and main dishes typically provide a significant source of protein.

The criteria for a 'source of dietary fibre' claim of 2 g per serve are equivalent to 6.7% of the daily reference value that is provided in the Table to sub-clause 7(3) in Standard 1.2.8. If applied to meal type and main dish products this is clearly too lenient if one considers that a meal type product, particularly a dinner meal, constitutes nearer to a third of the day's intake of food. Therefore qualifying criteria of 5.5 g dietary fibre per serve will be applied for meal type products (see section 14.8 of Attachment 6, Part 1).

10.5.2 Disqualifying criteria for General Level Health Claims

Under the US food regulatory system, disqualifying criteria for meals and main dishes are set at different levels. Meals are considered larger in volume, and as making a greater nutritional contribution to the total diet. Hence disqualifying criteria for meals are set at a higher level than for main dishes, which are considered only part of a meal.

FSANZ considers that the same disqualifying criteria can be set for meals and main dishes. The same risk-increasing nutrients that have been selected for disqualifying criteria for all General Level Health Claims will be the basis of disqualifying criteria for the 'meals and main dishes' category (see Attachment 5, Chapter 3.6.4 and Appendix 5.3).

10.5.2.1 Derivation of disqualifying nutrients for meals and main dishes

The levels for disqualifying nutrients for meal and main dish General Level Health Claims have been set using an analysis of a dietary pattern that complies with the good health recommendations of the Australian Guide to Healthy Eating. This is the same approach that was used to benchmark levels set for disqualifying criteria for other General Level Health Claims.

The first step in the calculation process was estimating the number of serves of each disqualifying nutrient that are likely to be contained within a meal or main dish product, see Table 1 below.

Then, for each disqualifying nutrient the number of contributing serves per meal or main dish was calculated as a proportion of the total number of contributing serves for that nutrient. Where a range of serves was reached, the midpoint of the range was used (for example for the range 1-2, 1.5 was used). This proportion was then applied to the daily intake recommendation for the disqualifying nutrient (see Attachment 5, p 48), as shown below.

$$\frac{\text{number of contributing serves per meal or main dish}}{\text{total number of contributing serves per day}} \times \text{daily intake recommendation}$$

Table 1: Number of daily serves of recommended foods and serves within 'meals and main dishes' contributing to daily intake of the General Level Health Claims disqualifying nutrients, for men and women, aged 19-60 years

Number of serves (daily)	Cereals	Veg	Fruit	Dairy	Meat	Extras	TOTAL
Total diet	5-6	6	3	3	1	0-2	19-20
Serves within daily intake that contribute to sodium intake	5	1	0	1	1	1	9
Serves within a meal or main dish that contribute to sodium intake	1	1	0	1		0	3
Serves within daily intake that contribute to saturated fat intake	0	0	0	3	1	2	6
Serves within a meal or main dish that contribute to saturated fat intake	0	0	0	1-2		0	1-2
Serves within daily intake that contribute to total sugars intake	1	0	3	2	0	1	7
Serves within a meal or main dish that contribute to total sugars intake	0-1	1		0-1	0	0	1-3

Calculations for each nutrient are given below:

(i) Sodium

$$\frac{3 \text{ serves}}{9 \text{ serves}} \times 2300 \text{ mg} = 766 \text{ mg (rounded to 775 mg)}$$

(ii) Saturated fat

$$\frac{1.5 \text{ serves}}{6 \text{ serves}} \times 28\text{g} = 7\text{g}$$

(iii) Total sugars

$$\frac{2 \text{ serves}}{7 \text{ serves}} \times 109\text{g} = 31\text{ g}$$

10.6 Unit measure for 'meals' and 'main dishes' disqualifying criteria

The unit measure for General Level Health Claims disqualifying criteria meals and main dishes will be per serve. This is consistent with the disqualifying criteria for other General Level Health Claims.

