ATTACHMENT 5

FINAL ASSESSMENT REPORT FOR PROPOSAL P293 – NUTRITION HEALTH & RELATED CLAIMS

Nutrition Content Claims

CONTENTS

Note: The information contained in Part 1 of this Attachment relates to the generic conditions that apply to all nutrition content claims. Part 2 of this Attachment provides the detail in relation to additional criteria and conditions that have been determined for certain nutrition content claims.

PART 1 – GENERAL ISSUES RELATING TO NUTRITION CONTENT CLAIMS

1. Regulatory approach for nutrition content claims

1.1 Decision

FSANZ recommends that generic food vehicle eligibility criteria will not be applied to nutrition content claims, but that specific disqualifying criteria may be applied to some nutrition content claims where considered appropriate.

1.2 Draft Assessment Report – proposed approach and submitter comments

In the Draft Assessment Report FSANZ proposed that the overall composition of the food would not be taken into consideration in permitting foods to carry nutrition content claims. However, specific disqualifying criteria in relation to certain nutrients would be applied where considered necessary. The approach was considered to be consistent with minimal effective regulation and was based on a risk management approach with the following rationale:

- there is no clear evidence that nutrition content claims are misleading with respect to the food vehicles;
- specific disqualifying criteria can be applied on a case-by-case basis where there is sufficient concern that inappropriate food choices may be made on the basis of a nutrition content claim. For example, polyunsaturated, monounsaturated and omega fatty acid claims are currently permitted on foods provided specified levels of saturated and *trans* fatty acids are not exceeded;
- consumers have diverse needs. In some cases, consumers may only seek information on one nutrient. Generic food vehicle eligibility criteria may eliminate certain products from making nutrition content claims and hence prevent consumers from choosing 'healthier' options within a food category with respect to a single nutrient, for example, *reduced fat,* even if the food category is not considered to be 'healthy' per se; and
- the approach supports the 'step-up' model recommended by FSANZ for the regulation of nutrition content and health claims where no generic food vehicle eligibility criteria apply to nutrition content claims but do apply to general level health claims.

Although FSANZ did not seek comment on the issue of generic food vehicle eligibility criteria from submitters to the Initial Assessment Report, during the early consultation phases of this Proposal some stakeholders expressed the view that there is potential for nutrition content claims to be misleading. At the time of writing the Draft Assessment Report FSANZ considered that the extent of consumer confusion with nutrition content claims was unclear.

However, FSANZ proposed percentage daily intake (%DI) labelling could be a useful risk management tool in assisting consumers with the interpretation of claims. Hence, FSANZ proposed to require %DI information for the claimed nutrient to be declared in the nutrition information panel whenever any nutrition content claim or health claim was made in relation to energy, protein, fat, saturated fatty acids, carbohydrate, sugars, sodium or salt or dietary fibre. In addition, it was proposed that the %DI for energy would also be included in the nutrition information panel when any nutrition content or health claim was made.

Submitters from government, public health and consumer stakeholder groups who commented on this issue consistently opposed the non-application of generic food vehicle eligibility criteria to nutrition content claims. The main reasons stated by submitters were:

- nutrition content claims influence purchasing decisions and therefore consumption patterns, therefore 'unhealthy' foods should not be permitted to make potentially misleading content claims;
- application of generic disqualifying criteria to nutrition content claims is consistent with the Policy Guideline;
- lack of disqualifying criteria for foods with nutrition content claims will pose a risk to lower socio-economic groups and those with lower literacy levels;
- if disqualifying criteria are applied there would be less onus on the consumer to assess the healthiness of the food; generally consumers are not able to make complex nutritional assessments;
- FSANZ research indicates consumers do not distinguish between nutrition content and health claims, therefore without preventing the use of content claims on less healthy foods, it is inevitable that nutrition content claims will remain dominant in the market to the detriment of consumer understanding and choice;
- evidence suggests that consumers assume any nutrition content or health claim means the food is healthy in every way [note only anecdotal evidence supplied];
- application of disqualifying criteria would achieve FSANZ's aims of protecting consumers from misleading or deceptive claims and assist consumers to select foods for healthy diets;
- disagree with FSANZ's position that nutrition content claims are [simply] statements of fact as they omit the full picture of a products' nutritional profile; and
- the requirement that some nutrients have specific disqualifying criteria, for example, the saturated and *trans* fat content claims while others do not is inconsistent.

The majority of industry submitters supported the proposed approach of not applying food vehicle eligibility criteria to nutrition content claims because they consider every food has its place in a balanced diet, that nutrition content claims help consumers identify appropriate foods, are statements of fact and are supported by the nutrition information panel, and that nutrition content claims have been in place for some time without the need for food vehicle eligibility criteria. In contrast, one industry submitter did not support the proposed approach and referred to FSANZ research which they consider indicates that nutrition content claims imply a health benefit and therefore the lack of food vehicle eligibility criteria would disadvantage horticultural produce compared with packaged products.
FSANZ also discussed the application of food vehicle eligibility criteria (referred to as nutrient profiling scoring criteria after the release of the Draft Assessment Report) to nutrition content claims directly with the jurisdictions. The types of concerns raised include:

- consumers may focus on one nutrient rather than the overall nutrient profile of the food when nutrition content claims are present;
- consumers may be unable to compare the healthiness of similar products when nutrition content claims are present;
- consumers may ascribe broader/more health benefits to a product when content claims are present than those associated with the nutrition content claims (halo effect);
- consumers may be confused by nutrition content claims about nutrients not normally present in the product;
- consumers may not have accurate understanding of recommended intakes of nutrients on which to base judgments about products;
- consumers may read nutrition information but not apply it accurately to make healthier diet choices; and
- characteristics of consumers may make them more vulnerable to misunderstanding nutrient content claims (e.g. education, socio-economic attributes).

Clearly the concerns are highest when nutrition content claims are used on products of lower nutritional quality.

FSANZ also received submitter comments to the Draft Assessment Report on the proposal to require %DI labelling on products with nutrition content claims and health claims. The majority of submitters opposed the proposed approach. The main reasons given were:

- the inappropriateness of reference values based on 8700 kJ for many population groups;
- the difficulty that consumers may have in understanding %DI information and in particular %DI for energy;
- %DI information may not reflect the healthiness of some foods;
- the likely increased confusion with additional values in the nutrition information panel;
- the possible confusion between %DI and percentage recommended dietary intake (%RDI) values;
- the need for the reference values used for %DI and %RDI to take account of bioavailability particularly in relation to zinc and iron;
- %RDI or %DI information could encourage consumers to over-consume particularly in relation to risk decreasing nutrients; and
- the lack of any evidence showing that nutrition content claims have resulted in over-consumption therefore there being no need for additional information.

1.3 Preliminary Final Assessment Report – proposed approach and submitter comments

In response to submitter comments opposing the proposed approach to requiring %DI labelling, FSANZ carried out qualitative research to investigate consumer understanding and use of %DI labelling (TNS Social Research, 2007). The research indicated that %DI labelling was not likely to be an effective risk management tool in helping consumers to interpret nutrition content claims because of the complexity of the concept. In addition, only requiring %DI values for energy and the claimed nutrient as opposed to all nutrients would likely hinder consumer use and interpretation of the information. Findings also suggested that with some education, current users of the nutrition information panel may make appropriate use of %DI information.

FSANZ therefore proposed in the Preliminary Final Assessment Report that %DI labelling would not be mandatory on products with nutrition content claims but could be used voluntarily (refer to Chapter 6 – Percentage Daily Intake and Percentage Recommended Dietary Intake in Part 1 of this Attachment for information on requirements for %DI labelling).

FSANZ also continued its recommendation to not require any generic food vehicle eligibility criteria for nutrition content claims but indicated that further research would be undertaken on consumer use of nutrition content claims to assist in determining whether the current approach should be reconsidered.

The majority of submitters from the government, public health and industry sectors agreed with FSANZ's approach to remove the requirement for mandatory %DI labelling on products with nutrition content and health claims for the following reasons:

- reference values based on 8700 kJ are problematic;
- %DI labelling may make less nutritious foods seem more attractive;
- there should be more research on the most effective way to convey information on food labels about the nutritional value of products;
- removes any additional cost to industry;
- research indicates the approach may not be effective; and
- the approach may negatively affect trade.

A few submitters commented that the need to educate consumers about %DI was not an argument for not requiring %DI labelling and that %DI labelling would provide consumers with more information at a minimal cost to industry. It was suggested that consideration should be given to the use of age specific Recommended Daily Intake values for foods that are intended for use by infants and children. While submitters generally agreed with the proposed approach there was support particularly from those in the government and public health sectors for on-going research on the extent to which nutrition content claims mislead consumers and following this the consideration of appropriate risk management options.

FSANZ did not specifically seek comment from submitters to the Preliminary Final Assessment Report on the recommendation to not require foods carrying nutrition content claims to meet generic food vehicle eligibility criteria. Nonetheless comments on the issue were received. The majority of comments were similar to those received in response to the Draft Assessment Report, and the following additional comments were made:

- there are a number of instances in the draft Standard where the degree of risk management applied to certain health claims is inconsistent with the nature and complexity of the claim. For example, nutrient profiling scoring criteria are to be applied to 'diet' and glycemic index claims, both of which are considered to be nutrition content claims;
- of 26 breakfast cereals marketed to children in New Zealand, over one half of these were at least one-third sugar and therefore consider content claims on these products are misleading;
- if nutrient profiling scoring criteria are not to be applied, suggest further labelling statements be required to indicate the food does not comply with eligibility criteria;

- for claims associated with a risk-increasing nutrient, food should meet the criteria for a *low* claim for the nutrient of interest, for example, a food carrying a *reduced fat* claim should meet the conditions for a *low fat* claim;
- without applying nutrient profiling scoring criteria to foods with nutrition content claims which are high in salt, fat and sugar, FSANZ is sanctioning the promotion of foods that contribute to dietary imbalances and obesity amongst the population which contradicts food and nutrition policies; and
- support the exclusion of nutrient profiling scoring criteria to nutrition content claims as the criteria would discriminate against people with medical conditions (such as anaemia, osteoporosis and severe weight loss) and athletes (who require high energy foods) as fewer foods would be able to carry nutrition content claims relevant to such conditions.

1.4 Consumer research

In response to submitter concerns about the potential for consumers to be misled from the presence of nutrition content claims on 'less healthy' products, FSANZ carried out a further two consumer research studies (refer to Attachment 10 for a summary of these studies and the complete reports). The overall objectives of the research were to investigate the extent to which nutrition content claims are used in purchase decisions in a real-world shopping environment (study 1) and to measure the impact of nutrition content claims (present on 'less healthy' mocked-up products) on consumer evaluations of the overall nutritional value of the products and self-reported intention to purchase (study 2). Briefly, study 1 took place in supermarkets and involved observing and interviewing shoppers who interacted with (purchased or not purchased) breakfast cereal and muesli bar products. In study 2, respondents were mailed 3D mock-up packages of a breakfast cereal and a sweet biscuit product and subsequently interviewed over the phone. Information was sought on a range of socio-demographic, cognitive and behavioural measures.

1.5 Rationale for final decision

FSANZ recommends that the proposed approach presented in the Draft Assessment Report is retained in the Final Assessment Report. That is, the food vehicle eligibility criteria (nutrient profiling scoring criteria) will not be applied to all nutrition content claims, but that specific disqualifying criteria may be applied to some nutrition content claims where considered appropriate.

Nutrition content claims do not claim a health effect but rather, simply note the presence (or absence) of particular nutritional properties. Results of the recent FSANZ studies supported the FSANZ view that, if a claim is used, products are chosen on the basis of the property offered, rather than for any assumed (as opposed to claimed) further health benefits – in this situation the overall nutritional profile of the food is not as critical as when a health effect is clearly attributed to the product. This was also evident in earlier FSANZ research (FSANZ, 2005).

FSANZ considers the recently commissioned consumer research supports the approach proposed by FSANZ in the Draft Assessment Report. The studies indicated that the presence of a nutrition content claim on a 'less healthy' product did not result in respondents evaluating the product as more nutritious or increase self-reported intention to purchase compared with a product with no claim; and that while a nutrition content claim (when present) was read by approximately 20% of shoppers, other label information such as brand/product/flavour, the ingredient list and the nutrition information panel was also used and had a similar degree of influence on purchase decision as the nutrition content claim.

The findings of the two recent studies have been considered in the context of other research (refer to Attachment 10).

Findings from the CIE benefit-cost analysis also support the recommended regulatory approach for nutrition content claims. CIE estimated only 14.4% of existing foods with nutrition content claims would not meet the nutrient profiling scoring criteria but that applying the scoring criteria to products with nutrition content claims would increase industry costs by $44 million due to product relabeling, changing marketing strategies and product reformulation or removal from the market (refer to Attachment 11).

The Policy Guideline does not give clear guidance in relation to the application of food vehicle eligibility criteria to nutrition content claims. The Guideline states: *The standard may also set out qualifying and disqualifying criteria for certain types of claims (e.g. nutrient content claims) and….* FSANZ has considered all relevant research and other information relating to this issue and concludes that there is insufficient evidence to amend the proposed approach to the risk management of nutrition content claims.

2. Units of Measure

2.1 Decision

FSANZ recommends the following with regard to the units of measure that act as the basis of the qualifying criteria for nutrition content claims:

- for risk increasing nutrients such as fat, cholesterol and sugar, the qualifying criteria are on a per 100 g basis for solid foods and a per 100 ml basis for liquid foods, and for most, the qualifying criteria for liquid foods are half that of the qualifying criteria for solid foods. For example, for the *low fat* claim, the qualifying criteria are no more than 1.5 g per 100 ml of liquid food and 3 g of fat per 100 g of solid food;
- for most risk decreasing nutrients (fibre, protein, omega-3 fatty acids, vitamins and minerals) the qualifying criteria are on a per serving basis;
- for *low proportion* of trans and/or saturated fatty acid claims, omega-6 and omega-9 fatty acids, and poly and monounsaturated fatty acids the qualifying criteria are on a percentage basis; and
- for gluten and lactose claims, the qualifying criteria are on a per 100 g basis.

These units of measure are specified in the Table to clause 11 of the draft Standard.

2.2 Amendments to current standards/CoPoNC recommendations

Currently the units of measure used as the basis of qualifying criteria in CoPoNC and Standard 1.2.8 for nutrition content claims are a mix of ‘per serve’ and ‘per 100 g’. In CoPoNC the qualifying criteria in relation to nutrition content claims for risk reducing nutrients such as dietary fibre are based on the ‘per serve’ model. Qualifying criteria for nutrition content claims relating to risk increasing nutrients such as fat, saturated fat, sugar and salt in CoPoNC are based on ‘per 100 g’ with different criteria for liquid foods with a serving size of 200 ml or more (on a 100 g basis). Under the draft Standard, the per serve basis will be retained for risk reducing nutrients.

For risk increasing nutrients, the 100 g basis will be retained for solid foods and for liquid foods the criteria will be based on 100 ml rather than 100 g and these will apply to all liquids, not just those with a serving size over 200 ml.

Currently in the Code, qualifying criteria for energy claims are based on 100 ml for beverages and other liquid foods and on 100 g for solids or semi-solid foods. Qualifying criteria for lactose, gluten and salt/sodium claims are on a 100 g basis. Omega-6 and omega-9, monounsaturated and polyunsaturated fatty acids are based on a percentage profile for the fatty acid content. Omega-3 fatty acid claims are based on a per serve amount. These units of measure will all be retained (except for the reference to 'semi-solid' in the conditions for energy claims). A 100 ml criterion will be introduced for claims about salt/sodium on liquid foods, in addition to the 100 g criterion that is currently in Standard 1.2.8.

The basis for vitamin and mineral claims has been changed from per *reference quantity* (as currently required under Standard 1.3.2 – Vitamins and Minerals) to a per serve basis (refer to Chapter 28 – Vitamins and Minerals, of this Attachment for further information).

2.3 Draft Assessment Report – approach taken and submitter comments

The units of measure recommended as the basis of the qualifying criteria for nutrition content claims in the Draft Assessment Report were the same as those recommended in this Report, except that cholesterol claims were based on 100 g only, rather than 100 ml for liquid foods and 100 g for solid foods.

One submitter considered that for claims about risk reducing nutrients based on serving size, the serving size was open to manipulation by food providers and therefore to use 100 g or 100 ml as the basis for all criteria would simplify and make more explicit the basis for claims. Another submitter considered that per serve requirements are more appropriate as consumers consume energy and nutrients by amount not by concentration. It was suggested that 'serving' be defined.

It was pointed out that as part of the Australian Food and Grocery Council (AFGC) Nutrition and Health Policy, food businesses have agreed to adhere to certain principles governing serving size, one of which is that *serve sizes will not be used inappropriately to manipulate energy or nutrient content per serve*.

Regarding the *low fat* criteria (which had specific qualifying criteria for liquid foods and for solid foods), one submitter questioned where semi-solid foods fit into the criteria. They suggested that criteria for semi-solid foods are added to the criteria for solid foods or that liquid and solid be defined.

2.4 Preliminary Final Assessment Report – approach taken and submitter comments

A minor amendment was made in the Preliminary Final Assessment Report, whereby a new criterion was included for *low* cholesterol claims on liquid food, i.e. 10 mg cholesterol per 100 ml for liquid foods, in addition to the existing criterion of 20 mg per 100 g for solid foods.

Concerns were again raised by submitters regarding the lack of standardisation of a 'serving' and it was suggested that 'serving' either be defined, or guidelines for serving sizes be provided in a User Guide.

A number of comments were received about the references to solid foods and liquid foods in the qualifying criteria specified in the draft Standard. There was concern that, without definitions, there was the risk that identical foods could bear different claims due to different interpretations of solid and liquid by different suppliers. It was considered that there was inconsistency between the requirements under the Australian Trade Measurement Regulations for unit measure declarations and the requirements under the Code for declarations in the nutrition information panel. Inconsistency with the nutrient profiling scoring criteria, which differentiates between foods and beverages rather than solid and liquid foods was also noted. Some submitters questioned whether the qualifying criteria for liquid foods should apply to foods other than milks, as the liquid criteria were originally developed so that low fat milk could make claims. Various recommendations were made as follows:

- 'solid', 'semi-solid' and 'liquid' should be defined in the Code;
- the criteria that currently apply to 'liquid' foods should only apply to 'dairy beverages'; and
- the statement from CoPoNC regarding application of criteria for liquid foods to those liquids with serving sizes of 200 ml or more only be inserted into the draft Standard.

It was noted that the criteria for the *low* sodium claim were the same for solids and liquids and that this is inconsistent with the approach for other qualifying criteria (where the criteria for liquids are generally half that of the criteria for solids).

2.5 Rationale for final decision

FSANZ does not intend to specify serving sizes for qualifying criteria for claims about risk reducing nutrients as suggested by submitters, due to inherent difficulties associated with this. For example, nominated serving sizes do not recognise that foods are used in different amounts for different occasions. Although this approach leaves it somewhat open for industry to manipulate (increase) serving sizes in order to meet the qualifying criteria, the serving size is required to be declared in the nutrition information panel and should not be misleading. FSANZ also notes the comment from the AFGC that member food businesses (in Australia) have agreed to adhere to certain principles governing serving sizes.

For most risk increasing nutrients, the qualifying criteria for liquid foods are half of those for solid foods. This is based on the fact that most liquid foods are less nutrient/energy dense than solid foods, hence it is logical to have different criteria (of a lesser value) for liquid foods. As noted by a submitter, the qualifying criteria for sodium claims are the same for both liquid and solid foods and this is inconsistent with the general approach the qualifying criteria for other risk increasing nutrients. However FSANZ recommends that this approach is retained, as the single qualifying criterion of 120 mg is consistent with both Codex and CoPoNC criteria.

Definitions of liquid, semi-solid and solid will not be provided by FSANZ and semi-solid foods are not specifically incorporated into the qualifying criteria. This is in the interests of minimal regulation and it is expected that industry will assess the state and intended use of their food and match it to the most appropriate criteria accordingly.

Such definitions could also be inconsistent with those under Australian Trade Measurement Regulations. Further information will be provided in a User Guide.