As noted for all General Level Health Claims disqualifying criteria (Attachment 5, section 3.6.4.3), it is recognised that the supplier determines the serving sizes for foods in Australia and New Zealand. Hence, FSANZ will monitor closely the application of serve size nutritional criteria in relation to general level health claims, and will review the issue at a later date, initiating work to standardise serve sizes if deemed necessary. Fair trading laws will provide an additional safeguard against blatant manipulation of serve sizes by suppliers in order to meet the disqualifying criteria.

10.7 Summary

The General Level Health Claims disqualifying criteria for 'meals and main dishes' are proposed as:

Sodium = 775 mg
Saturated fat = 7 g
Total sugars 31 g

The qualifying criteria will be as for other content claims except in the case of fibre claims were the 'source' claim is 5.5 g of dietary fibre per serve and the good source claim criterion is 11 g of dietary fibre per serve.

Bibliography To Part 2

Anon (2005) *National Alcohol Strategy 2005-2009*. Australian Government. Department of Health and Ageing. http://www.alcohol.gov.au/consultation.pdf. Accessed on 17/10/05 2005.

Ashwell, M. (2002) *Concepts of Functional Foods*. ILSI Europe. p 6. http://europe.ilsi.org/publications/pubslist.cfm?publicationid=419. Accessed on 04/10/05.

Caballero, B. (1988) Nutritional implications of dietary interactions: a review. *Food and Nutrition Bulletin* **10**(2). http://www.unu.edu/unupress/food/8F102e/8F102E00.htm. Accessed on 23/09/05.

Canadian Food Inspection Agency (2003) *Guide to Food Labelling and Advertising.* http://www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml. Accessed on 28/09/2005.

Elwood, J.M. (1992) *Causal Relationships in Medicine*, Oxford University Press, New York.

Institute of Food Technologists (2005) *Functional Foods: Opportunities and Challenges. Expert Report*, p 44. http://members.ift.org/IFT/Research/IFTExpertReports/functionalfoods_report.htm. Accessed on 28/09/05.

Jacobs Jr, D.R. and Steffen, L.M. (2003) Nutrients, foods, and dietary patterns as exposures in research: a framework for food synergy. *Am. J. Clin. Nutr.* **78 (suppl)**: 508s-513s.

Joint Health Claims Initiative (1995) *Code of Practice on Health Claims on Food*. p 11. http://www.jhci.org.UK/info/code.pdf. Accessed on 04/10/2005.

Liu, S., Willett, C.W., Stampfer M.J., Hu F.B., Franz, M., Sampson, L. Hennekens, C.H., and Manson, J.E. (2000) A prospective study of dietary glycaemic load, carbohydrate intake, and risk of coronary heart disease in United States women. *Am. J. Clin. Nutr*. **71**(6): 1455–1461.

Munro, J.A. (2004) Virtual food components: functional food effects expressed as food components. *Euro. J. Clin. Nutr*. **133**: 4256–4258.

NHMRC (2003) *Dietary Guidelines for Children and Adolescents in Australia*. NHMRC, Commonwealth Of Australia 2003.

Tapsell, L.C. (2005) Functional Foods: definition and commercialisation. *Food Australia*, **57** (9): 384-386.

University of Sydney (2005) *Home of the Glycemic Index.* http://www.glycemicindex.com. Accessed on 17/10/2005.

Acronyms and Abbreviations

Acronym/abbreviation	***Explanation***
COAG	Council of Australian Governments
Code	*Australia New Zealand Food Standards Code*
CoPoNC	Code of Practice on Nutrient Claims in Food Labels
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DI	Daily Intake
DPA	Docosapentaenoic acid
DRV	Dietary Reference Value
EPA	Eicosapentaenoic acid
ESADDI	Estimated Safe and Adequate Daily Dietary Intake
EU	European Union
FSANZ	Food Standards Australia New Zealand
GI	Glycaemic Index
GL	Glycaemic Load
JHCI	Joint Health Claims Initiative
kCal	Kilo Calories
kJ	Kilo Joules
mmHg	Millimetres mercury
mmol	Millimoles
NHF	National Heart Foundation
NHMRC	National Health and Medical research Council
NZ	New Zealand
PER	Protein Efficiency Ratio
RDI	Recommended Dietary Intake
UK	United Kingdom
USA	United States of America