Submitter concerns regarding inconsistency between the requirements under the Trade Measurement Regulations for net weight/volume declarations and the requirements under the Code for declarations in the nutrition information panel are noted. However FSANZ considers that declarations in the nutrition information panel do not necessarily have to be consistent with the net weight/volume declaration on the label. The net weight/volume declaration serves a different purpose and FSANZ considers that there is no disadvantage to the consumer if this declaration is inconsistent with the units used in the nutrition information panel. In addition, although the unit (g or ml) used in the nutrition information panel should be reflected by the qualifying criterion used to determine whether the food complies with the claim or not (i.e. as based on the qualifying criteria for liquid or solid food), it is not within the scope of Proposal P293 to amend the requirements for the units that should be used for declaration in the nutrition information panel.

The reference to 'beverage' in the nutrient profiling scoring criteria (NPSC) is based on the UK nutrient profiling model, which was used as the basis for the development of the NPSC. The UK nutrient profiling model differentiated between beverages and other foods rather than solid foods and liquid foods.

The statement in CoPoNC that criteria for liquid foods only refer to liquid foods with a serving size of 200 ml or more has not been incorporated into the draft Standard. This is because the statement does not resolve whether a food is a liquid or solid food, and the requirement is unclear and adds complication. In addition, the criteria currently referring to liquid foods will not be limited to dairy beverages as suggested by submitters because this would be inequitable with the qualifying criteria for other beverages, and it may necessitate the need to define 'dairy beverage' which could be problematic. Also, these approaches are not consistent with the criteria specified in the Codex Alimentarius Guidelines for use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005).

The criteria based on per 100 g of food for claims in relation to gluten and lactose are considered to be appropriate given these are provided for reasons of health and safety. Therefore, it is more important to have an absolute value that is not influenced by serving size or differences in concentration of these substances between solid and liquid foods.

It should be noted that the qualifying criteria for general level health claims will be based on the qualifying criteria for nutrition content claims, where specified. The units of measure for nutrition content claims will therefore carry over to general level health claims, for those nutrients with specific qualifying criteria.

3. Methods of analysis

3.1 Decision

FSANZ recommends the following for analytical methods to substantiate nutrition content claims:

- analytical methods will not be prescribed, apart from existing methodology for determining the fibre content of foods; and
- the method for determining glycemic index of carbohydrates in foods is not prescribed in the draft Standard however an editorial note describes the preferred method for determining GI, that is using the Standards Australia Australian Standard® Glycemic Index of foods (AS 4694 – 2007) which is a voluntary standards scheme.

The method of analysis that must be used to determine total dietary fibre and specifically named fibre content of foods is prescribed in clause 12 of the proposed amended Standard 1.2.8. – Nutrition Information Requirements. The method for determining glycemic index of carbohydrates in food is referenced in an editorial note in clause 1 of the draft Standard.

3.2 Amendments to current standards/CoPoNC recommendations

The method of analysis that must be used to determine total and specifically named dietary fibre as currently prescribed in Standard 1.2.8 will be retained (and was not reviewed under Proposal P293). At present, the Code does not make reference to methodology for determining the glycemic index of carbohydrate in food.

3.3 Draft Assessment Report – approach taken and submitter comments

The approach proposed in the Draft Assessment Report has been retained, except in relation to glycemic index claims. Refer to Chapter 18 – Glycemic Index, in Part 2 of this Attachment for information about the method of analysis for glycemic index.

One submitter noted their agreement with the recommended approach.

3.4 Rationale for final decision

FSANZ has not favoured prescribing acceptable laboratory methods for nutrient analysis because methods are subject to continual improvement. To generally prescribe methods would impose a considerable burden on the regulator, enforcement agencies and the industry to remain up-to-date, which is not commensurate with the risk to consumers. FSANZ expects that even without specific regulation, laboratory analyses carried out by the food industry would be appropriate for the food matrix and conducted according to the most up-to-date methods. The choice of an inappropriate method could also be construed as deceptive and contrary to fair trading legislation.

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

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

For the rationale for the proposed approach for methods of analysis for glycemic index, refer to Chapter 18 – Glycemic Index (GI) in Part 2 of this Attachment.

4. Claims about nutrients naturally present or absent in a food

4.1 Decision

FSANZ recommends that for nutrition content claims about nutrients that are naturally or intrinsically present or absent in a food, the claim must refer to the generic food that carries the claim, rather than the specific brand name of that food.

This is prescribed in clause 5 of the draft Standard.

4.2 Amendments to current standards/CoPoNC recommendations

Currently in Standard 1.2.8 – Nutrition Information Requirements, editorial notes to clauses 14 and 17 indicate that claims about low joule and low sodium respectively, should refer to the whole class of similar foods rather than the name of the food, if on foods that are intrinsically low in energy/sodium.

Similarly, under CoPoNC, claims made about nutrients which occur at a naturally or intrinsically high or low level in a food must be expressed in terms that make it clear the claim refers to the whole class of similar foods and not only to the particular brand of food on which the claim appears.

Rather than being in editorial notes and a voluntary code of practice (neither legally enforceable), this requirement will now be a prescribed condition in the draft Standard for all nutrition content claims.

4.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report, the approach proposed was that claims made regarding the property of a food which occurs naturally or intrinsically at a high or low level in a food must be expressed in terms of the category of a food and not the individual brand of food.
Submitters noted that the drafting of this requirement did not accurately reflect the intent, because it omitted the reference to the nutrient being 'naturally' present or absent, hence the requirement would apply to all claims about nutrients in all situations.
It was suggested that the word 'normally' (present or absent) is added.

Another concern was that the required wording of the claim would be meaningless to consumers. For example, submitters questioned whether consumers interpret 'bread – a low fat food' in the same way as 'low fat bread'. It was also noted that naturally occurring levels of certain nutrients can vary from brand to brand, therefore it is incorrect and misleading to state that the claim is applicable across all foods of the same type.

One submitter considered that it restricted the ability for companies to advertise in competition with other companies. One jurisdiction considered that the requirement may be difficult to enforce as they would be unlikely to invest in resources to determine the normal level of a nutrient in a food group. Another jurisdiction had concerns around the meaning of *similar food in the same category*.

4.4 Preliminary Final Assessment Report – approach taken and submitter comments

In response to the submitter concerns, the drafting of this condition was amended to better reflect the intent and to clarify certain aspects. Specifically, the drafting was amended to reflect that this requirement applies to properties of the food that are *naturally* present or absent. In addition, reference to 'category of food' was omitted as 'foods' also captures categories of foods and reference to 'brand of food' replaced 'individual food' to clarify that the nutrition content claim could not refer to the brand of food carrying the claim. This was outlined in Section 9 of the Preliminary Final Assessment Report.

There were no submitter comments received in response to this. The drafting as proposed in the Preliminary Final Assessment Report has been retained.

4.5 Rationale for final decision

FSANZ considers that the principles in CoPoNC and Standard 1.2.8 of the Code should be retained, that is, claims made about a property of the food that is naturally present or absent in that food must be expressed in terms of the type of food and not the individual brand of food that carries the claim. This approach is justified on the basis of preventing misleading and deceptive claims, for example, a claim that one brand of vegetable oil is virtually cholesterol free, when in fact all vegetable oil is naturally virtually free of cholesterol. The general approach was also supported by the majority of submitters in response to the Draft Assessment Report.

In response to the concern about enforcement, enforcement authorities can refer to food composition databases which are readily available, to determine the natural level of most nutrients in foods.

5. Use of descriptors and synonyms

5.1 Decision

FSANZ recommends the following regarding the use of descriptors in nutrition content claims:

- Nutrition content claims (and health claims) using descriptors that imply a certain quantity of the nutrient or other property of the food is present in the food, such as *good source, high, reduced, increased* and *low* will be permitted only for energy and for nutrients and substances:

    - for which there is a reference value in the Code, i.e. vitamins and minerals (which have an RDI or ESADDI), and energy, protein, fat, saturated fatty acids, carbohydrate, sodium, sugars, and dietary fibre; or

- for which there are specific conditions in the draft Standard for making claims, e.g. potassium, polyunsaturated fatty acids; or
- when the claim is specifically permitted elsewhere in the Code, e.g. certain vitamin and mineral claims permitted under Part 2.9 of the Code.

- For all other properties of the food, e.g. biologically active substances, the claim cannot include a descriptor implying a certain quantity of the nutrient or substance is present. The presence of any substance may be indicated by claims such as *with…, source of …, contains*…. etc or by using numerical values.
- For nutrition content claims for which descriptors are permitted, the list of descriptors (*rich in, more than, fewer* etc) in the Code is not exhaustive, but examples of descriptors synonymous with those provided in the Code will be included in a User Guide.
- Where there are no specific conditions for nutrition content claims in the Code but the use of descriptors is permitted, for example, *low carbohydrate* or *very high in protein* claims, the claim is regulated by fair trading legislation.
- Terms that do not precede a nutrient or substance, but imply a nutritional aspect, such as *lean, trim, skim* etc will continue to be permitted as per relevant compositional standards.

General permission for nutrition content claims is provided in clause 5 of the draft Standard. Permission for the use of descriptors is provided in clause 5(1) of the draft Standard. Specific conditions for the use of certain nutrition content claims are provided in the Table to clause 11. Subclause 11(1) provides permission for the use of synonyms for claim descriptors listed in this Table.

5.2 Amendments to current standards/CoPoNC recommendations

This approach differs to that currently in the Code. There are currently no restrictions on the use of descriptors in relation to any property of the food, except for nutrients for which there are provisions in the Code for making claims, e.g. vitamins, minerals, polyunsaturated fatty acids. For example, currently under the Code biologically active substances are not specifically addressed and subsequently there is no prohibition on the use of descriptors to describe the level of a biologically active substance that is present in a food.

CoPoNC also lists conditions for making nutrition content claims about certain nutrients, for example fat, but this is not an exhaustive list and claims for which specific conditions are not included are still permitted under CoPoNC.

5.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report it was proposed that in order to make claims that specifically referred to a *source* of a property, there had to be a reference value[1] for that property in the Code.

[1] 'Reference value' will be defined in Standard 1.1.1 as the RDI, ESADDI or a reference value under the Table to subclause 7(9) of Standard 1.2.8. The table to subclause 7(9) includes reference values for macronutrients such as carbohydrate, as well as sodium and energy.

For claims that a food is a *good source* of a property, it was proposed that there must either be a reference value for the property or specific criteria for the use of that term in relation to the property, in the Code. Terms such as *lean, trim, skim* etc were permitted and there were no specific qualifying criteria for their use.

There were no specific comments received from submitters about the approach for making *source* and *good source claims.* Some submitters agreed that qualifying criteria should not be prescribed for claims such as *lean* whereas one submitter recommended that specific qualifying criteria be set for *lean* claims. Submitters agreed that it was too prescriptive to list synonyms in the draft Standard and that a list be provided in a User Guide.

5.4 Preliminary Final Assessment Report - approach taken and submitter comments

In the Preliminary Final Assessment Report, the conditions proposed in the Draft Assessment Report were amended with the removal of the general conditions that restricted the use of *source* claims. The use of descriptors, including *good source,* were only permitted when there was either a reference value for the property of the food, or conditions for making claims about that property of the food in the Code (including in the Table to clause 11 of the draft Standard). An editorial note was inserted at the end of the Table to clause 11 to clarify that claims were not restricted to those listed in that Table. This amended approach has been retained.

There were very few submitter comments specifically about this approach. One submitter thought that the editorial note to clause 11 had a wider scope than intended because as well as permitting claims about additional properties not listed in the Table to clause 11, it indicated that additional descriptors not in the table could be used (this is FSANZ's intention).

5.5 Key changes from proposed approach in the Preliminary Final Assessment Report

From communications with stakeholders during the development of the draft Standard FSANZ has become aware there is confusion about the general permissions for making nutrition content claims. Some stakeholders have assumed that the descriptors specified in the Table to clause 11 are an exhaustive list and no other descriptors are permitted. Other stakeholders have assumed that the properties specified in the Table to clause 11 are an exhaustive list and claims about other properties are not permitted. Both of these assumptions are incorrect and FSANZ has therefore tried to clarify the draft Standard, both in terms of permissions for nutrition content claims in general, and permissions for use of certain claim descriptors. The drafting of clause 11 has been clarified and the explanatory editorial note has been rewritten and relocated to precede the Table to clause 11, to make it clear that the Table does not provide an exhaustive list of the type of nutrition content claims that may be made.

Specific permission was also provided for the use of descriptors in relation to the level of alcohol in the Preliminary Final Assessment Report. This permission has now been removed as claims about alcohol content have been excluded from the definition of nutrition content claims (see Attachment 4, Section 2.2 – Foods Containing Alcohol). As a consequence specific permission for such claims is no longer required. Declaration of alcohol by volume, standard drink information and representations of *low* alcohol content are regulated under Standard 2.7.1 – Labelling of Alcoholic Beverages and Food containing Alcohol.

5.6 Rationale for final decision

Descriptors such as *good source* and *low*, when used to describe the quantity of a property in a food, have established meanings in relation to particular nutrients, as they are linked to a proportion of the reference value for that nutrient. To avoid the potential for confusion or misleading claims, descriptors that describe the level of a substance in a food, such as *good source*, will only be permitted where:

- reference values have been established in the Code, for example, for vitamins and minerals, protein, energy etc;
- if there are criteria for such claims in the Code, or
- if there are criteria for claims about the property of the food in the Table to clause 11 of the draft Standard (i.e. potassium, omega fatty acids, poly and monounsaturated fatty acids).

These will provide guidance for what would be considered a *good source* or *very low* etc (except for potassium claims. Refer to Chapter 21 – Potassium in Part 2 of this Attachment). In all other cases, claims may be made that indicate the presence of the property without using a descriptor that implies a certain level of the property in the food. For example, *source* and *contains* may be used. Specific permission is provided in the draft Standard for the use of numerical values to indicate the level of a substance in the food, e.g. GL = 12, even if other descriptors are not permitted.

The draft Standard permits the use of synonyms in addition to the claim descriptors listed in the Table to clause 11, as long as the appropriate qualifying criteria are met. FSANZ considers that it would be unduly prescriptive and not commensurate with the level of risk associated with nutrition content claims to limit the use of synonyms for these claims. Furthermore, it would be difficult to ensure that all appropriate terms and descriptors are captured and maintained in the draft Standard. For these reasons, an exhaustive list of synonyms for nutrition content claims is not considered to be appropriate.

Nonetheless, some guidance is needed in relation to the use of alternative descriptors for nutrition content claims, particularly as consumer research has shown that there are more descriptors being used in nutrition content claims than those specified in regulation or in CoPoNC (Williams *et al,* 2003). On this basis, FSANZ will include an illustrative list of synonyms for nutrition content claims in a User Guide.

Terms that do not precede a nutrient or substance but imply a nutritional aspect of a food, such as *lean, trim, skim* etc will continue to be permitted and are not specifically addressed under the draft Standard. The use of these types of terms is regulated under fair trading legislation and in some cases is guided by commodity specific standards in the Code, e.g. s*kim milk* is defined in Standard 2.5.1 – Milk and Standard 2.2.1 – Meat and Meat Products has requirements for declaring the fat content when an express or implied reference is made in relation to the fat content of mince.

6. Percentage daily intake and percentage recommended dietary intake

6.1 Decision

FSANZ recommends the following for percentage daily intake and recommended dietary intake labelling:

- Continue to allow voluntary percentage daily intake (%DI) labelling in the nutrition information panel with the additional permission of the abbreviated '8700 kJ' statements:
  - 'based on an average adult diet of 8700 kJ'; or
  - 'Percentage daily intakes are based on an average adult diet of 8700 kJ'.
- Permit %DI labelling information for energy alone or together with protein, fat, saturated fatty acids, carbohydrate, sugars and sodium outside the nutrition information panel, all in one place with serving size information, (without the information being considered a claim) provided %DI information for energy and the prescribed nutrients are all presented in the nutrition information panel.
- Require the declaration of the percentage of the Recommended Dietary Intake (%RDI) in the nutrition information panel (for those nutrients for which there is a RDI specified in the Code) when nutrition content or health claims are made in relation to the presence of vitamins and minerals.
- Permit %RDI labelling outside the nutrition information panel together with serving size information, without the information being considered a claim.

The provisions for voluntary %DI labelling are provided in clause 7 of amended Standard 1.2.8 – Nutrition Information Requirements. The provisions for %RDI labelling are provided in clause 7A of amended Standard 1.2.8 – Nutrition Information Requirements.

6.2 Amendments to current standards/CoPoNC recommendations

Currently voluntary %DI labelling is permitted in the nutrition information panel as prescribed in Standard 1.2.8 – Nutrition Information Requirements. Percentage DI labelling outside the nutrition information panel is currently considered to be a claim and therefore must comply with any relevant qualifying criteria. However, there are no specific requirements for %DI labelling outside the nutrition information panel. FSANZ is now recommending that %DI labelling outside the nutrition information panel be not considered a claim and in addition, that there be some specific requirements if %DI labelling is used.

Currently, if a nutrition content or health claim is made in relation to the presence of a vitamin or mineral, the %RDI of that vitamin or mineral is required to be declared on the label as prescribed in Standard 1.3.2 – Vitamins and Minerals. This requirement will be now located in Standard 1.2.8 – Nutrition Information Requirements, and the information will now be required to be in the nutrition information panel. The facility for %RDI information to be presented outside the nutrition information panel is similar to that for %DI labelling.

6.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report it was recommended that products with nutrition content or health claims be required to have %DI values for energy and the %DI or %RDI value for the claimed nutrient in the nutrition information panel (see Chapter 1 – Regulatory Approach for Nutrition Content Claims in Part 1 of this Attachment for further discussion of this approach and submitter comments). Abbreviated 8700 kJ statements within the nutrition information panel were also recommended. In addition, it was proposed that provisions for %RDI labelling be moved from Standard 1.3.2 to Standard 1.2.8 and that %RDI information 'must' be in the nutrition information panel rather than 'may' be.

There were no comments specifically relating to %RDI labelling requirements. Comments were made on %RDI labelling in the context of FSANZ mandating %DI labelling for products with nutrition content and health claims (see Chapter 1 – Regulatory Approach for Nutrition Content Claims in Part 1 of this Attachment).

6.4 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report FSANZ recommended that the mandatory requirements for %DI labelling on products with nutrition content or health claims be removed. Consequently, FSANZ reviewed the voluntary provisions for %DI labelling and recognized that under the draft Standard, which contains nutrition content claim conditions, the voluntary presentation of %DI information outside the nutrition information panel would technically be considered as nutrition content claims. Since some of the %DI values may not qualify as a nutrition content claim based on proposed claim conditions (e.g. protein), FSANZ recommended that %DI labelling presented outside the nutrition information panel not be considered a claim. In addition, it was proposed that %DI labelling for energy alone or together with the prescribed nutrients would be permitted outside the nutrition information panel provided %DI for energy and the prescribed nutrients were in the panel. The permission for abbreviated 8700 kJ statements proposed in the Draft Assessment Report was retained. In relation to %RDI labelling, a new clause 7A in Standard 1.2.8 was included to specifically cover the requirements.

The majority of submitters in industry and government stakeholder groups who commented on voluntary %DI labelling supported the proposed approach. However a few submitters in these stakeholder groups considered that there should be no constraints on %DI labelling outside the nutrition information panel (e.g. being able to present %DI for any combination of the prescribed nutrients) while in contrast to this some considered that %DI labelling should only be permitted in the nutrition information panel. While there was some support for the proposed approach from submitters in public health and consumer stakeholder groups, submitters from these groups tended to either support restricting the use of %DI labelling outside the nutrition information panel to only those products meeting claim conditions for energy, macronutrients or sodium, or only permitting %DI labelling to be presented in the nutrition information panel. There were a number of more specific comments as follows:

Regulatory approach

- %DI labelling should be permitted in the nutrition information panel but the legislative provision should be sunset for a regulatory review of %DI labelling outside the nutrition information panel without being considered a nutrition content claim, subject to an evaluation of an industry programme educating consumers about %DI labelling and a regulatory review of the usefulness and effectiveness of food labelling systems.
- A labelling scheme that genuinely supports healthier food choices might be useful but there needs to be more research and also labelling options need to be considered in conjunction with front-of-pack labelling discussions (via the Food Regulation Ministerial Council) and the review of the Code in relation to the 2006 NHMRC nutrient reference values.
- An investigation of consumer understanding of %DI labelling should be part of the review of the implementation of Standard 1.2.7.
- Permitting %DI labelling for energy only is a marketing tool for industry.
- %DI labelling could be misleading on high energy density foods which have small serve sizes, it does not account for nutrient density which could be misleading, and the presence of the information may cause consumers to consider the food to be healthy.
- Since industry is already using front-of-pack %DI labelling, FSANZ is simply amending the Standard to permit what is currently being placed on labels despite difficulties with consumers understanding the information, 8700 kJ not being appropriate for all age groups and %DI labelling not being intended for use on foods targeted at children/adolescents.

Labelling requirements and 8700 kJ statement

- Specify that %DI/%RDI labelling outside the nutrition information panel needs to be for the same form and serve size as in the nutrition information panel.
- Require serve size and the 8700 kJ statement near %DI values outside the nutrition information panel.
- There is a question about the relevance and value of %DI labelling because they are based on an 8700 kJ diet and non-standardized serve sizes.
- For foods marketed to young children, it was suggested that consumers are informed that energy requirements of young children are likely to be significantly less than 8700 kJ.
- Need to clarify whether %DI labelling of energy plus %RDI for vitamins and minerals is permitted.
- Allow %DI values for nutrients present in negligible amounts (%DI<1) to be omitted from labelling requirements outside the nutrition information panel.
- The 2006 NHMRC and Ministry of Health nutrient reference values should be used to review the reference values used for calculating %DI values.

6.5 Rationale for final decision

The approach taken in the Preliminary Final Assessment Report, that %DI labelling for energy alone or together with the prescribed nutrients can be presented outside the information panel, will be retained.

FSANZ considers that while international literature and its own research (TNS Social Research, 2007) on %DI labelling raises some questions about consumer understanding and use of the concept, the increasing interest in front-of-pack labelling from consumer, public health and industry stakeholders supports the voluntary permission for %DI labelling. In addition, given the relatively recent use of %DI information on food labels, the impact of consumer education and marketplace exposure on the usefulness of %DI information for consumers cannot yet be evaluated. In response to direction from the Ministerial Council, the Food Regulation Standing Committee is currently reviewing front-of-pack labelling systems which includes %DI labelling (see Section 39 – Front-of-Pack Labelling of the Final Assessment Report). Until the outcome of this review and any subsequent direction from the Ministerial Council to FSANZ is known (likely to be late 2008), FSANZ considers it is appropriate to permit voluntary %DI labelling both inside and outside the nutrition information panel.

In response to submitter suggestions to only permit %DI labelling outside the nutrition information panel on those products meeting claim conditions, FSANZ considers that the purpose of permitting voluntary %DI labelling is to allow industry the option of providing information to consumers in a more visible format for any products and not to restrict the information to some products. Under such an approach it would be possible that only some %DI values would be present, rather than values for all prescribed nutrients. FSANZ research (TNS Social Research, 2007) indicates that consumer understanding of %DI information may be hindered if values for some of the prescribed nutrients are omitted. Although %DI labelling is voluntary, ultimately such information is potentially of most benefit to consumers if values for all prescribed nutrients are present on the majority of products within a product category.

In situations where %DI information for energy and all prescribed nutrients is presented outside the nutrition information panel, FSANZ considers that the same information needs to be presented in the nutrition information panel, because this ensures that all supporting information is in the one place, i.e. the 8700 kJ statement and the serving size.

Permission to present %DI labelling for energy alone outside the nutrition information panel is justified on the basis that this information may encourage consumers to consider overall energy intake. If %DI for energy is presented alone, then all %DI values must be given in the nutrition information panel to ensure that consumers have access to the %DI values for all prescribed nutrients. Percentage daily intake labelling for energy together with %RDI labelling for vitamins and/or minerals outside the nutrition information panel is permitted. FSANZ is aware of submitter comments claiming that products with %DI for energy on the front-of-pack may be incorrectly considered as healthy and acknowledges that research has indicated consumers can find it difficult to interpret %DI values for energy (TNS Social Research, 2007). However, consumer understanding and the use of front-of-pack information will be considered in the FRSC front-of-pack review.

In response to some of the issues raised by submitters the drafting has been amended to clarify intent. The %DI/%RDI labelling information presented outside the nutrition information panel is required to be for the same form of the food and serving size as that presented in the nutrition information panel. In addition the serving size needs to be stated alongside %DI/%RDI information presented outside the nutrition information panel. These requirements will assist consumers with the interpretation of %DI information.

FSANZ considers that presenting the 8700 kJ statement outside the nutrition information panel is not necessary as it does not vary from product to product and is included in the nutrition information panel. While FSANZ acknowledges that the 8700 kJ basis for %DI values is not appropriate for many population groups, any review of this is outside the scope of Proposal P293. The use of this value will be reviewed when consideration is given to the incorporation of the 2006 NHMRC nutrient reference values into the Code. This will include consideration of developing %DI criteria for a wider range of age groups than is currently permitted. In addition, reference to this issue will be made in the User Guide which will indicate that the use of %DI on foods marketed to children can be misleading.

FSANZ has considered the suggestion that %DI values for nutrients present in negligible amounts be permitted to be omitted when presenting information outside the nutrition information panel. In order to be consistent with the nutrition information panel which requires that 'zero' values are reported, FSANZ maintains that all %DI values should be presented. Research would need to be undertaken to investigate the impact of varying this approach on consumer use and understanding of %DI labelling in conjunction with understanding of the nutrition information panel.

Since %DI labelling is voluntary FSANZ does not consider it necessary to provide alternative approaches for small packages, other than the provision for presenting the %DI for energy alone.

7. Conditions regarding the basis for claims – as sold or as prepared

7.1 Decision

FSANZ recommends the following conditions as the basis of all nutrition content claims and health claims (i.e. the qualifying criteria and nutrient profiling scoring criteria must both be applied to the food in the specified form):

- for foods that require reconstituting with water (according to directions) prior to consumption, the claim must be based on the food after it has been reconstituted and is ready for consumption;
- for foods that are required to be drained (according to directions) prior to consumption, the claim must be based on the food after it has been drained and is ready for consumption;
- when a food is required to be prepared with other foods according to specific directions (prior to consumption), the claim must be based on the food as prepared according to those directions;
- when a food can be either prepared/consumed with other food or consumed in the same state as it is sold, the claim must be based on the food in the state in which it is sold;
- for foods that can be prepared in a variety of ways with other foods, e.g. flour, oil, and for foods that are consumed in the same state as which they are sold, the claim must be based on the food in the state in which it is sold;
- the claim must indicate the form of the food to which the claim applies; and
- the nutrition information panel must provide appropriate information to support the claim (for example, a third column for nutrient declarations for the food 'as prepared' may be required).

These conditions are prescribed in the draft Standard under clause 6 and the Table to clause 6.

7.2 Amendments to current standards/CoPoNC recommendations

Currently in the Code, conditions for the basis of claims when the food is required to be prepared with other foods or diluted or reconstituted are not specified except in certain situations. Under Standard 1.2.8 – Nutrition Information Requirements, *low joule* claims must be calculated for the food as prepared, when a food is required to be prepared as directed on the label. This specific requirement will be replaced with the generic requirements covering all claims, as outlined in the recommendations above.

The voluntary CoPoNC stipulates that the conditions for making claims apply to the food in the form in which it is intended to be consumed. If the claim depends for its accuracy on the method of preparation by the consumer, then the label must include information which allows the consumer to prepare the food in such a way that the prepared food meets the claim. If directions are given for mixing the food with other ingredients, such that the final food does not comply with the claim made for the food, the label must draw attention to the fact that the final product will not meet the claim.

These conditions will be replaced by those outlined in the recommendations above. Specifically, the requirement that the label must draw attention to the fact that the final product will not meet the claim if the food is mixed according to directions will not apply. Instead, if specific directions are provided such that the food must be prepared with other foods, the claim must be based on the prepared food.

7.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report, we did not specifically address whether the qualifying criteria and the nutrient profiling scoring criteria should be based on the food in the 'as sold' or 'as prepared/consumed' state. This approach was based on the assumption that to do so would be inconsistent with the requirements in the Code which apply to the food 'as sold' rather than 'as consumed'. There was one exception to this which was for *low energy* claims, where the conditions were carried over from Standard 1.2.8 and included that where the 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. In addition, the Substantiation Framework stated that: *The content should be determined on the form of the food in which it is intended to be consumed. For packaged foods, this will generally be the form suggested in the directions for use included in the label.*

Submitters that commented on this aspect (industry and government) were of the opinion that the claim should apply to the food as prepared/consumed rather than as sold, as FSANZ did not provide any evidence that the claim could be misleading if based on the prepared food. One submitter suggested that for foods such as Milo, the qualifying criteria could be based on the prepared food but the disqualifying criteria (now referred to as nutrient profiling scoring criteria) be based on the food as sold. In addition, it was considered that if clear directions for use are provided on the label it should be sufficient that the claim is based on those directions. It was noted that as this was not clear in the draft Standard, it could be clarified in a User Guide.

Other submitters pointed out that although it was stated in the Draft Assessment Report that conditions for consumption could not be specified in the Code, such conditions are already specified in other Standards in the Code, for example Standards 1.2.8, 1.3.2 and 2.9.3.[2] It was recommended that the CoPoNC criteria for conditions under which nutrient claims can be made be adopted without change as there has been no evidence of market failure.

7.4 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report FSANZ acknowledged that as noted by submitters, the conditions under which certain claims can be made are currently regulated in various Standards of the Code, and this was taken into consideration and the conditions for the basis of claims were reviewed. Conditions for the form of the food to which the claim should apply were developed and provided for consultation in the Preliminary Final Assessment Report. It was proposed that:

- when the food is required to be drained or reconstituted with water prior to consumption, the claim must be based on the food when drained or reconstituted;
- when the food is intended to be consumed with other food and the supplier provides directions for preparation or consumption with other food, then the claim must be based on the food in the prepared state;
- for foods that can either be prepared with other food prior to consumption or consumed in the 'as sold' state, then the claim can be based on either form of the food; and
- in the absence of directions for preparation or consumption, the claim should be based on the food in the 'as sold' state.

A number of submitters supported this proposed approach although some submitters disagreed or suggested it be refined. Some submitters objected to permission to base the claim on the food 'as prepared' considering it is to be misleading because:

- this allows foods to make claims based on added foods, e.g. the milk added to flavoured sugar or breakfast cereal;
- consumers may not follow directions for use on the label; and
- manufacturers may add or manipulate directions for use in order to meet the conditions for making the claim.

Other submitters did not support permission for the claim to be based on the food in its 'as sold' state if the food as prepared no longer qualifies for the claim (if directions for use include added ingredients). It was suggested that the draft Standard should apply to the food as intended to be consumed, where a food is labelled with directions for use.

[2] The definition of 'reference quantity' in Standard 1.3.2 – Vitamins and Minerals, for foods that require dilution, reconstitution, draining or preparation according to directions, is the quantity of the food which when diluted, reconstituted, drained or prepared produces a normal serving. According to the definition of 'serving' in Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods, claims can be based on the food when prepared according to manufacturer's directions. In Standard 2.9.4 – Formulated Supplementary Sports Foods, certain claims must be based on these products when prepared as directed.

If there is uncertainty as to how a food will be prepared or consumed, then the claim should apply to both the food as sold and as intended to be consumed, to avoid manipulation of directions for use. It was considered that claims on foods such as breakfast cereals should be based on the food in its 'as sold' state.

There was some submitter concern around whether the requirement for the claim to refer clearly to 'as sold' or 'as prepared' would be enforceable, as the Report stated that this requirement would be outlined in a User Guide.

Some submitters commented the Report stated that 'the as sold product needs to be eligible for a source claim' and that the conditions for the claim could not be based solely on added foods in the process of preparation, but they questioned how this would be enforceable. These submitters felt that the food in the state in which it is sold needs to be eligible for a 'source' claim even if the claim applies to the food when prepared according to directions.

7.5 Key changes from proposed approach in the Preliminary Final Assessment Report

The submitter comments outlined above were considered and the approach has been refined since the release of the Preliminary Final Assessment Report. The main amendments to the approach that was proposed in the Preliminary Final Assessment Report are:

- The claim must be based on the food as prepared according to directions, when the food is required to be prepared according to specific directions provided by the supplier; i.e. when it would not be eaten in the state in which it is sold, e.g. cake mixes, custard powder, milk flavouring. This has strengthened the previous approach which required the claim to be based on the food as consumed when the food was 'intended' to be consumed with other food.
- The claim must be based on the food in the state in which it is sold, if the food can be consumed either in the state in which it is sold, or with added foods, e.g. breakfast cereal, bread, meat. This differs to the previous approach where a choice was given as to the form of the food to which the claim should apply.

7.6 Rationale for final decision

Although the Ministerial policy guideline is not explicit on this issue, claim pre-requisite 5 states that a claimed benefit must be *derived from the food or component in question for which the claim is made and not from consuming the food with a combination of specific foods*. The requirements for labelling information to clearly indicate the basis of any claim are considered necessary to provide clarity for consumers and enforcement officers, and to avoid misleading claims. Clause 11 of Standard 1.2.8 currently allows for the option to include a third column in the nutrition information panel to specify the nutritional details for that food when prepared or consumed with at least one other food. This third column must be provided on the label of foods where the claim is based on the food in its 'as consumed' state and there must be consistency between this information, the basis for the claim, and the directions for use of the food as provided on the label. The recommended approach therefore provides for consistency of regulation across the Code.

Clause 9 of Standard 1.2.8 requires that where a food is labelled with directions for reconstituting with water before consumption, the nutrition information panel must relate to the reconstituted food. Clause 10 of Standard 1.2.8 requires that where a food is labelled with directions for draining the food before consumption, the nutrition information panel must relate to the drained food. FSANZ considers that this approach should also apply to nutrition content claims and health claims on foods requiring reconstituting with water or draining prior to consumption. Therefore both the qualifying criteria and the nutrient profiling scoring criteria must be applied to the reconstituted/drained food. This will ensure that the claim is based on the form of the food that is most likely to be consumed and the values that the claim is based on will be reflected in the nutrition information panel.

When a food is required to be prepared with other foods prior to consumption according to directions provided for that food, the claim must be based on the food as prepared according to those directions. This requirement is intended to apply only to foods that would not be consumed in the state in which they are sold, and that have specific directions for use, for example, cake mixes, custard powder, milkshake flavour. Once again this will ensure that the claim is based on the form of the food that is consumed by the consumer. It also takes into account the addition of other foods that either dilute or increase the concentration of certain nutrients, which could make the claim invalid if not taken into account. This approach allows the qualifying criteria to be met by the added food alone, however, the claim must clearly indicate that it is based on the added food, and the nutrition information panel must include the third column as outlined above, thus reducing the potential for consumers to be misled into thinking the food itself provides the claimed nutrient(s). In addition, the claim can only be based on the added food, if this is way that the food is required to be consumed.

For consistency and to prevent misleading claims, it is required that both the qualifying criteria and the nutrient profiling scoring criteria are met by the food in the same form, i.e. the food ‘as sold’ meets both the qualifying and nutrient profiling scoring criteria, or the food as prepared/consumed meets both the qualifying criteria and the nutrient profiling scoring criteria. This also means that a health claim cannot be based on the added food alone; for example, powdered milkshake flavouring labelled with directions for adding milk could not make a health claim about the protein from the milk unless the powder and the milk combined meet both the qualifying criteria and the nutrient profiling scoring criteria.

For foods that may either be consumed in the state in which they are sold or consumed with other foods (which may often vary), for example, breakfast cereals and bread, the claim must be based on the food in the state in which it is sold. This approach addresses submitters concerns that where there is uncertainty as to how the food would be consumed, the basis for the claim is clear. It will also reduce the potential for manufacturers to add or manipulate directions for use in order to be able to qualify to make a certain claim. The third column in the nutrition information panel as currently permitted under clause 11 of Standard 1.2.8 is still permitted on these foods; however the claim cannot be based on the information provided in this third column.

If directions for preparation/consumption are not provided on a label, but an intended use of the food is as an ingredient, for example, vegetable oil, flour, it would be misleading to base the claim on the final food product. Hence the claim should be based on the food ‘as sold’.

It must be clear from the presentation of the claim, the form of the food to which the claim applies. This provides clarity for enforcement agencies and consumers. This requirement has been included in the draft Standard (rather than in a User Guide as was stated in the Preliminary Final Assessment Report) and therefore will be enforceable.

PART 2 – ADDITIONAL SPECIFIC CONDITIONS FOR CERTAIN NUTRITION CONTENT CLAIMS

8. Biologically active substances

8.1 Decision

FSANZ recommends the following approach for regulating nutrition content claims about biologically active substances:

- Nutrition content claims about biologically active substances must meet the general conditions for nutrition content claims.

A definition of 'biologically active substance' is provided in clause 1 of Standard 1.2.8.

These claims are regulated by clause 5 of the draft Standard.

8.2 Amendments to current standards/CoPoNC recommendations

Currently, the Code (Standard 1.2.8) defines a biologically active substance as *a substance, other than a nutrient, with which health effects are associated.* This definition will be retained in the Code.

There are no qualifying criteria for nutrition content claims about biologically active substances in the Code or CoPoNC. 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 if a nutrition claim is made.

Some of the general conditions for nutrition content claims set out in the draft Standard will be new and will apply to nutrition content claims about biologically active substances. For example, a claim may only include descriptors for the level of the property of the food if there are reference values or conditions for making a claim in relation to that property set out in the Code.

8.3 Draft Assessment Report – approach taken and submitter comments

The approach taken in the Final Assessment Report is the same as the approach that was described in the Draft Assessment Report, except that in the Draft Assessment Report it was also required that the basis for the amount of the substance that was required to be consumed per day was stated in the actual wording of the claim.

Most submitters supported the proposed approach in principle, and agreed that nutrition content claims about biologically active substances should be permitted, but raised some specific objections to the regulatory approach.

Some submitters explicitly stated that all biologically active substance claims should be prohibited. Others suggested that nutrition content claims for biologically active substances should only be permitted on a case by case basis subject to the implementation of further regulatory measures; such as regulation of the addition of substances other than vitamins and minerals to food. They argued that biologically active substances are not essential, and are not present in a wide range of products.

There were also some concerns about the definition of biologically active substance used in the Code and the applicability of the regulatory approach to non-culinary herbs used in food. It was suggested that this and other issues could be better addressed as part of the policy on addition to food of substances other than vitamins and minerals currently under development by the Food Regulation Standing Committee (refer to Section 41 - Review of Addition of substances other than Vitamins and Minerals, of the Final Assessment Report) and through Standard 1.5.1 – Novel Foods.

Industry stakeholders expressed very strong opinions on the proposed restriction of the use of descriptors when making biologically active substance claims. They argued that any restriction on the use of descriptors would limit the ability of manufacturers to effectively communicate the levels of biologically active substances found in a food, would discourage innovation and would not encourage manufacturers to include meaningful amounts of a biologically active substance in their products when making a nutrition content claim.

In submissions to the Draft Assessment Report and during further consultation, industry stakeholders stated that the need to state in the wording of the claim the basis on which the amount of the substance that needs to be consumed per day has been determined could be onerous.

8.4 Preliminary Final Assessment Report – approach taken and submitter comments

Minor changes to the drafting in respect of nutrition content claims about biologically active substances were made in the Preliminary Final Assessment Report (section 9). This included removing the requirement that the wording of the claim include the basis on which the amount of the substance that needs to be consumed per day has been determined

Some comments on the approach to regulating nutrition content claims about biologically active substance were received in response to the Preliminary Final Assessment Report. Issues raised were similar to those raised in response to the Draft Assessment Report.

Submitters further commented about a number of potential inconsistencies in the drafting, in particular regarding conditions for nutrition content claims about biologically active substances set out in the Table to clause 11 of the draft Standard.

All stakeholder comments were considered by FSANZ before deciding on the final approach.

8.5 Changes from proposed approach in the Preliminary Final Assessment Report

FSANZ has retained the general approach presented in the Draft and Preliminary Final Assessment Report, as well as the changes to the drafting proposed in the Preliminary Final Assessment Report. In addition FSANZ proposes further changes to the drafting.

In particular, the reference to biologically active substance in the Table to clause 11 has been removed as it is considered to be redundant because the conditions set out in the Table are the same as those required for nutrition content claims in general, by clause 5 of the draft Standard. This does not change the requirements for making nutrition content claims about biologically active substances.

8.6 Rationale for final decision

The final approach taken in the draft Standard is that nutrition content claims based on biologically active substances must meet the same general conditions as nutrition content claims about other nutrients or properties of the food, e.g. the supplier has records to substantiate the claim and the nutrition information panel includes particulars of the quantities of biologically active substances (as required under Standard 1.2.8). Claims that indicate the presence of the biologically active substance, such as *source of* or *contains* are permitted.

In general, nutrition content claims may include descriptors for the level of the property of the food that is present if there is either a reference value for the property of the food in the Code, or there are specific conditions in relation to the property set out in the draft Standard. Biologically active substances do not have nationally agreed reference values and therefore descriptors cannot be used that describe a certain level of the substance in the food, for example *rich* or *good source,* because there is no basis from which to set qualifying criteria for making these claims. Use of descriptors for the level of the property of the food, e.g. that a food is a *good source* (*high in*, *rich in*, and synonyms thereof), imply the existence of reference values or dietary recommendations and therefore may mislead or confuse consumers. Consumers cannot verify or assess such a claim, or choose between comparable foods based on such claims.

Similarly, claims that use comparison statements, e.g. *increased,* are only meaningful if the amount of the substance that provides the health effect is well understood by the consumer; otherwise, consumers cannot verify if purchasing the food with the comparatively higher or lower amount of a biologically active substance provides any additional value to them. Therefore, comparative claims about biologically active substances (and other nutrients or substances with no reference value in the Code or conditions in the Table to clause 11 of the draft Standard) will not be permitted, because the requirement that the reference food be a *source* of the substance (i.e. that the reference food contains a pre-requisite amount of substance as defined by qualifying criteria) cannot be applied, because the *source* concept is not applicable to these substances.

Compositional and safety aspects are not managed by the draft Standard, but are addressed by other Standards, such as Standard 1.4.4 – Prohibited and Restricted Plants and Fungi and Standard 1.5.1 – Novel Foods.

The policy on the addition to food of substances other than vitamin and minerals, currently under development by the Food Regulation Standing Committee will, in due course, provide additional guidance on the risk management necessary to protect public health and safety, and will complement the management of biologically active substance claims set out in the draft Standard.

9. Carbohydrate

9.1 Decision

FSANZ recommends that nutrition content claims about carbohydrate will be permitted but there will be no specific qualifying criteria for such claims.

9.2 Amendments to current standards/CoPoNC recommendations

There are currently no specific qualifying criteria for claims about carbohydrates, in the Code or in CoPoNC. CoPoNC includes general conditions that apply to all comparative claims including those in relation to carbohydrate, e.g. *increased carbohydrate*, however in the draft Standard, conditions for comparative claims about carbohydrate are not specified.

9.3 Draft Assessment Report – approach taken and submitter comments

The approach in the Draft Assessment Report for claims about carbohydrate content has been retained.

Some submitters recommended that criteria be developed for carbohydrate claims, particularly with respect to *low carbohydrate*. Reasons given for this were that:

- there are a number of these claims on the market place, all using divergent/inconsistent criteria;
- enforcement of these claims is difficult; and
- fair trading legislation is not effective.

The Australian Consumers Association noted that FSANZ will rely on the Australian Competition and Consumer Commission (ACCC) to take action against misleading claims, however, they are concerned that without guidance from FSANZ it would be difficult for them to determine when a *low carbohydrate* claim is misleading.

It was also suggested that these claims should be prohibited, as *low carbohydrate* claims are not in line with dietary guidelines, these claims will result in consumer confusion and misunderstanding of the role of carbohydrates in the diet, and because of the increased cost of products carrying them. Another suggestion was that FSANZ raise a separate proposal to consider the regulation of carbohydrate claims.

Submitters noted an investigation published in the CHOICE magazine (2005) which found the energy content only marginally lower in *low carbohydrate* foods compared with regular counterparts.

9.4 Preliminary Final Assessment Report – approach taken and submitter comments

The regulation of claims about carbohydrate content was not amended or consulted on in the Preliminary Final Assessment Report, although some submitters provided comment about these claims.

In addition to similar comments to those made in response to the Draft Assessment Report, it was noted that Australians do not have a high carbohydrate intake by international standards, despite the guidelines indirectly promoting a high carbohydrate diet. It was felt that clear guidance is needed on what constitutes high carbohydrate foods and beverages.

9.5 Rationale for final decision

Claims such as *low carbohydrate and good source of carbohydrate* will be permitted because there is a lack of evidence of a public health risk associated with carbohydrate claims to support their prohibition. It is also in the interests of minimal effective regulation to not prohibit these claims. Where there are clear cases of misleading labelling, fair trading legislation can be utilised.

Specific qualifying criteria for claims about carbohydrate will not be prescribed. This approach is supported by the 2006 NHMRC Nutrient Reference Values for Australia and New Zealand which provide an Adequate Intake (AI) for carbohydrate for infants (0 – 6 months and 7 - 12 months) but no other specific recommendations for other age groups, citing the reason of limited data on which to base an estimate of requirements (NHMRC and Ministry of Health, 2006). There is therefore no appropriate nutrient reference value on which to base qualifying criteria for claims about carbohydrate.

In addition, although *low carbohydrate* claims are permitted (by virtue of no prohibition), qualifying criteria for these claims will not be set because setting such criteria implies that there would be a health benefit from a low carbohydrate diet and this has not been established. 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.

Further rationale for not providing criteria for *source* or *good source of carbohydrate* claims is that national nutrition guidelines encourage the consumption of complex carbohydrates rather than carbohydrate per se. Concern has been expressed by public health professionals that claims such as *source of carbohydrate* are misleading, if not ambiguous, as they do not distinguish between high levels of complex carbohydrates and high levels of sugars. In addition, consumers could easily confuse them with the issue of Glycemic Index and Glycemic Load. Providing such criteria would potentially act to encourage the use of carbohydrate claims.

In the United Kingdom, claims regarding carbohydrate content are not regulated. The Codex Guidelines for Use of Nutrition and Health claims (Codex Alimentarius Commission, 2005) do not include conditions for making claims in relation to carbohydrate content. However in Canada, claims such as *source of complex carbohydrates*, *low carbohydrate*, and *light* claims referring to the carbohydrate content are prohibited. In the European Union *low carbohydrate* claims are also not permitted and specific conditions for making *source of carbohydrate* claims are not prescribed.

10. Cholesterol

10.1 Decision

FSANZ recommends the following conditions for nutrition content claims about cholesterol:

Claim	Conditions
Cholesterol *free*	The food must comply with the conditions for a nutrition content claim in relation to *low* saturated fatty acids. Note – cholesterol content will be regulated by fair trading legislation
Low (in) cholesterol	The food must not contain any more than 10 mg cholesterol per 100 ml for liquid food and 20 mg cholesterol per 100 g for solid food. The food must comply with the conditions for a nutrition content claim in relation to *low* saturated fatty acids.
Reduced (in) cholesterol	
Light claims in relation to cholesterol content	The food must comply with the conditions for a nutrition content claim in relation to *low* saturated fatty acids. The comparison should be based on a reduction of at least 25% in the cholesterol content compared to a 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 together.

These conditions are specified in the Table to clause 11 of the draft Standard.

10.2 Amendments to current standards/CoPoNC recommendations

Claims in relation to cholesterol content are not currently regulated by the Code, hence these conditions will be new.

CoPoNC includes conditions for *reduced cholesterol*, *low cholesterol* and *cholesterol free* claims. For all these claims, CoPoNC includes additional conditions around the total fat or fatty acid content of the food (the food must either meet the conditions for *low fat* claims or the fatty acid component of the food must contain no more than 20% saturated fatty acids and not less than 40% of polyunsaturated or of monounsaturated fatty acids). These conditions have not been carried over into the draft Standard. Other differences are that CoPoNC did not include a criterion for liquid foods for *low cholesterol* claims, and for the *reduced cholesterol* claim, under CoPoNC the food also has to meet the conditions for a *low cholesterol* claim (rather than a *low saturated fatty acid* claim). Conditions for the *cholesterol free* claim also differ to those in CoPoNC, where up to 3 mg of cholesterol per 100 g of food were permitted.

10.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report, the approach for claims about cholesterol content was similar to that outlined above, except that conditions were not included for liquid foods. For further details about *reduced cholesterol* claims, refer to Chapters 11 and 12 in Part 2 of this Attachment.

Some submitters (mainly from government and public health sectors) opposed the permission of cholesterol claims, because they:

- perpetuate consumer confusion;
- are not important in terms of heart disease; and
- are misleading on products that do not normally contain cholesterol.

It was suggested that if permitted, they be restricted to animal based foods only.

Some industry submitters opposed the use of additional criteria around the level of saturated fatty acids because:

- this is an absolute claim;
- justification is based on a 'belief' that consumer knowledge about the relationship between dietary cholesterol and blood cholesterol is poor; and
- it makes no sense to assume that foods with less saturated fatty acids also have less cholesterol, for example, the cholesterol *free* claim would be prohibited on avocado due to the saturated fatty acid level.

Submitters recommended that the conditions in CoPoNC (the food must either meet the conditions for *low* fat or the fatty acid component of the food must contain not more than 20% saturated fatty acids and not less than 40% of polyunsaturated or of monounsaturated fatty acids) are applied instead.

10.4 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report, conditions were included for *low cholesterol* claims on liquid foods, to provide consistency with Codex guidelines (Codex Alimentarius Commission, 2005) (as intended in the Draft Assessment Report) and with the approach used for criteria for most other risk increasing nutrients, i.e. separate criteria for solid and liquid foods. The conditions were also amended for *cholesterol free* claims – refer to Chapter 16 – Free Claims, in Part 2 of this Attachment).

Most submitters who commented about cholesterol claims recommended that these claims be prohibited. It was noted by submitters that FSANZ's basis for permitting these claims is that there is a long history of such claims and a reliance on them by consumers. They noted that FSANZ's research however, indicated consumers were misled by the claims, based on their poor knowledge of the relationship between dietary cholesterol and blood cholesterol. Another submitter concern was that these claims are often on plant foods that do not naturally contain cholesterol. It was thought that even with an additional criterion relating to the level of saturated fat, permission for these claims does nothing to address the confusion, which may only be worsened by the high level health claim based on the pre-approved food-disease relationship regarding blood cholesterol and saturated fatty acid intake. Also there are no reference values for cholesterol in the 2006 Nutrient Reference Values for Australia and New Zealand. It was suggested that the two year transition period and the ability to change the focus to claims about other nutrients such as saturated fat would help negate the impact on industry if claims about cholesterol were prohibited.

10.5 Rationale for final decision

FSANZ consumer research (FSANZ, 2003a) indicates 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. FSANZ acknowledges that permission for these claims will not reduce consumer confusion about the relationship between dietary cholesterol and blood cholesterol. However it is recommended that cholesterol claims continue to be permitted. The inclusion of a criterion about the level of saturated fatty acids for all cholesterol claims (including *cholesterol free)* will restrict their use in the marketplace, thus partly addressing submitter requests that these claims be prohibited.

The application of the additional criterion for the level of saturated fatty acids is supported by dietary guidelines which place a greater emphasis on reducing the intake of saturated fatty acids rather than dietary cholesterol. This additional risk management tool is aimed at ensuring foods carrying cholesterol claims are appropriate in terms of their fatty acid content. Application of the qualifying criteria for the *low* saturated fatty acid claim maintains consistency with *the low saturated fatty acid* claim, including the rationale for the criteria associated with saturated fatty acids (see Chapter 25 – Saturated and Trans Fatty Acids, in Part 2 of this Attachment).

The general requirement in the draft Standard that the claim refers to the whole food rather than the brand name where a food is naturally low in a nutrient, should also reduce the potential for claims about cholesterol on plant foods to be misleading. Similarly to nutrition content claims on foods that do not normally contain the nutrient that is the subject of the claim, for example, claims about fat content on sugar-based confectionary, there are insufficient reasons to prohibit claims about cholesterol on plant foods.

Although, as noted by submitters, there is no nutrient reference value for cholesterol intake, the criterion of no more than 20 milligrams per 100 grams for *low cholesterol* claims is consistent with criteria in Canada, Codex Guidelines for Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005) and the United States and also in CoPoNC. The Codex Guideline also specifies criteria of no more than 10 milligrams per 100 ml for *low cholesterol* claims on liquid foods. The criteria in the Codex Guideline for *low* and *free* cholesterol claims also take into account the level of saturated fatty acids in the food.

The rationale for the recommended approach for *reduced* cholesterol claims can be found in Chapters 11 and 12 in Part 2 of this Attachment, and the rationale for *light* claims in relation to cholesterol content can be found in Chapter 20 – Light/Lite Claims in Part 2 of this Attachment.

11. Comparative claims – definition of reference food

11.1 Decision

FSANZ recommends the following definitions in relation to comparative claims:

Reference food is defined as a food that is –

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

(b) a dietary substitute for the food in the same food group as the food for which a claim is made.

Food group is defined as any of the following groups:

(a) *Bread (both leavened and unleavened), grains, rice, pasta and noodles; or*
(b) *Fruit, vegetables, herbs, spices, and fungi that is one ingredient or more than one ingredient of that class; or*
(c) *Milk and milk products as standardised in Part 2.5 of the Code and analogues derived from legumes and cereals mentioned in column 1 of the Table to clause 3 in Standard 1.3.2; or*
(d) *Meat, fish, eggs, and legumes that is one ingredient or more than one ingredient of that class; or*
(e) *Fats including butter, edible oils, and edible oil spreads.*

'Reference food' and 'food group' are defined in clause 1 of the draft Standard. Conditions for comparative claims are prescribed in the Table to clause 11 of the draft Standard.

11.2 Amendments to current standards/CoPoNC recommendations

Conditions for comparative claims are not currently provided in the Code, hence there are currently no definitions for 'reference food' or 'food group' in the Code.

Conditions are provided in the voluntary CoPoNC for comparative claims, including a definition for 'reference food'[3] and conditions for comparative claims between different foods from the same food group or foods that may substitute for one another in the diet. The definitions recommended in this Report are based on these, with the following amendments:

- references to the 'weighted average', the 'regular product' and to food composition tables in the definition of 'reference food' have been removed;
- 'food group' has been defined.

11.3 Draft Assessment Report – approach taken and submitter comments

Comparative claims are those claims that compare the nutrient or energy content of a food with that in another food. Examples of comparative claims are those using the terms *reduced*, *increased* or *less than*. The food carrying the claim is compared to a 'reference food' (i.e. the 'reference food' is not the food that carries the claim).

The definition of 'reference food' proposed in the Draft Assessment Report was as follows:

[3] CoPoNC definition - 'Normal counterpart' or 'reference foods', against which a food may be compared in making a nutrient claim, must fall into one of the following categories:
- the 'weighted average' food of that type based on an industry norm for the particular type of food – this category is not appropriate where the composition of 'normal' foods of that type on the market varies over a wide range;
- the 'regular' product which has been produced for a significant period by the manufacturer making the claim;
- food of the type in question whose composition is determined by reference to published food composition tables.

reference food means a food that is –

(a) equivalent to the food in relation to which the claim is being made; and
(b) a regular product in the same category of food as that food in relation to which a claim is being made.

Comparisons between foods that can substitute for one another in the diet were not permitted.

Some submitters expressed concern about this definition in relation to the words 'equivalent', 'regular' and 'category of food'. It was also noted that companies may delete standard reference products (the regular product), resulting in the need for monitoring against competitors' products or an industry average in order to determine the reference food.

Some industry submitters were concerned that this approach was not the same as in CoPoNC because foods that are substitutes for one another in the diet could no longer be compared.

11.4 Preliminary Final Assessment Report – approach taken and submitter comments

In response to the submitter comments outlined above, the definition of 'reference food' was revised and included in the Preliminary Final Assessment Report for further consultation.

In the Preliminary Final Assessment Report it was recommended that the definition of 'reference food' be amended to avoid reference to 'equivalent', 'regular' and 'category of food'. The following definition was proposed:

Reference food means a food that is –

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

This definition was supported by most submitters however, a public health submitter was concerned over part (a) (food of the same type). Their concern related to products that have been altered with respect to a nutrient or energy, that could not be compared to other products that have also been modified with respect to the same nutrient or energy, for example, comparing low fat yoghurt with other low fat yoghurt. In this case they suggested that suppliers would have to compare these products to a non-modified product which could exaggerate the comparison and therefore mislead consumers.

Some submitters wanted the reference to 'of the same type' to be broadened whilst others preferred it be narrowed.

In the Preliminary Final Assessment Report the definition of 'reference food' was also extended in order to permit comparisons between foods that can substitute for one another in the diet. Comparisons between 'dietary substitutes' were limited to comparisons between foods in the same food group and the following definition of 'food group' was proposed:

(a) bread (both leavened and unleavened) and other cereal products; or
(b) fruit and vegetables, herbs, spices and fungi, (fresh, cooked, frozen, preserved, pickled, pureed or dried); or
(c) milk and milk products and milk alternatives; or
(d) meat, seafood, eggs, nuts, seeds and legumes; or
(e) fats and oils.

There were a number of submitter comments in relation to the regulation of comparative claims about dietary substitutes (part (b) of the reference food definition) and the definition of food group. Comments included that:

- the approach doesn't clarify the situation for composite foods which contain components from several food groups;
- the definition of dietary substitutes needs widening as some dietary substitutes may not be within the same food group as those defined;
- the food groups are not consistent with Australian and New Zealand food and nutrition guidelines;
- the scope of 'cereal products' could permit misleading comparative claims, e.g. between bread and biscuits or certain breakfast cereals;
- the fruit and vegetable group doesn't include juices and fruit and vegetable products;
- 'milk alternatives' and 'milk products' need defining;
- comparisons between milk and milk alternatives and meat and meat alternatives could be misleading and compromising to public health as the differing nutrient profiles are not taken into account;
- it is unclear which group wholegrains fit into; and
- wholegrains should not be able to be compared with meat.

11.5 Key changes from proposed approach in the Preliminary Final Assessment Report

In response to these submitter concerns, and in order to limit the scope for comparisons under the 'dietary substitute' option and to clarify what is meant by certain terms within the individual food groups, the definition of 'food group' in the Final Assessment Report has been revised as follows:

- references to 'that is one ingredient or more than one ingredient of that class' have been inserted into the fruit and vegetable group and the meat group with an editorial note added to clarify what is meant by this terminology;
- references to specific definitions in Chapter 2 – Food Product Standards, of the Code, for example, edible oils, have been included;
- 'cereal products' have been excluded from the bread and cereal group;
- reference to 'fresh, cooked, frozen, preserved, pickled, pureed or dried' have been excluded from the fruit and vegetable group (with reliance on the definition of 'fruit and vegetable' for defining this group); and
- references to legume and cereal analogues as permitted to be fortified in Standard 1.3.2 have been included as alternatives in the meat and milk groups.

The wording of the 'reference food' definition has been amended slightly to improve clarity.

Refer to Section 11.1 – Decision, above, for the complete definition.

11.6 Rationale for final decision

Comparative claims under two different situations will be permitted – (a) the food can be compared to another food of the same type that has not been modified in terms of the nutrient or energy that is the subject of the claim; and (b) between foods that may substitute for one another in the diet. Both these types of comparisons are permitted under CoPoNC.

Under part (b) (comparisons between dietary substitutes within the same food group), useful information about the nutritional benefits of the food compared to a dietary substitute can be provided to consumers. This will be particularly useful for consumers who have specific dietary requirements or preferences, such as those with lactose intolerance or vegetarians, by enabling provision of further information about a food compared to suitable alternatives. It also provides more scope for a wider range of claims to be made by industry and for an alternative reference food if the 'regular' product is withdrawn from the market.

Without defining 'food group' the determination of 'dietary substitutes' could be very subjective. The purpose of the definition of 'food group' is therefore to limit the scope for comparisons about dietary substitutes in order to prevent inappropriate comparisons between foods, for example, milk and fruit juice.

The definition of 'food group' has been strengthened from that proposed in the Preliminary Final Assessment Report to clarify that comparative claims about composite foods or products, i.e. foods made up of foods from more than one individual food group, are not permitted under the 'dietary substitute' option. Where certain foods are defined in the Code, these definitions have been incorporated into the definition of 'food group' to provide further clarification as to what is intended to be captured within each group, for example, edible oils. It is not possible to achieve absolute consistency with the food groups referred to in Australian and New Zealand food and nutrition guidelines, as these food groups differ between the two countries.

FSANZ has attempted to find a balance between permitting comparative claims between foods of similar nutrient profile or that are realistically substituted in the diet, and prohibiting comparisons with foods that could be considered inappropriate or misleading, particularly where nutrient profiles are considerably different. Additional risk management measures are in place to reduce the potential for consumers to be misled by inappropriate comparisons. These include the requirement to declare the reference food as part of the claim and the prohibition of comparisons about the content of vitamins, minerals and biologically active substances (see Chapter 12 – Comparative Claims - Conditions). There will still be some reliance on industry to ensure that claims are sensible and realistic in terms of suitable dietary substitutes and on fair trading legislation which prohibits misleading or deceptive claims.

12. Comparative claims – conditions

12.1 Decision

FSANZ recommends the following conditions for comparative claims:

- Conditions for comparative claims in relation to fibre, protein, cholesterol, energy, fat, polyunsaturated fatty acids, monounsaturated fatty acids, omega-3, -6 and-9 fatty acids, salt, sodium, saturated fatty acids, trans fatty acids, and sugar will be prescribed in the draft Standard.

Reduced/less than: A claim stating that the energy content or content of 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.

Increased: A claim stating that the energy content or content of one or more nutrients has been increased may be made where the reference food meets the conditions for a *source* claim and the increase in content is at least 25% compared to a reference food.

The identity of the reference food and the difference in 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 the one place.

Comparative claims about vitamins and minerals and substances without a reference value in the Code, including biologically active substances, are not permitted under the draft Standard.

Conditions for comparative claims are prescribed in the Table to clause 11 of the draft Standard.

12.2 Amendments to current standards/CoPoNC recommendations

Comparative claims are not currently regulated in the Code except for the prohibition on comparing the vitamin or mineral content of a food with that of any other food (which has been retained).

Conditions were provided in the voluntary CoPoNC for comparative claims and the requirement for a 25% increase or reduction in the energy or nutrient that is the subject of the claim, has been retained. The requirement from CoPoNC that the food contain an absolute reduction of energy or the nutrient on a 100 g or ml basis has not been retained. For *increased fibre* claims, the requirement that the food carrying the claim contains at least 3 g of dietary fibre per serve has also not been retained; instead there is a requirement that the 'reference food' meet the conditions for a *source of fibre* claim. The recommendation for the wording of the claim is similar to that provided under CoPoNC except for the additional requirement in the draft Standard that the entire claim be presented in the one place in the label or advertisement.

12.3 Draft Assessment Report – approach taken and submitter comments

The approach recommended in the Draft Assessment Report was similar to the recommendation outlined above, except that foods carrying an *increased* claim were required to meet the conditions for a *source* claim prior to enrichment. Conditions were not prescribed for comparative claims in relation to polyunsaturated and monounsaturated fatty acids and omega-3, -6 and -9 fatty acids.

One submitter disagreed with the additional qualifier for the food to meet a *source* claim before being eligible to make an *increased* claim.

For comparative claims in relation to fat and sugar an additional requirement for a reduction in energy content was recommended by some submitters because they considered that consumers may assume that foods carrying *reduced fat/sugar* claims will also have a significant reduction in energy content. Alternatively it was suggested that a disclosure statement be required as to whether the food is high or low in energy. Another submitter felt that placing conditions around energy content for fat or sugar claims was counterproductive and education is a better way to address this.

There was opposition from submitters to the requirement for all elements of the claim to be presented in the one place.

It was felt that rather than specify conditions for comparative claims for individual nutrients and energy, there should be general criteria which would apply to all comparative claims. These conditions would then encompass nutrients that do not have conditions for comparative claims such as omega fatty acids.

12.4 Preliminary Final Assessment Report – approach taken and submitter comments

Subsequent to the Draft Assessment Report the conditions for *increased* claims were revised. Conditions were included for comparative claims about particular fatty acids, e.g. omega-3 fatty acids. These amendments were included in the Preliminary Final Assessment Report for consultation. The position in the Draft Assessment Report to not require a disclaimer or conditions in terms of energy content was retained and hence was not consulted on in the Preliminary Final Assessment Report.

In the Preliminary Final Assessment Report, conditions for making *increased* claims (in relation to dietary fibre and protein) were revised such that the reference food must meet the conditions of a *source* claim rather than requiring the food carrying the claim to meet the *source* conditions prior to enrichment. This was because of the permission to compare dietary substitutes, meaning the food carrying the claim does not necessarily need enrichment in order to carry an *increased* claim. It also prevents inappropriate claims where the fibre or protein content of a food is compared to that of a food that does not normally contain fibre or protein.

Conditions were included for claims in relation to monounsaturated and polyunsaturated fatty acids as well as omega-3, -6 and -9 fatty acids to provide consistency with the conditions for other nutrients for which conditions were previously proposed.

There was concern from some submitters over the requirement for the reference food to meet the *source* criteria, for example, *fibre increased* claims would not be permitted on white bread as standard white bread does not meet the *source* criteria. Some submitters stated that comparative claims should be permitted for biologically active substances, vitamins and minerals.

12.5 Rationale for final decision

Conditions for comparative claims in relation to fibre, protein, cholesterol, energy, fat, salt, sodium, saturated fatty acids, *trans* fatty acids, and sugar will be prescribed in the draft Standard to reduce the potential for misleading claims. Apart from *trans* fatty acids, claims about these nutrients have been self-regulated under CoPoNC and have been in the market place for some time. In accordance with the preferred regulatory Option 3 these conditions will be moved into regulation (refer to chapter 7 of the Final Assessment Report). Permission for *reduced trans fat* claims aligns with the current recommendation for industry to voluntarily reduce the level of *trans* fatty acids in food.

Conditions for comparative claims in relation to polyunsaturated fatty acids, monounsaturated fatty acids, and omega-3, -6 and -9 fatty acids, will be also prescribed in the draft Standard to reduce the potential for misleading claims about these nutrients.

The current prohibition in Standard 1.3.2 of comparative claims in relation to vitamins and minerals will be retained in accordance with the original rationale for Standard 1.3.2, i.e. that permission to make such claims would allow fortified products to be favourably compared with primary foods and the nutrition information panel on the reference food may not indicate the value of the nutrients being compared. Consumers may therefore interpret the reference food as being nutritionally inferior to the fortified food.

Comparative claims in relation to biologically active substances (and other nutrients or substances with no reference value in the Code or conditions in the Table to clause 11 of the draft Standard) will not be permitted, because the requirement that the reference food be a *source* of the substance (i.e. that the reference food contains a pre-requisite amount of substance as defined by qualifying criteria) cannot be applied, because the *source* concept is not applicable to these substances.

The requirement for a relative difference of at least 25% in the claimed nutrient or energy is consistent with international and Codex Alimentarius criteria.

12.5.1 Reduced claims

The additional criteria from CoPoNC for a reduction of an absolute amount (per 100 g or 100 ml) of the nutrient that is the subject of the claim will not be required. FSANZ has instead chosen to simplify the criteria and require a 25% reduction only. This is because, on foods with high levels of the ‘reduced’ nutrient, where the risk of comparative claims misleading consumers about the absolute content of that nutrient in the food is higher, the additional criteria for a reduction of an absolute amount would not have any effect. For example, if the fat content of a food containing 20 g of fat per 100 g is reduced by 25%, the absolute reduction in fat would be 5 g per 100 g, which is above the additional reduction required under CoPoNC of 3 g per 100 g.

In addition, the requirement that the absolute content of the 'reduced' nutrient is declared in the nutrition information panel helps to prevent consumers from being misled that the food is *low* in that nutrient. At low levels of a claimed nutrient the inclusion of a requirement for an absolute level of reduction is predicted to have little benefit because manufacturers are more likely to use a *low* claim.

Additional risk management approaches were considered in the Initial Assessment and Draft Assessment Reports to reduce the risk that consumers may consider products carrying *reduced fat* or *reduced sugar* claims as low in energy. The use of disclosure statements and disqualifying criteria in terms of the energy content were considered. In the Draft Assessment Report it was concluded that there was sufficient evidence to indicate that disclosure statements are not effective in addressing misconceptions that arise from comparative claims. It was also concluded that there was not enough evidence to justify the use of disqualifying criteria relating to energy content. In the Draft Assessment Report, the requirement to declare %DI in the nutrition information panel was considered adequate risk management of these claims. However, this will now not apply since it will not be mandatory to declare %DI for energy when a claim is made (refer to Chapter 6 – Percentage Dietary Intake and Percentage Recommended Dietary Intake of Part 1 of this Attachment). From the recent FSANZ research (Colmar Brunton Social Research, 2008; Roy Morgan Research, 2008) it has been concluded that additional risk management is not warranted (refer to Chapter 1 – Regulatory Approach for Nutrition Content Claims in Part 1 of this Attachment for further information).

Currently, consumers can still use nutrition information panels to determine the absolute fat or sugar content of the food and whether a product carrying a *reduced* fat/sugar claim is also reduced or low in energy or not (energy per 100 g). It is considered that there is enough information provided on a label (wording conditions for the claim as well as the nutrition information panel) for consumers to evaluate the claim. This approach is consistent with claims such as *fat free* which do not include disqualifying criteria associated with energy.

12.5.2 Increased claims

The intent of the requirement for the reference food to meet the *source* criteria for the nutrient that is the subject of an *increased* claim is to ensure that a minimal absolute amount of the claimed nutrient is present in the claimed food. For example, in order for milk to carry an *increased protein* claim, the unmodified milk (the reference food) must contain at least 5 g of protein per 100 g, meaning that the *increased protein* milk will contain at least 6.25 g of protein per 100 g. This will ensure that there is a meaningful increase of the nutrient in the food carrying the claim. It will also prevent claims between foods that may be considered inappropriate or misleading from a public health perspective, for example, a comparison of the fibre content in red kidney beans with that in meat. In the case of fibre enriched white bread, it is acknowledged that *increased fibre* claims could not be made however, *source of fibre* claims would be permitted.

12.5.3 Wording conditions

The identity of the reference food and the difference in the nutrient or energy content must be stated as part of the claim. The difference in the nutrient or energy content may be stated as an absolute figure or as a percentage. This approach is consistent with Codex.

The entire claim must be presented in the one place. This is because comparative claims are claims that make a comparison between two different foods. For the claim to be complete, clear and not misleading, the information relating to both foods (including identification of the reference food and the difference between the two foods) needs to be presented in the same place. This rationale applies equally to claims in advertising and on labels.

13. Dietary fibre

13.1 Decision

FSANZ recommends the following conditions for nutrition content claims about dietary fibre:

Claim	Conditions
Source of fibre	The food must contain no less than 2 g dietary fibre per serving of food.
Good source of fibre	The food must contain no less than 4 g dietary fibre per serving of food.
Excellent source of fibre	The food must contain no less than 7 g of dietary fibre per serving of food.
Increased fibre	The reference food must meet the *source* criteria and there must be a minimum increase of 25% in dietary fibre compared to the 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 together.

Dietary fibre is permitted to be declared in the nutrition information panel without having to meet the conditions for a *source* claim.

These conditions are outlined in the Table to clause 11 of the draft Standard. The permission for voluntary declaration of dietary fibre in the nutrition information panel when the amount of dietary fibre does not meet the conditions for a *source* claim is in clause 5 of amended Standard 1.2.8.

13.2 Amendments to current standards/CoPoNC recommendations

The Code does not currently include conditions for nutrition content claims in relation to dietary fibre content, hence the potential for legal enforcement of these conditions will be new.

CoPoNC includes conditions for *source, good source, and excellent source of* fibre claims, as well as *increased fibre and added fibre* claims. The amount of fibre required in order to meet the *source, good source* and *excellent source* of fibre claims is less in CoPoNC (1.5 g, 3 g and 6 g per serve respectively) than those recommended above. Another difference is that in CoPoNC, the *increased fibre* claim is only permitted when the food carrying this claim contains at least 1.5 g of dietary fibre per serve, prior to enrichment.

13.3 Draft Assessment Report – proposed approach and submitter comments

In the Draft Assessment Report conditions were proposed for fibre claims on meals and main dishes in addition to those outlined above for *source* and *good source of fibre* claims. Conditions for *excellent source* claims were not proposed. For discussion about *increased fibre* claims refer to Chapters 11 and 12 in Part 2 of this Attachment.

Submitters from industry and the public health sector who made specific comments regarding the conditions for dietary fibre claims were opposed to the increase in qualifying criteria for *source* and *good source* claims from those in CoPoNC. They supported retaining the CoPoNC conditions. Some of the specific issues raised were:

- there is no evidence for increasing the levels or justification for deviating from the proposed Codex values;
- the reference value for dietary fibre has not changed;
- there is no evidence of market failure to justify the increase;
- the increase in criteria may result in fewer claims and therefore decreased consumption of dietary fibre;
- minimally processed foods are penalised, for example Weet-bix contains only 3% non-wholegrain ingredients but will not qualify for a *high fibre* claim; and
- serving sizes may be manipulated.

It was noted that the increase in criteria will mean that some foods currently carrying *source* claims will not be able to make claims about fibre at all, and some foods carrying *good source* claims will be required to downgrade these to a *source* claim. Data were provided by some industry submitters to support this. Submitters claimed that this will result in:

- costs to industry from reformulation or relabelling;
- consumer confusion due to changing claims; and
- inconsistency with public health messages.

An opposing view was that the criteria are lower than the approach used for other nutrients (10% or 25% of the RDI).

Other concerns were that only one descriptor should be permitted, because there may be confusion if fruits and vegetables can only make *source* claims and processed foods containing polydextrose, e.g. cakes, can make *good source* claims. It was suggested that dietary fibre claims should be subject to specific disqualifying criteria, given recent approval of polydextrose and resistant maltodextrin which allows products not normally high in fibre, e.g. confectionery, to make claims.

13.4 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report the conditions for *source* and *good source* of fibre claims on meals and main dishes were removed and additional conditions for *excellent source* of fibre claims were added. For discussion about *increased fibre* claims refer to Chapters 11 and 12 in Part 2 of this Attachment.

There was some support from submitters for the removal of the conditions for meals/main dishes, and for the introduction of conditions for an *excellent source* of fibre claim. One submitter considered that the provision of conditions for an *excellent source* of fibre claim would encourage manufacture and consumption of foods rich in fibre. However there was some opposition to the use of the descriptor *excellent*, particularly as it was thought that consumers may misinterpret *excellent source* as meaning the food is 'excellent' and it may also give the impression that fibre requirements can be met by a serving of the claimed food. It was suggested that the descriptor *very high* is used instead. Other submitters wanted this type of claim prohibited as it is 'not needed'.

Concerns about the increase in fibre content needed to meet the conditions for *source* and *good source* claims compared to CoPoNC conditions, were also noted for similar reasons to those stated in response to the Draft Assessment Report. These concerns were also considered to be relevant to the conditions for *excellent source* claims. In contrast, one submitter preferred that the conditions for making fibre claims are consistent with the conditions for making claims about other risk-reducing nutrients, i.e. 10% of the reference value.

There was some comment about the basis for conditions for these claims, with some submitters supporting a per serve basis and others a 100 g basis.

It was suggested that voluntary declaration of dietary fibre in the nutrition information panel should be permitted without restriction, as this is useful information.

It was also suggested that the definition of dietary fibre be reviewed, including that it should reflect the emphasis on fruits and vegetables and wholegrain foods as sources of dietary fibre. One reason for this was because if a substance such as inulin or maltodextrin is the sole source of fibre in a food, it would be unlikely to have the benefits normally attributed to dietary fibre although the food would be permitted to carry a fibre claim. It was thought that manufacturers may add large quantities of 'artificial' fibre into foods considered less healthy or inappropriate to carry fibre claims, for example cakes, chocolate bars.

13.5 Key changes from proposed approach in the Preliminary Final Assessment Report

FSANZ reconsidered submitter concerns about the increase in the qualifying criteria from those in CoPoNC and the submitter suggestion that it would be useful to consumers for dietary fibre to be declared in the nutrition information panel. Although it was decided that the proposed qualifying criteria be retained, provision has been made in the drafting to permit voluntary declaration of dietary fibre in the nutrition information panel as currently permitted in the Code, without requiring the food to meet the conditions for a *source* claim.

13.6 Rationale for final decision

Claims in relation to dietary fibre content will be permitted as these provide useful information to consumers and there is currently considerable usage of these claims by industry (FSANZ, 2007a). Permission for the use of these claims is supported by national dietary guidelines which recommend consumption of fibre rich foods (NHMRC, 2003; Ministry of Health, 1996, 2003, 2006).

The conditions proposed in the Draft Assessment Report for *source* of fibre and *good source* of fibre claims have been retained however, the separate criteria that were proposed for meal and main dish products have been removed (refer to the Preliminary Final Assessment Report for rationale). Conditions for an *excellent source* claim for capturing increased fibre content on these products is recommended instead.

FSANZ notes submitter concerns around the descriptor *excellent.* Although no studies have been conducted to assess consumer understanding of this claim, FSANZ is not aware of any complaints about its use, as currently permitted under CoPoNC. To prohibit the use of this claim is overly prescriptive and inconsistent with the regulation of other nutrition content claims.

Although the majority of submitters did not support the increase in qualifying criteria from those in CoPoNC, FSANZ considers the criteria in CoPoNC 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 under CoPoNC conditions is only equivalent to 5% of this 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, and similarly for protein, 10% of the reference value is required for a *source* claim. The revised qualifying criteria for *source, good source* and *excellent source* claims equate to 6.67%, 13.3% and 23.3% respectively of the reference value of 30 g. These values have been chosen in order to enable an appropriate range of products to carry fibre claims and to prohibit claims on foods containing only small amounts of dietary fibre in relation to the reference value, as these could be misleading to consumers about the amount of dietary fibre present in the food. While the reference value for dietary fibre has not changed (25 g per day for women and 30 g per day for men in the latest nutrient reference values document (NHMRC and Ministry of Health, 2005)), an increase in the criteria for fibre claims will assist consumers in identifying foods with higher levels of fibre and will encourage the food industry to develop foods with higher levels of this beneficial nutrient, thus potentially increasing the consumption of dietary fibre.

The voluntary declaration of a nutrient in the nutrition information panel is considered a nutrition content claim under the Code. Therefore the food would need to meet the conditions for making a *source* claim in order for most nutrients to be voluntarily declared. The recommendation to permit voluntary declaration of fibre content in the nutrition information panel, even when the food does not contain enough fibre to meet the conditions for a *source* claim means that consumers can be provided with this useful but factual information. It also partly addresses submitter concerns around consumer confusion when existing claims on products have to be removed or altered, given that the fibre declaration in the nutrition information panel can remain on foods currently carrying claims that will no longer be permitted under the new qualifying criteria. This permission will also simplify enforcement relating to when dietary fibre is declared in the nutrition panel at less than 2 g per serve. This is because dietary fibre is required to be declared in the nutrition information panel under certain situations, including when the fibre content may be negligible, for example, when claims about sugars are made. Although this approach is not consistent with the voluntary declaration of vitamins and minerals (which can only be declared voluntarily when the food contains at least 10% of the RDI for the vitamin or mineral), it is consistent with the permission to declare biologically active substances (as there are no minimum criteria set for making claims about the presence of these substances) and risk-increasing nutrients such as *trans* fatty acids.

It is noted that under Proposal P167 – Review of Nutrition Labelling, it was recommended that the provisions for voluntary declaration of dietary fibre in the nutrition information panel be retained and FSANZ is not aware of any reasons to overturn that decision.

In determining the qualifying criteria for dietary fibre claims, FSANZ considered the dietary fibre content contributed by various foods, international criteria and the latest nutritional data from both countries which indicates that population intakes of fibre and fibre-rich food groups are generally below target levels (Australian Bureau of Statistics, 1995; Russell *et al*., 1999).

The Codex Alimentarius Commission is currently drafting conditions for fibre claims. However it will be some time before these conditions are confirmed, so they can not be used as clear guidance at this time. Conditions are not consistent internationally, for example, in Canada the food must contain at least 2 g and 4 g per serving and per reference amount for a *source* and *good source* claim respectively whereas in the European Union, the conditions are based on per 100 g and per 100 kilocalorie amounts. It is therefore difficult to align with international standards generally.

The unit of measure recommended for dietary fibre claims is per serve as this recognises the amount of food that an average person actually consumes. This approach provides consistency with the conditions for other risk-reducing nutrients such as vitamins, minerals and protein. Dietary modelling carried out by FSANZ indicated that using a 100 g basis would mean that a number of foods, notably fruit and vegetable products, which qualify under the per serve approach would no longer qualify for making a fibre claim. While suppliers 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. However FSANZ notes concern from submitters regarding the potential for manufacturers to benefit from increasing the serving sizes of their products and will therefore monitor the marketplace as necessary. 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.

FSANZ notes submitters' concerns that dietary fibre claims could be made on foods containing added polydextrose and maltodextrin, including foods containing high amounts of fat or sugar. However FSANZ recommends that the nutrient profiling scoring criteria (or alternative specific disqualifying criteria) are not applied to dietary fibre claims (refer to Chapter 1 – Regulatory Approach for Nutrition Content Claims, in Part 1 of this Attachment). The addition of an energy density criterion was modelled but was found to exclude a number of foods such as many bran and oat based breakfast cereals, most nuts and some dried fruits. In not applying the nutrient profiling scoring criteria, consistency is provided with the approach to other nutrition content claims as well as with the Codex Guideline (Codex Alimentarius Commission, 2005) and other countries.

In response to submitter concerns certain types of dietary fibre will not have the benefits normally attributed to dietary fibre, the definition of dietary fibre in the Code must be noted. This definition ensures that all substances included in the claimed dietary fibre content promote at least one of the following beneficial health effects:

- laxation;
- reduction in blood cholesterol; or
- modulation of blood glucose.

Amendments to the definition of dietary fibre in the Code are not within the scope of Proposal P293.

For the discussion about *increased* fibre claims, refer to Chapters 11 and 12 in Part 2 of this Attachment.

14. Diet claims

14.1 Decision

FSANZ recommends the following in relation to diet claims:

- claims of *diet* (with no additional wording indicating a health effect) are considered to be nutrition content claims;
- the nutrient profiling scoring criteria for general level health claims apply;
- the food must a) meet the conditions for *low energy* claims; or b) contain at least 40% less energy compared to the same quantity of the reference food;
- if b) is used as the qualifying criteria, the claim must state the identity of the reference food and the difference between the energy value of the food and the reference food and the claim must be presented so that all elements of the claims are together.

The conditions for *diet* claims are prescribed in the Table to clause 11.

14.2 Amendments to current standards/CoPoNC recommendations

Clause 14 of Standard 1.2.8 - Nutrition Information Requirements prescribes requirements for *low energy* claims. These conditions currently apply to any claim that is to the effect that the food is *low* in energy and the draft Standard is consistent with these conditions.

CoPoNC stipulates that a food carrying a *diet* claim must meet the conditions for a *low energy* claim or contain at least 40% less energy compared to the reference food and have a reduction in absolute energy content of at least 170 kJ per 100 g or 80 kJ per 100 ml. The draft Standard differs from the approach in CoPoNC in that foods carrying a *diet* claim need to meet the conditions for a *low energy* claim or meet the criteria relating to a 40% energy reduction compared to the reference food but do not have to meet the requirement of a minimum absolute reduction in energy content.

14.3 Draft Assessment Report – approach taken and submitter comments

The proposed approach in the Draft Assessment Report for *diet* claims was as follows:

1. The food must meet the disqualifying criteria (now referred to as nutrient profiling scoring criteria) for general level health claims; and
2. 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; and
(d) the claim must be presented so that all elements of the claim are in one place.

This approach evolved from the proposal in the Initial Assessment Report to require *diet* claims to meet the conditions for *low energy* claims. In the Draft Assessment Report, FSANZ considered submitter comments to the Initial Assessment Report and re-evaluated relevant consumer research before deciding to incorporate the more flexible CoPoNC criteria for *diet* claims into the conditions. There was opposition from some industry submitters to the application of generic disqualifying criteria to the *diet* claim and a recommendation that existing CoPoNC criteria should be used without the disqualifying criteria proposed in the Draft Assessment Report, for the following reasons:

- the salt content is irrelevant;
- diet products will be relatively lower in fat or sugar than comparable products;
- FSANZ did not make an evidence based decision; and
- the approach would have a considerable impact on the dairy industry where whole product lines have been established on the *diet* claim.

FSANZ maintained that given the implication of *diet* claims (i.e. as part of an energy reduced diet), the overall nutrient profile of the food vehicle is important and the disqualifying criteria (now referred to as nutrient profiling scoring criteria) should apply.

14.4 Preliminary Final Assessment Report – approach taken and submitter comments

Following the Draft Assessment Report, it was noted that the approaches to setting qualifying criteria for *reduced energy* and *diet* claims were inconsistent and that a more consistent approach would be appropriate for regulating claims based on reduction in energy content.

In the Preliminary Final Assessment Report, FSANZ reassessed the CoPoNC criteria for *diet* claims. The need for the food to be reduced in energy content by at least 170 kJ per 100 g or 80 kJ per 100 ml was removed. It was proposed that *diet* claims be required to meet either *low energy* requirements or contain at least 40% less energy than the same quantity of reference food. Several submitters supported this proposed approach, as they believed it would allow minimally processed foods to make *diet* claims.

Submitters suggested that FSANZ remove the nutrient profiling scoring criteria for *diet* claims as it was thought the requirements in the Table to clause 11 were sufficient to ensure appropriate use of this claim. It was also suggested that the term *diet* should be able to apply to products designed for weight maintenance or weight increase.

14.5 Rationale for final decision

FSANZ maintains the approach presented in the Preliminary Final Assessment Report in relation to *diet* claims. Whilst a *diet* claim can be considered a nutrition content claim because it relates to a property of the food (its energy content), it also implies an effect on the body (i.e. weight loss). Qualitative consumer research (FSANZ, 2003a) found that participants in focus groups associated *diet* claims with products that are part of a weight loss regime.

Diet claims do not easily fit into the health claims classification framework and FSANZ has chosen to view *diet* claims as a special case. Given this perceived link between *diet* claims and weight management, FSANZ considers it appropriate to apply the nutrient profiling scoring criteria to *diet* claims as is done for weight loss/maintenance claims. Some submitters objected to the application of the generic nutrient profiling scoring criteria to foods carrying this claim. However, the change in approach to a nutrient profiling system means that some foods not eligible to carry the *diet* claim under the disqualifying criteria proposed in the Draft Assessment Report may be eligible under the new approach. For example, several *diet* yoghurt products become eligible to make the claim.

The requirement under CoPoNC for a minimum absolute reduction in energy content in addition to the requirement for at least 40% less energy than the reference food has not been retained. This is because this requirement only impacts on foods that contain relatively low levels of energy, and is therefore considered unnecessary. This is also consistent with the approach for *reduced energy* claims, where the requirement under CoPoNC for a minimum absolute reduction in energy content has not been retained.

In preparing the assessment reports, FSANZ has considered relevant international approaches to *diet* claims. The USA and Canada allow *diet* claims and these are largely regulated under Foods for Special Dietary Use. Generally *diet* claims must be accompanied by a *low in energy* or *reduced energy* claim. The Codex Alimentarius Guidelines for Use of Nutrition and Health Claims does not define criteria for this claim (Codex Alimentarius Commission, 2005).

FSANZ considers it inappropriate for the term *diet* to refer to foods designed for weight gain. This is because consumers associate *diet* products with low/reduced energy content and could therefore be misled by *diet* claims on high energy foods. High energy foods, including foods designed for weight gain can be regulated separately in the Code under Standard 2.9.3 - Formulated Meal Replacements and Formulated Supplementary Foods and Standard 2.9.4 - Formulated Supplementary Sports Foods.

15. Energy claims

15.1 Decision

FSANZ recommends the following conditions for nutrition content claims in relation to energy:

Claim	Conditions
Low energy, *low* calorie, *low* joule	The average energy content of the food must be no more than 80 kJ per 100 ml for liquid foods and no more than 170 kJ per 100 g for solid foods.
Reduced energy, *reduced* calorie, *reduced* joule	
Light/lite (in relation to energy content)	The comparison should be based on a reduction of at least 25% in the energy content compared to a reference food. The identity of the reference food and the difference between the energy 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 together.

Nutrition content claims such as *high in energy* will not be subject to specific qualifying criteria.

Nutrition content claims relating to energy content will be regulated in the Table to clause 11 of the draft Standard.

15.2 Amendments to current standards/CoPoNC recommendations

Currently claims relating to *low* energy must comply with clause 14 of Standard 1.2.8 - Nutrition Information Requirements; these are the same requirements as recommended in this Final Assessment Report. At present the Code does not prescribe criteria for other types of energy claims. CoPoNC stipulates that foods carrying a *reduced* energy claim must not contain more than 75% of the energy of the same quantity of the reference food. The draft Standard differs from CoPoNC in that the Standard does not require a food carrying a *light* or *reduced* energy claim to contain at least 170 kilojoules less energy per 100 g or 80 kilojoules less energy per 100 g of liquid food compared to the reference food, in addition to a 25% reduction in energy compared to the reference food.

15.3 Draft Assessment Report – approach taken and submitter comments

The approach taken for energy claims was the same in the Draft Assessment Report as that recommended in this Final Assessment Report.

Submitters suggested that claims such as *high* energy should be prohibited as they are used on foods that some submitters did not consider to be 'nutritious'. It was suggested that *low energy* and *reduced energy* claims should be expressed as *low kilojoule* or *low calorie* instead, as consumers may otherwise equate the term 'energy' with physical energy rather than with kilojoules.
As the approach in the Draft Assessment Report was largely supported by stakeholders and FSANZ considered drafting changes were not required, claims in relation to energy content were not consulted on in the Preliminary Final Assessment Report.

15.4 Rationale for final decision

Given that *low joule* claims were revised as part of the development of the Code and that the Code criteria are consistent with criteria in the Codex Alimentarius Guidelines for Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005), it is recommended that the existing criteria for this claim in Standard 1.2.8 be retained.

FSANZ recommends that the term 'energy' is retained in the Table to clause 11 of the draft Standard, as this is consistent with the terminology used in the Codex Guidelines for Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005) and suppliers have the option of using alternative terminology such as 'kilojoule' or 'calorie' in the claim, if appropriate. The word 'energy' is also specifically mentioned in the definition of a 'property of the food' and the properties listed in the Table to clause 11 of the draft Standard need to be consistent with this definition. It is also noted that a kilojoule is a measure of the energy value of a food, rather than an actual property of the food.

For the rationale for the conditions for *reduced energy* claims refer to Chapters 11 and 12 in Part 2 of this Attachment.

FSANZ considers claims in relation to *high energy* or *source of energy* are useful for consumers that require increased energy intake and should be permitted however, criteria for making these claims will not be included in the draft Standard. Compliance for such claims will default to fair trading provisions meaning that *high energy* type claims must not be misleading to the consumer. High energy foods are regulated under Standard 2.9.3 - Formulated Meal Replacements and Formulated Supplementary Foods and Standard 2.9.4 - Formulated Supplementary Sports Foods.

16. Free claims

16.1 Decision

FSANZ recommends the following conditions for free claims:

Claim	Conditions
Free	No provisions (except for gluten, lactose, saturated fatty acids, *trans* fatty acids and cholesterol).
Gluten free	No detectable gluten; and no oats or oat products; or no cereals containing gluten that have been malted, or their products.
Lactose free	No detectable lactose. The nutrition information panel indicates the lactose and galactose content.
Cholesterol free	The food must meet the requirements for the *low (in) saturated fatty acid* claim.
Saturated fatty acid free	No detectable saturated fatty acids and no detectable *trans* fatty acids
Trans fatty acid free	No detectable *trans* fatty acids. The food must contain:

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

Specific conditions for *gluten free, lactose free, saturated fatty acid free* and *trans fatty acid free* are included in the Table to clause 11 of the draft Standard. *Free* claims do not include qualified free claims; for example *99% fat free*.

16.2 Amendments to current standards/CoPoNC recommendations

Currently the Code does not contain provisions for the use of *free* claims, except for claims about gluten and lactose which will remain unchanged. Fair trading laws are relied on to ensure appropriate use of *free* claims. CoPoNC includes conditions for *free* claims in relation to fat, cholesterol, sodium and sugar. In each case, a small but finite limit for the nutrient is specified. These limits will not be carried over into the draft Standard as it is expected that *free* means the food contains no detectable amount of the particular nutrient.

16.3 Draft Assessment Report – approach taken and submitter comments

FSANZ's preferred option for *free* claims in the Draft Assessment Report was to stay silent (except for gluten, lactose and cholesterol), in recognition of the role of fair trading law in relation to such claims.

Conditions were carried over from Standard 1.2.8 for *gluten free* and *lactose free* claims to the draft Standard.

As saturated fat intake is of greater concern to public health than cholesterol intake, and because consumers may potentially be misled in respect of health benefits by *cholesterol free* claims on foods high in saturated fat, conditions were set to limit *cholesterol free* claims to products *low* in saturated fat. No additional requirements were considered necessary for *free* claims about other nutrients such as sugar or sodium.

Submitter comments in response to the Draft Assessment Report focused on the lack of conditions for *sugar free* claims. Some submitters recommended that FSANZ adopt the Codex Guideline for *sugar free* claims which allows a maximum of 0.5g sugar/100g in products with the claim. These submitters commented that trace amounts of sugar are nutritionally and physiologically insignificant. *Percentage sugar free* claims were considered by some submitters to imply that sugar has been added whereas this may not be the case when trace amounts of sugar are present in a non-sugar ingredient.

Other comments were as follows:

- it is inappropriate to regulate some sugar claims and some *free* claims in the Code and yet leave *sugar-free* to fair trading legislation;
- the approach is inconsistent internationally;
- provision for sugar free claims in CoPoNC should be retained (permits <0.2g sugar/100g);
- literal interpretation of a *sugar free* claim would require industry to reformulate flavours used;
- as members of WTO and Codex, Australia and New Zealand are obligated to permit trade in food products claimed to be *sugar free* unless there is scientific justification for prohibiting the claim;
- there are consumer benefits for *sugar free* products and consumers understand this claim;
- there is inconsistency with a ‘no detectable’ principle in the Code for ‘gluten free’ and ‘lactose free’ claims;
- *x% sugar free claims* will allow clever marketers to manipulate the claim and lead to consumer confusion;
- products with *sugar free* claims have been in the market for some time; and
- analytical methods are becoming increasingly sensitive, so limits of detection could be specified; otherwise these claims will not be used by industry.

An enforcement agency commented that all *free* claims should either be subject to disqualifying criteria or should be accompanied by a statement stipulating whether or not the food is lower in kilojoules. This submitter considered this would prevent misleading claims and provided the example of confectionary high in sugar marketed as *fat free*.

16.4 Preliminary Final Assessment Report – approach taken and submitter comments

Following the release of the Draft Assessment Report the draft Standard was amended to prescribe that a food making a *trans fatty acid free* claim be also low in saturated fat and that those foods carrying a *saturated fatty acid free* claim be free of *trans* fatty acids. For clarity, the draft Standard was amended to prescribe that food carrying a *saturated fatty acid free* claim is free in saturated fatty acids, in addition to being free of *trans* fatty acids.

The Preliminary Final Assessment Report contained a minor amendment to the draft Standard. Specific reference to *free* in relation to cholesterol claims in the Table to clause 11 was omitted, to clarify that for any claim regarding cholesterol, including *free* claims, the food must meet the conditions for a *low* saturated fatty acid claim, and to remove confusion around the conditions for *cholesterol free* claims.

16.5 Key changes from proposed approach in the Preliminary Final Assessment Report

The requirement for the food to be 'free' of saturated and/or trans fatty acids for the *free of trans fatty acids* and *free of saturated fatty acids* claims was replaced with the requirement for the food to contain 'no detectable' saturated or *trans* fatty acids (as appropriate to the claim).

16.6 Rationale for final decision

FSANZ's general approach towards *free* claims is the same as that proposed in the Draft Assessment Report; that is to stay silent with the exception of the nutrients mentioned above.

The food regulatory regime in Australia requires State and Territory food laws to enforce the Food Standards Code. However the regulatory regime that considers misleading and deceptive conduct and breaches of the Trade Practices Act CTH is undertaken by the Commonwealth in Australia, that is the Australian Competition and Consumer Commission (ACCC). There is a potential with respect to food labelling for a regulatory overlap in enforcement procedures and requirements of the respective legislation. There is an Australian constitutional legislative restraint that may be applied, where if there is an inconsistency between Commonwealth (i.e. *Trade Practices Act 1974*) and State laws (i.e. food legislation), the Commonwealth law will prevail to the extent of the inconsistency.

The ACCC and New Zealand Commerce Commission's interpretation of *free* is that *free* means 'zero'. It is considered misleading under the respective fair trading legislation to include a *free* claim on a product containing a detectable quantity of a specified nutrient. It is very important that the regulatory regimes that have the potential to overlap are consistent in their enforcement approaches. Therefore FSANZ will maintain the proposed approach.

Gluten free and *lactose free* claims will be permitted providing these substances are not detectable. These claims are useful in assisting allergic or food-intolerant consumers to choose foods that will not adversely affect their health. The conditions for *gluten free* and *lactose free* claims are slightly different to other *free* nutrition content claims in that they are defined by a 'no detectable' provision. Analytical testing methods have limitations in their ability to detect certain gluten equivalent fractions.

Products may thus contain some gluten but in laboratory analysis reveal 'nil detected' gluten levels. Given these limitations, a 'no detectable' provision is therefore the most appropriate regulatory measure.

Conditions for *saturated fatty acid free* and *trans fatty acid free* claims have also been included in the draft Standard. Because of the interrelationship of these two fatty acids on blood cholesterol levels, they are both included in the conditions for claims about the individual fatty acid. For example, for the *saturated fatty acid free* claim, the conditions include that the food must not contain any detectable *trans* fatty acids, as well no detectable saturated fatty acids. These requirements were included to avoid confusion around the conditions for these claims. The use of 'no detectable' rather than 'free' is consistent with the provisions for other *free* claims in the draft Standard and provides for the situation whereby analysis results in a 'no detectable' result rather than 'free'.

Manufacturers can use alternative claims to *free* such as *99.5% fat free* or *contains less than 1% fat*. Although CoPoNC does not allow *x% free* claims on foods other than for 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. X*% sugar free* claims must also meet the criteria for *low sugar*.

17. Gluten

17.1 Decision

FSANZ recommends the following conditions for nutrition content claims about gluten:

Claim	**Conditions**
Gluten *free*	The food must not contain any detectable gluten; and no oats or their products; or no cereals containing gluten that have been malted, or their products.
Low (in) gluten	The food must not contain any more than 20 mg gluten per 100 g of food.

Nutrition content claims in relation to *low gluten* or *gluten free* only, will be permitted.

These conditions are specified in the Table to clause 11 of the draft Standard.

17.2 Amendments to current standards/CoPoNC recommendations

These claims are currently regulated by Standard 1.2.8 – Nutrition Information Requirements and the status quo has been maintained. These conditions will be moved from Standard 1.2.8 into the draft Standard.

17.3 Draft Assessment Report – approach taken and submitter comments

The criteria recommended in the Draft Assessment Report were the same as the criteria proposed in this report.

Some stakeholders noted their support for the criteria.

According to one submitter, the New South Wales Coeliac Society recommends their members do not consume food carrying *low* gluten claims as they may react to gluten as low as 2 mg per 100 g. They therefore suggested that these criteria are changed from no more than 20 mg to no more than 2 mg of gluten per 100 g of food.

It was noted that the condition of no detectable gluten for *free* claims is not helpful when a 'zero tolerance' is not necessary or practical. Some submitters recommended that the outcomes from the Codex review of gluten claims are considered. Others commented that scientific evidence shows that oats are safe for people with coeliac disease.

17.4 Rationale for final decision

The criteria for *free* and *low* gluten claims are consistent with those presently prescribed in Standard 1.2.8 of the Code. FSANZ considers that gluten claims should continue to be regulated in the Code as they provide essential information to consumers regarding appropriate food choices, specifically consumers with coeliac disease and dermatitis herpetiformis. Submitter comments support this view.

FSANZ has considered regulating these claims (and lactose claims) under Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, as suggested by some submitters in response to the Initial Assessment Report. However Standard 1.2.3 regulates mandatory statements and declarations (including the presence of milk and milk products and cereals containing gluten), not voluntary claims. Claims of a voluntary nature made in relation to gluten (and lactose) should be included in the Standard for nutrition, health and related claims to be consistent with the approach for regulating voluntary claims about other similar substances.

The criterion of 20 mg gluten per 100 g for *low gluten* claims was determined during the development of the Code. At that time there was international agreement by the medical profession that the level of 20 mg per 100 g food is tolerated by the majority of people with coeliac disease. The *low gluten* claim provides for a gluten claim where it cannot be guaranteed that the food will meet the *free* criteria. The Code also requires that the average quantity of gluten is declared in the nutrition information panel when this claim is made, thus providing consumers with adequate information regarding whether they can tolerate the food.

The inclusion of oats in the criteria was considered under Proposal P264 –Review of Gluten Claims with Specific Reference to Oats and Malt, which was finalised by FSANZ in October 2004. As a result of this proposal it was concluded that the *gluten free* criterion should include reference to oats for the protection of sensitive coeliacs and that the *low gluten* criterion will not include reference to oats. The conditions for *low gluten* claims therefore allow for adequate protection with a greater choice of suitable foods for less sensitive for people with coeliac disease.

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 fair trading law which requires that information is not false, misleading or deceptive. Therefore, to permit a food to be called *gluten free* when the food contains detectable gluten was not considered possible, as such a claim would be false.

Furthermore, the Australian Competition and Consumer Commission reiterated in its submission that the criterion of no detectable gluten supports its position.

FSANZ has been monitoring the progress of the Codex review of the Draft Revised Standard for Gluten-free Foods (recently renamed the Draft Revised Codex Standard for Foods for Special Dietary Use For Persons Intolerant to Gluten). This review is currently at step 8 of the Codex step procedure and cannot be used as a definitive standard upon which to model the criteria for claims about gluten in the Code.

FSANZ does not propose to specify analytical methods for the determination of *gluten free* foods for the reasons discussed in Chapter 3 – Methods of Analysis, in Part 1 of this Attachment.

18. Glycemic Index (GI)

18.1 Decision

FSANZ recommends the following approach to regulating Glycemic Index (GI) claims:

- suppliers of the food carrying GI claims must have records that substantiate the claim;
- the claim itself or the nutrition information panel must include the numerical value of the GI of the food;
- a food carrying a GI claim must meet the nutrient profiling scoring criteria in Schedule 1 of the draft Standard;
- the claim may include the descriptors *low*, *medium* or *high* as specified in the draft Standard;
- GI claims do not have to be linked to a GI (or any other) endorsement program; and
- the method for determining GI of carbohydrates in foods is not prescribed in the draft Standard however the editorial note describes the preferred method for determining GI, that is using the Standards Australia Australian Standard® Glycemic Index of foods (AS 4694 – 2007) which is a voluntary standards scheme. In particular, GI testing is carried out by the determination of glycemic (blood glucose) responses in human volunteers.

A definition of 'glycemic index' is provided in clause 1 of the draft Standard.

In the draft Standard, clause 5 and the Table to clause 11 prescribe the responsibilities of the supplier of a food carrying a GI claim.

18.2 Amendments to current standards/CoPoNC recommendations

At present, the Code does not prescribe criteria for making claims about glycemic index, commonly referred to as GI claims. The draft Standard will set out specific criteria for making GI claims including numerical values for descriptors and criteria based on the food's nutrient profile. The Standards Australia method for determining GI is identified in an editorial note.

18.3 Background

The GI is a property of the carbohydrates in foods, specifically the blood glucose raising ability of the digestible carbohydrates. It compares the carbohydrate content of a food on a weight for weight basis, in the physical state in which the carbohydrate is normally consumed. *Low GI* foods are characterised by having less impact on blood glucose levels compared with *high GI* foods.

The Australian and New Zealand Dietary Guidelines specifically recommend consumption of *low GI* cereal-based foods. GI claims are becoming more prevalent in the market place and there appears to be significant consumer interest in such claims.

It should be noted that GI does not specifically relate to one nutrient or biologically active substance. Whilst it can be considered a nutrition content claim because it relates to a property of the food (its carbohydrate composition and level), it also reflects an effect on the body (i.e. on blood glucose levels). GI does not easily fit into the health claims classification framework and FSANZ has chosen to view GI claims as a special case.

Standards Australia has published a standard for the determination of GI of foods (AS 4694—2007, Australian Standard® - Glycemic Index of foods). The objective of the Standard is stated to be 'to establish the recognised scientific method as the standard method for the determination of the GI of foods'. The Standard specifies a method for determination of the GI of carbohydrates in foods, defines the GI, and provides qualifying factors and requirements for its application. GI testing is appropriate only when the food in question contains relevant amounts of digestible carbohydrate. In the Australian Standard®, the minimum amount is specified as '10 or more grams of glycemic carbohydrate per serving'.

In addition to outlining a detailed methodology for the determination of GI values for foods, the Australian Standard® includes guidance on the interpretation of GI values as follows:

Low GI	55 and below
Medium GI	between 56 and 69
High GI	70 and above

18.4 Draft Assessment Report – approach taken and submitter comments

The proposed approach for the regulation of GI claims in the Draft Assessment is summarised as follows:

- GI claims that are linked with an endorsement would be regulated as a pre-approved endorsement (e.g. Glycemic Index Limited symbol);
- for those not linked with an endorsement, the GI could only be claimed in the form of a numerical index and *reduced, high, medium, low* claims or other descriptors would not be allowed; and
- if the claim refers to a health effect then it would be regulated appropriately as either a general level health claim or a high level health claim.

There were divergent views from stakeholders regarding how GI claims should be regulated. While some stakeholders considered that GI claims such as *low GI* are nutrition content claims, other stakeholders consider them to be health claims.

Stakeholders raised issues in relation to the scope of the regulations with some stating that the Code should remain silent on GI claims while others believe there is insufficient scientific evidence to support GI claims, and therefore manufacturers should not be allowed to use them. On the other hand, it was argued that a prohibition on the use of descriptors might confuse consumers who have become accustomed to using such claims.

From an industry perspective, the approach taken in the Draft Assessment Report restricted the full use of GI claims by some suppliers, because information about GI that uses descriptors could only be placed on a label in association with a relevant endorsement. From a public health perspective, there were concerns that GI claims potentially mislead consumers with regard to the beneficial nutritional properties of a food. In particular, some stakeholders considered that it was not appropriate to place *low GI* claims on foods which are high in fat. Further, it was argued that all GI claims imply a health effect, or indirectly refer to a biomarker or serious disease.

After considering submitter comments and the impact of a proposed change in approach to regulating endorsements generally, FSANZ decided on an alternative approach to regulating GI claims to that proposed in the Draft Assessment Report. Furthermore, the publishing of the Australian Standard in the intervening period allowed the use of descriptors of GI by providing accepted reference values and thus avoiding concerns over use of numerical values only.

18.5 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report, FSANZ proposed that GI claims using descriptors would not have to be linked to an endorsement; the descriptors *low, medium* and *high* would be permitted in accordance with values provided in the draft Standard; nutrient profiling scoring criteria would apply and the preferred method for determining GI of carbohydrates in foods would be that described in the Standards Australia Australian Standard® Glycemic Index of Foods.

Many submitters broadly agreed with the regulatory approach. However, some stakeholders argued that the ongoing scientific debate and the lack of consensus over whether GI is useful for consumers meant that GI claims should not be permitted. Most submissions criticised some parts of the approach but were generally supportive of GI claims being permitted and regulated in some way.

Industry supported the idea that GI claims no longer have to be linked to an endorsement and the permission to use descriptors had very wide support. Some industry and government stakeholders supported the application of nutrient profiling scoring criteria to foods with GI claims while some opposed this and argued that GI was merely a nutrition content claim and should be regulated as such. On the other hand, some stakeholders felt that all GI claims are health claims and should be regulated accordingly.

Some stakeholders asked that the Australian Standard® be referenced in the Code. However, there was also disagreement amongst stakeholders with regard to the methodology of the Australian Standard® and some concerns with the cost and affordability of such tests.

It was also raised that other claims on glycemic properties of food should be permitted and that use of figures and graphical representations should also be allowed. In contrast, some stakeholders wanted claims on other measurements such as Glycemic Load prohibited.

There was a view that the numerical values assigned to descriptors were not appropriate and that a descriptor of *medium* should not be allowed. Others suggested that only descriptors should be allowed rather than values and that a different statistical approach should be taken to calculate GI categories. One stakeholder suggested that descriptor and value should be included on the label in the same place to avoid consumer confusion.

18.6 Rationale for final decision

18.6.1 GI claims place in the regulatory framework

Due to their unique nature, GI claims are effectively being treated as a hybrid nutrition content/health claim, unless they refer to a health effect, in which case the claim would be considered to be a health claim.

GI claims have some of the characteristics of health claims, i.e. they may imply a physiological function in relation to the property of the food, specifically the ability to modulate the blood glucose of the digestible carbohydrates. Therefore, in accordance with the 'step-up' approach for the regulation of nutrition content and health claims, the nutrient profiling scoring criteria will apply to foods carrying GI claims.

18.6.2 Nutrient profiling scoring criteria

Both the Australian and New Zealand nutrition guidelines discuss GI and its place within dietary recommendations. They conclude that the GI of foods needs to be evaluated in conjunction with other dietary constituents and recommendations. Applying the nutrient profiling scoring criteria to food carrying GI claims is consistent with national dietary guidelines and will assist consumers with meeting dietary recommendations when selecting foods on the basis of GI.

Some stakeholders were of the opinion that GI claims were used irresponsibly in the marketplace to promote foods that are high in fat, especially saturated fat, and energy. Given that some foods that are high in fat can also have a low GI, this might give a misleading impression of the property of the food. Organisations that provide GI based endorsements have acknowledged this problem and have developed category-based nutrient criteria. FSANZ also considers it appropriate and consistent that the nutrient profiling scoring criteria be applied to GI claims to mitigate this concern.

In the Preliminary Final Assessment Report it was shown that considerable overlap is likely between the criteria that would apply to a GI endorsement made available by an endorsing organisation and the nutrient profiling scoring criteria that would apply to GI claims. For example, GI Limited (who may qualify to be an endorsing organisation as defined in the draft Standard) have developed category-based nutrient criteria for fat, sodium and dietary fibre, and in some cases calcium, energy and carbohydrate content have to be met for a food to qualify to carry the GI Symbol (which may qualify to be an endorsement as defined in the draft Standard). Consequently, the type of foods that can carry a GI Symbol and those that make a GI-based claim would be very similar.

The regulatory approach to *endorsements* is further discussed in Attachment 9, Chapter 1 – Endorsements.

18.6.3 Disclosure of GI numerical value

Claims that a food has a *low* GI without disclosing the numerical value carry the risk of consumers having inadequate information to make an informed purchase. Consumers cannot readily assess such a claim or choose between comparable foods. The draft Standard therefore requires that any GI claim must also declare in the nutrition information panel, a numerical value of the GI of the food. This approach is consistent with the requirements for declaration in the nutrition information panel when making a nutrition content claim and it ensures consumers get adequate information.

18.6.4 Substantiation of GI claims

Suppliers of foods carrying such a claim must have records that substantiate the claim as is the case for all nutrition content claims. Since January 2007, an Australian Standard® for determining GI has become available for use by food manufacturers, testing laboratories, research organisations, regulators, and enforcement agencies in Australia and New Zealand. FSANZ considers that this Standard® comprehensively addresses the issue of best industry practice when determining GI and provides an appropriate basis for substantiation. The Editorial note in the draft Standard refers to this preferred method of determining GI in carbohydrates. Broadly, the Australian Standard® system of standards is a voluntary system which has been developed as nationally recognised standards in areas of public benefit and national interest.

18.6.5 Use of descriptors

Prior to the development of the Preliminary Final Assessment Report, the major obstacle for allowing the general use of descriptors was the absence of a widely accepted and documented method for measuring GI, and defined categories to describe *low*, *medium* and *high* GI. The Australian Standard® now provides consistency and clarity in this regard. Consequently, FSANZ proposes the use of descriptors be allowed using the values specified in the Australian Standard®.

18.6.6 Claims on glycemic properties of food other than GI

The draft Standard does not provide specific qualifying criteria for claims on glycemic properties of food (such as glycemic load) other than GI. These claims are not common in the marketplace and currently there no generally accepted descriptors or methods of measurement. In accordance with the general requirements of the draft Standard that permit the use of descriptors only if a reference value for the property is included in the Code or conditions are prescribed for the specific property in the draft Standard, glycemic load claims with descriptors are not permitted (e.g. *low GL*), however, the claim may include the numerical value for the property of the food (e.g. *GL = 12*).

18.6.7 Benefits of final approach

The final approach to regulating GI claims has the following major benefits:

- The use of *low*, *medium* and *high* descriptors is available to suppliers of foods carrying GI claims.
- GI claims do not have to be linked to an *endorsement*, giving suppliers more flexibility when making GI claims.
- Consumers can continue to use GI claims and the familiar descriptors when making food purchases.
- Consumers get sufficient information to make informed decisions and are protected from potentially misleading information when purchasing foods with GI claims because:

    - numerical values must be disclosed along with the claim;
    - such claims must be substantiated;
    - the method for determining GI of carbohydrates in foods is described in an Australian Standard®; and
    - claims are subject to nutrient profiling scoring criteria.

- The approach taken in the draft Standard to regulate GI claims is consistent with the relevant Australian Standard®.
- Endorsement programs in relation to GI can continue to be used under the provisions proposed for endorsements.

19. Lactose

19.1 Decision

FSANZ recommends the following conditions for nutrition content claims about lactose:

Claim	Conditions
Lactose free	The food must not contain any detectable lactose. The nutrition information panel must indicate the lactose and galactose content of the food.
Low lactose	The food must not contain any more than 2 g of lactose per 100 g of food. The nutrition information panel must indicate the lactose and galactose content of the food.

Only nutrition content claims in relation to *low* lactose or lactose *free* will be permitted.

These conditions are prescribed in the Table to clause 11 of the draft Standard.

19.2 Amendments to current standards/CoPoNC recommendations

Claims in relation to the lactose content of food are currently regulated in Standard 1.2.8 – Nutrition Information Requirements. The conditions for *lactose free* claims have been retained. The conditions for *low lactose* claims have been amended (from no more than 0.3 g to 2 g of lactose per 100 g) and *reduced lactose* claims have been prohibited. The conditions have been moved from Standard 1.2.8 into the draft Standard.

19.3 Draft Assessment Report – approach taken and submitter comments

The proposed approach for lactose claims in the Draft Assessment Report has been retained.

Some stakeholders noted their support for the criteria. However it was noted by some industry submitters that the condition of 'no detectable lactose' for *free* claims is not helpful when zero tolerance is not necessary or practical, and maximum tolerance levels were requested instead.

There were conflicting views regarding prohibition of *reduced lactose* claims, with one industry submitter suggesting they be permitted but another noting that they may mislead consumers.

19.4 Rationale for final decision

The criteria for *lactose free* claims are consistent with those presently prescribed in Standard 1.2.8. The criterion of 0.3 g of lactose per 100 g of food currently in the Code for *low lactose* claims has been changed to 2 g lactose per 100 g.

The degree 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 affect the intolerance. There is evidence 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 *et al*, 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' (Dietitians Association of Australia website). This translates to a value of approximately 4.4 g of lactose per 100 g of milk.

The criterion of 0.3g per 100 g of food is therefore considered to be too stringent. Increasing the criterion for *low* claims to 2 g of lactose per 100 g of food will permit claims on a wider range of foods, providing the potential for better informed choice for people with lactose intolerance. This 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. In addition, the amount of lactose is required to be declared in the nutrition information panel. Education is, however, required so that the individuals with greater sensitivity are not confused.

An increase in the criterion for *low lactose* has meant that there is little need for a *reduced lactose* claim. Also, *reduced by x% lactose* 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 a tolerable absolute amount, hence the claim is unhelpful. 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 also provides consistency with gluten claims.

FSANZ acknowledges the potential difficulties associated with the *no detectable* criterion 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 in their submission that the criterion of no detectable lactose supports their position. Therefore, FSANZ considers that the criteria for *lactose free* claims should be retained. For further information about *free* claims, refer to Chapter 16 – Free Claims, in this Attachment.

20. Light/lite claims

20.1 Decision

FSANZ recommends the following conditions for *light/light* claims:

- claims relating to a nutrient, energy or salt must comply with the corresponding *reduced* nutrition content claim conditions (i.e. at least 25% reduction compared to a reference food);
- the identity of the reference food and the difference in quantity of the claimed nutrient in the claimed food compared to the quantity in the reference food must be indicated; and
- the claim must be presented so that all elements of the claim are in the one place.

Conditions for *light/lite* claims are co-located with each of the *reduced* descriptors in the Table to clause 11 of the draft Standard. The draft Standard includes criteria for *light/lite* claims about energy, fat, sodium/salt, sugar, saturated fatty acids, *trans* fatty acids and cholesterol.

20.2 Amendments to current standards/CoPoNC recommendations

Currently the Code does not contain provisions for the use of *light* or *lite* claims and fair trading laws are relied upon to ensure appropriate use of these claims. CoPoNC states that to make a *light/lite* claim, the food must comply with the conditions for the corresponding *reduced* or *low* claim. Under the draft Standard the option of complying with *low* criteria will be removed and food will need to meet the conditions for a *reduced* claim to be eligible to make a *light/lite* claim.

20.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report FSANZ proposed that a food making a *light/lite* claim would need to comply with the conditions for a *reduced* nutrition content claim in relation to that nutrient or energy. It was also proposed that the claim be presented so that all elements of the claim are in the one place. This is consistent with the approach presented in this Final Assessment Report. The Draft Assessment Report also proposed that the characteristic that makes the food *light/lite* be stated adjacent to the claim, regardless of whether the term applies to energy, a nutrient or a non-nutritional characteristic of the food.

A number of industry submitters objected to a *light/lite* claim having the same conditions as *reduced* claims and requested the option of applying conditions for the corresponding *low* claim. Reasons for this included that:

- it is not consistent with the US and UK requirements;

- there is lack of evidence to support the need for less variation in criteria due to consumer confusion; consumer confusion was related to which nutrient the claim referred to rather than whether that nutrient was low or reduced;
- *light/lite* claims that meet the *low* criteria support dietary guidelines;
- it is inappropriate that a product lower in fat than a product making a *reduced* claim, cannot be labelled as *light/lite*.

Some submitters recommended that the conditions for light/lite claims in CoPoNC be retained.

20.4 Preliminary Final Assessment Report – approach taken and submitter comments

Based on legal advice received following the Draft Assessment Report FSANZ proposed in the Preliminary Final Assessment Report that it was not appropriate to regulate claims about *light/lite* that relate to the flavour, texture or colour of food in the draft Standard. This is because non-nutritional properties are not captured by the definition of 'nutrition content claim' since such characteristics are not claimed for nutritional or health purposes.

Several submitters thought it necessary to regulate non-nutritional *light/lite* claims to protect consumers from misleading claims. Some submitters quoted FSANZ's qualitative study (2003) that found consumers interpret *light/lite* as referring to nutrition or health related properties, even when it is describing a non-nutritional property. One submitter suggested capturing these types of claims in Standard 1.1.1 with a statement regarding the need to qualify the property of the food to which the term *light/lite* applies. Another submitter commented on the need to provide information in a User Guide to assist enforcement agencies.

In the Preliminary Final Assessment Report FSANZ also proposed a minor format change to the draft Standard in relation to *light/lite* claims. The proposed change was to not list *light/lite* as a property of the food in the Table to clause 11 but to co-locate these claims with the corresponding *reduced* conditions for the relevant nutrients and energy in this Table.

A number of submitters requested that the conditions for *low* claims be used in addition to *reduced* conditions to determine eligibility for *light/lite* claims, as stated in CoPoNC. Submitters' rationale for this request was consistent with points raised in submissions to the Draft Assessment Report on this issue (see above). In addition, one industry submitter raised concern over the impact on products that have brand names that are not trade marked (e.g. Light & Creamy ice cream). Another submitter stated that some product ranges no longer have a standard for comparison as the *'light/lite'* range is so popular. It was suggested the wording such as *25% less fat than the reduced fat product* will confuse consumers.

One government submitter was opposed to the use of *light/lite* claims and considered that *low* and *reduced* were adequate descriptors in relation to nutrient content. There was also a request to prohibit *light/lite* claims relating to carbohydrate due to the lack of national dietary guidelines for this nutrient. In contrast, another submitter suggested including conditions for these types of carbohydrate claims in order to maintain consistency with other nutrients.

An industry submitter thought that presenting the reference food with the other elements of the claim as proposed, would cause clutter, consumer confusion and increase re-labelling costs. This submitter asked if it is acceptable to use the back of the pack as the 'one place on the label' and duplicate the key selling elements on the front.

20.5 Rationale for final decision

The approach that was proposed in the Preliminary Final Assessment will be retained. FSANZ maintains that claims about *light* or *lite* that relate to properties such as flavour, colour or texture do not have a health effect and are therefore outside the scope of the draft Standard. An editorial note has been included following the Table to clause 11 to clarify that claims relating to non-nutritional qualities of food are regulated under New Zealand fair trading legislation, State or Territory fair trading legislation or the *Trade Practices Act 1974.*

FSANZ continues to view a *light/lite* claim as a comparative claim and therefore has not changed its position with regard to alternate use of the conditions for *low* claims to determine eligibility for *light/lite* claims. This position is supported by consumer research that found consumers considered *light/lite* claims should be accompanied by a comparative claim (FSANZ, 2003a). While FSANZ acknowledges the recommended approach differs from that in CoPoNC and is not consistent with the UK and US approach, the approach will provide consistency with Canada (for *light/lite* claims about fat and energy), Codex and the European Union. If a product meets the criteria to make a *low* claim, it can be labelled as such.

For the rationale for comparative claims, including wording conditions, refer to Chapter 12 – Comparative Claims – Conditions, in Part 2 of this Attachment.

21. Potassium

21.1 Decision

FSANZ recommends that:

- claims about potassium content are permitted;
- there are no specific qualifying criteria for such claims; and
- if a claim about potassium is made, both sodium and potassium content must be declared in the nutrition information panel.

These conditions are prescribed in the Table to clause 11 of the draft Standard.

21.2 Amendments to current standards/CoPoNC recommendations

Claims in relation to potassium content are currently regulated under Standard 1.2.8 – Nutrition Information Requirements, which requires that both sodium and potassium are declared in the nutrition information panel if a claim about potassium is made. The status quo has therefore been retained however, this condition will be moved into the draft Standard.

21.3 Draft Assessment Report – approach taken and submitter comments

Claims in relation to potassium were not specifically mentioned in the Draft Assessment Report however in the draft Standard potassium claims were permitted.

An unintentional consequence of the drafting was that as potassium is a mineral, the conditions applying to claims about minerals would apply to claims about potassium where applicable, i.e. that the food carrying the claim is a claimable food and that comparative claims are not permitted.

Comments specifically relating to potassium claims were not received from submitters in response to the Draft Assessment Report.

21.4 Key changes from proposed approach in the Draft Assessment Report

The consequences of the drafting as proposed in the Draft Assessment Report are not considered appropriate. The drafting was also inconsistent with current provisions for claims about potassium content. The drafting has therefore been amended to reflect the status quo, i.e. that claims about potassium are permitted with no specific qualifying criteria applicable to their use. This issue was not included in the Preliminary Final Assessment Report.

21.5 Rationale for final decision

The recommended approach is the same as that currently prescribed in Standard 1.2.8 for potassium claims. As there is no RDI or ESADDI in the Schedule to Standard 1.1.1 for potassium, there are no specific criteria for the amount of potassium that must be present in order for claims to be made. However, fair trading legislation will apply meaning the claim must not be false or misleading.

As potassium is a mineral, claims in relation to potassium have been specifically exempted from the conditions applying to claims about other minerals. This allows voluntary declaration of potassium in the nutrition information panel. This is useful information for renal patients and should therefore not be prohibited.

22. Protein

22.1 Decision

FSANZ recommends the following conditions for nutrition content claims about protein:

Claim	Conditions
Source of protein	The food must contain at least 5 g of protein per serving
Good source of protein	The food must contain at least 10 g of protein per serving
Increased protein	The reference food must contain at least 5 g of protein per serving. There must be a minimum increase of 25% in protein compared to the 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 together.

These conditions are prescribed in the Table to clause 11 of the draft Standard.

22.2 Amendments to current standards/CoPoNC recommendations

Claims in relation to protein content are not currently regulated by the Code; hence these conditions will be new.

Conditions for protein claims are also not included in CoPoNC.

22.3 Draft Assessment Report – approach taken and submitter comments

The conditions proposed for protein claims in the Draft Assessment Report have been retained except for those in relation to *increased protein* claims (refer to Chapters 11 and 12 in Part 2 of this Attachment).

Some submitters noted their agreement with these conditions.

It was noted by industry submitters that whole milk does not meet the criteria for *good source* claims and it was suggested that there be separate criteria for liquids.

One industry submitter proposed that there be an alternative criterion of percentage of energy from protein, to take account of smaller serve sizes, however this option was not supported by another industry submitter. It was queried why the criteria are not 10% and 25% of the reference values for *source* and *good source* claims respectively.

Another industry submitter expressed concern that the criteria do not take account of protein quality and they recommended that the Protein Digestibility Corrected Amino Acid Score should be taken into account.

22.4 Rationale for final decision

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

- there are nutrition guidelines for protein;
- criteria are needed to support the protein general level health claim that is specified in the list of nutrient function statements in the Scientific Substantiation Framework (refer to Schedule 2 in the draft Standard in Attachment 1 of this Report);
- provision of conditions for protein claims were supported by submitters;
- there are specifications for protein 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 for *source of protein* claims is 10% of the reference value for protein in Standard 1.2.8 – Nutrition Information Requirements. This is consistent with the approach taken in the Code for *source* claims for vitamins and minerals and with the criterion in the Codex Guidelines for the Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005). Submitters were not opposed to this criterion. A criterion of at least 10 g of protein per serve is proposed for *good source* claims as it is twice that of the criteria for *source* of protein claims, which is the approach adopted by Codex for protein.

The unit of measure for protein claims is per serve in order to provide consistency with other risk decreasing nutrients such as vitamins and minerals and dietary fibre. The per serve approach recognises the contribution provided by different foods as it identifies the amount that an average person actually consumes and it compensates for the lower relative protein content of foods such as legumes, which have higher serving sizes than those for meat, fish or chicken.

A criterion using percentage of energy from protein in addition to the absolute protein content was considered because it was thought this would prevent some relatively large serving sizes of relatively low quality protein foods from carrying protein claims. However, after further analysis it appears that these types of foods (for example some soups and wheat based noodles, pastas and gnocchi) can still make *source of protein* claims using the absolute protein criteria and hence the additional criterion did not have the desired effect. FSANZ acknowledges that because serving sizes are not standardised, a manufacturer could determine a size that is advantageous to making a claim. FSANZ notes concern from submitters regarding the potential for manufacturers to benefit from increasing the serving sizes of their products and will therefore monitor the marketplace as necessary. 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. A per serve basis with only one criterion for both solids and liquids is consistent with the per serve approach used in the Codex Guidelines (Codex Alimentarius Commission, 2005) and this approach maintains consistency with the qualifying criteria for other risk reducing nutrients specified in the draft Standard.

The criterion for *good source* claims will not be adjusted to allow whole milk to carry this claim. Low protein intake has not been identified as an issue across the general populations in Australia or New Zealand and whole milk meets the criterion for *source of protein* claims and therefore also meets the qualifying criteria to make a general level health claim in relation to protein. Low fat milks do meet the *good source* criterion and such claims on these products instead of on whole milks are supported by dietary guidelines which recommend consumption of low or reduced fat milks (Ministry of Health 2003, NHMRC 2003). FSANZ recognises that the protein quality will not be equivalent in all foods that carry protein claims. However the quality or bioavailability of a number of other nutrients or substances may also differ from food to food and for consistency within the draft Standard, regulation is not being placed around the quality or bioavailability of any substance at this stage.

For the rationale for the criteria for *increased protein* claims refer to Chapters 11 and 12 in Part 2 of this Attachment.

23. Salt/sodium claims

23.1 Decision

FSANZ recommends the following conditions in relation to nutrition content claims about salt and sodium:

Claim	Conditions
Low salt/sodium	The food must not contain any more than 120 mg of sodium per 100 g of solid food; and 120 mg of sodium per 100 ml of liquid food. The nutrition information panel must indicate the potassium content of the food.
Very low salt/sodium	No specific provisions. Regulated by fair trading legislation.
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 together. The nutrition information panel must indicate the potassium content of the food.
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 of the food.	
Unsalted	The food must comply with the conditions for a nutrition content claim in relation to *no added salt*.
Salt/sodium *free*	No specific provisions. Regulated by fair trading legislation.
Conditions relating to salt/sodium nutrition content claims are prescribed in the Table to clause 11 of the draft Standard.	

23.2 Amendments to current standards/CoPoNC recommendations

Note that the terms salt and sodium are synonymous in the Code. Currently clause 17 of Standard 1.2.8 mandates that a claim to the effect that a food is *low* in salt or sodium can only be made when the food contains no more than 120 mg of sodium per 100 g of food. This requirement is the same as recommended in CoPoNC and will not change under the draft Standard. Standard 1.2.8 also states that both the sodium and potassium content of the food must be presented in the nutrition information panel when a claim is made in relation to sodium/salt. Currently there are no provisions in the Code for claims in relation to *very low salt/sodium, reduced salt/sodium, no added* or *salt free claims*. CoPoNC stipulates criteria for these claims; some of these criteria have been incorporated into the draft Standard. FSANZ proposes to not include CoPoNC criteria for *very low salt/sodium* and *salt free* but to rely on fair trading legislation. This approach achieves consistency with the approach proposed for other nutrition content claims relating to *very low* and *free*.

23.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report, the approach for claims about salt/sodium content was similar to that outlined above. An exception is that in the Draft Assessment Report it was proposed that foods with a *no added* salt or *unsalted* claim, which contain naturally occurring sodium, be required to state a disclaimer that the food contains naturally occurring sodium.

Submitter comments focussed on the requirement for the disclaimer for *no added* and *unsalted* claims, with the majority of those who provided comment on this matter opposed to this requirement. Reasons given for this opposition included:

- The disclaimer for *no added* claims was thought to be unnecessary given that FSANZ consumer research (FSANZ, 2003a) showed that *no added* was unequivocally understood to mean that the product had only ‘natural salt’. In addition, this research found that consumers did not interpret *no added* claims to mean that the product had none of the nutrient in question.

- If the disclaimer is continued to be required for *no added* salt claims, a threshold should be established before the extra words are required – if required on all foods with *no added* claims then this is potentially alarmist when the food contains a very low level of the nutrient.

- If label space is a concern the extra wording may be a deterrent from making a *no added* claim.

- The disclaimer adds ‘negativity’ to the claim.

- The disclaimer for *no added* claims is not evidence based and is likely to mislead consumers; any risk is managed by full disclosure on the nutrition information panel.

- A disclaimer for *no added* claims would be meaningless, as nearly all food contains naturally occurring sodium. An alternative suggestion was that foods without naturally occurring sodium should be required to state they ‘contain no naturally occurring sodium’.

Other more general submitter comments in response to the Draft Assessment Report in relation to sodium/salt claims included support for the *low* and *reduced* sodium/salt criteria. It was suggested that there be a requirement for potassium to be displayed directly under sodium in the nutrition information panel when a claim is made in relation to salt/sodium. A submitter recommended that a maximum sodium level be provided for *salt free* claims, as in CoPoNC.

23.4 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report FSANZ proposed to remove the requirement for the disclaimer for *no added* salt claims (i.e. a statement that the food contains naturally occurring sodium). As a consequence of this amendment the requirement for the disclaimer to accompany *unsalted* claims was also removed. This option received a great deal of support from submitters. Some submitters representing government departments thought it necessary to require foods to meet the criteria for *low salt* claims before being eligible for an exemption from the disclaiming statement.

One submitter was concerned that hydrolysed vegetable protein (HVP) could be added to a food carrying a *no added salt* claim as it was not captured in the proposed conditions.

23.5 Rationale for final decision

FSANZ maintains that claims about *low salt, no added salt, and reduced salt/sodium* claims should be permitted and regulated. Submitters to the assessment reports either supported or were silent in relation to these claims. This approach is supported by both Australian and New Zealand dietary guidelines which recommend choosing foods low in salt (NHMRC, 2003, Ministry of Health, 2003).

It is recommended that the existing criterion of no more than 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 the criterion in the Codex Guidelines for the Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005) and was supported by nearly all submitters. The addition of the criterion based on per 100 ml for liquid food will ensure consistency with the 100 ml basis for other nutrition content claims. It is noted that this qualifying criterion of 120 mg for liquid foods is the same as that for solid foods, which is not consistent with the approach for other nutrition content claims, where the qualifying criterion for liquid foods are generally half that of the criterion for solid foods. This is because of the intent to remain consistent with Codex and CoPoNC criteria as noted above.

FSANZ recommends that specific qualifying criteria for *very low (in) sodium/salt* claims not be included in the draft Standard in order to achieve consistency with other risk increasing nutrition content claims. The majority of submitters agreed with this approach.

For the rationale for the conditions for *reduced salt/sodium* claims, refer to Chapters 11 and 12 and for *free of salt/sodium* claims refer to Chapter 16 – Free Claims, in Part 2 of this Attachment.

Conditions for *no added salt/sodium* and *unsalted* claims have remained the same as those currently in CoPoNC (which were previously regulated by the Australia Food Standards Code).

FSANZ re-evaluated consumer research and considered submitter comments before deciding to remove the requirement for a disclaimer statement to accompany *no added* and *unsalted* claims. FSANZ qualitative research (FSANZ, 2003a) found that respondents unequivocally understood a *no added* salt claim to mean that the product had only 'natural' salt, with none added. While research participants thought that a *no added* claim on a product did not imply that the product had no salt, they did think that the product would be low in salt.

In response to submitter comments to the Preliminary Final Assessment Report, a survey of the sodium content of products carrying a *no added* claim revealed that for the majority of products, the sodium content was substantially less than similar products with added salt. For example, the sodium content of peanut butter with *no added* salt is approximately 20 mg/100 g compared with approximately 360 mg/100 g in the standard version of the product. If *no added* claims were required to meet the criteria for *low salt* claims, fewer product lines would qualify to promote lower sodium versions. FSANZ considers that this would potentially disadvantage consumers given the public health significance of dietary sodium. FSANZ maintains the view that it is unnecessary to require products making *no added* claims to meet the conditions for a *low* salt claim.

Hydrolysed vegetable protein (HVP) and related products such as textured vegetable protein (TVP) can be produced in a variety of ways. Some manufacturing methods may use added sodium whereas others may not. Therefore while some foods containing HVP will be able to carry the *no added* claim, others will not, depending on the composition of the HVP. FSANZ is unaware of any products carrying a *no added salt* claim that contain HVP.

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 – Nutrition Information Requirements and provides useful information to renal patients.

24. Fat

24.1 Decision

FSANZ recommends the following conditions for nutrition content claims about fat:

Claim	Conditions
Low (in) fat	≤3 g fat per 100 g solid food; and ≤1.5 g fat per 100 ml liquid food.
Reduced (in) fat	

Light/lite (in relation to fat content)	The comparison should be based on a relative reduction of at least 25% in the fat content compared to a reference food. 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 together.	
Fat *free*	No provisions (regulated by fair trading legislation).
x% *fat free*	The food must meet the requirements specified for the *low fat* claim.
These conditions are specified in the Table to clause 11 of the draft Standard.	

24.2 Amendments to current standards/CoPoNC recommendations

Claims in relation to fat content are not currently regulated by the Code; hence these conditions will be new.

CoPoNC includes conditions for *reduced fat, low fat, fat free* and *x% fat free* claims. The conditions for the *low fat* and *x% fat free* claims are the same as in the draft Standard. For the *reduced fat* claim, under CoPoNC the food also had to have a reduction of at least 3 g of fat per 100 g of food or 1.5 g of fat per 100 ml of food. Conditions for the *fat free* claim also differ to those in CoPoNC, where up to 0.15 g of fat per 100 g of food was permitted.

24.3 Draft Assessment Report – approach taken and submitter comments

The criteria recommended in the Draft Assessment Report were the same as the criteria recommended in this Report (except in relation to *light* claims and *reduced* claims as outlined in Chapter 20 – Light/Lite Claims and Chapters 11 and 12 in Part 2 of this Attachment).

Regarding the criteria for *x% fat free* claims, it was suggested by some industry submitters that the criteria are changed to less than or equal to 5% and 10% total fat content for liquid and solid foods respectively, because a way is needed to indicate a relatively low fat content that does not meet the qualifying criteria for *low* or *reduced* claims. It was thought that FSANZ misinterpreted their own consumer research in relation to whether a 94% fat free food was a *low fat* food by assuming that consumers use the same cut off of 3% fat for *low fat* foods.

Some public health submitters recommended that the *x% fat free* claim be prohibited, particularly on foods high in sugar and energy that do not normally contain fat. For comments in relation to *fat free* claims, refer to Chapter 16 – Free Claims, in Part 2 of this Attachment.

24.4 Rationale for final decision

Permission for claims around fat content should continue, given that these claims are supported by national dietary guidelines which recommend moderating fat intake (NHMRC, 2003, Ministry of Health, 2003) and they are already present in the market place.

The existing CoPoNC criteria for *low fat* claims have been retained as they are consistent with the criteria in the Codex Alimentarius Guidelines for Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005), international criteria and were supported by most submitters.

Claims of *x% fat free* are considered to be warranted as consumers are positive about claims that are definitive and these claims have been in the market place for a number of years. An *x% fat free* claim on a food containing 10% fat could be misleading to consumers who cannot determine the actual fat content or the level of fat (i.e. low, high etc) from this claim. FSANZ's recommendation to limit such claims to foods that meet the criteria for *low fat* claims prevents consumers from being misled about the total fat content of the food. The provisions are consistent with Canada and the USA and were widely supported by submitters from all sectors.

The general requirement in the draft Standard that the claim refers to the whole food rather than the brand name where a food is naturally low in a nutrient, should also reduce the potential for claims about fat content on foods not normally containing fat, to be misleading.

For the rationale for *reduced fat* claims, refer to Chapters 11 and 12 in Part 2 of this Attachment, for *fat free* claims, refer to Chapter 16 – Free Claims in Part 2 of this Attachment, and for *light* claims in relation to fat content, refer to Chapter 20 – Light/Lite Claims in Part 2 of this Attachment.

25. Saturated and *Trans* fatty acids

25.1 Decision

FSANZ recommends the following conditions for nutrition content claims about saturated and/or *trans* fatty acids:

Claim	Conditions
Low in saturated fatty acids	
Low in saturated and *trans* fatty acids	The food must not contain any more than 0.75 g of saturated and *trans* fatty acids per 100 ml of liquid food and 1.5 g of saturated and *trans* fatty acids per 100 g of solid food.
Free of saturated fatty acids	No detectable saturated and *trans* fatty acids.
Reduced in saturated fatty acids	
Light claims in relation to saturated fatty acid content	The comparison should be based on a reduction of at least 25% in the saturated fatty acid content compared to a reference food. The food must not contain more *trans* fatty acids than in the same quantity of the reference food. The identity of the reference food and the difference between the saturated fatty acid 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 together.
Reduced in saturated and *trans* fatty acids	
Light claims in relation to saturated and *trans* fatty acid content	The comparison should be based on a reduction of at least 25% in the saturated and *trans* fatty acid content compared to a reference food. There must be a reduction of both saturated and *trans* fatty acids compared to the reference food.

The identity of the reference food and the difference between the saturated and *trans* fatty acid 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 together.
Free of *trans* fatty acids No detectable *trans* fatty acids.
The food contains:

- no more saturated fatty acids than 0.75 g per 100 ml of liquid food and 1.5 g per 100 g of solid food; or

no more than 28% saturated fatty acids as a proportion of the total fatty acid content.
Reduced in *trans* fatty acids

Light claims in relation to *trans* fatty acid content The comparison should be based on a reduction of at least 25% in the *trans* fatty acid content compared to a reference food.
The food must not contain more saturated fatty acids than in the same quantity of the reference food.
The identity of the reference food and the difference between the *trans* fatty acid 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 together.
x% free of *trans* fatty acids Not permitted.
Low in *trans* fatty acids Not permitted.
Saturated fatty acids as a *low proportion* of total fatty acid content The food contains no more than 28% saturated and *trans* fatty acids as a proportion of the total fatty acid content.

Saturated and *trans* fatty acids as a *low proportion* of total fatty acid content The food contains no more than 28% saturated and *trans* fatty acids as a proportion of the total fatty acid content.

These conditions are prescribed in the Table to clause 11 of the draft Standard.

25.2 Amendments to current standards/CoPoNC recommendations

CoPoNC includes conditions for *low* and *reduced* claims about saturated fatty acids only. These conditions do not include the *trans* fatty acid content, but *trans* fatty acids are included in the conditions for claims about saturated fatty acids in the draft Standard. In CoPoNC the conditions for the *reduced* saturated fatty acid claim include additional requirements for the total saturated fatty acid content of the food and the percentage of cis-monounsaturated and cis-polyunsaturated fatty acids in the food. These conditions have not been carried over into the new Standard.

The Code does not currently include any specific conditions for making the above claims, hence these conditions will be new.

25.3 Draft Assessment Report – approach taken and submitter comments

Conditions proposed for the following nutrition content claims were the same in the Draft Assessment Report as those recommended above (Section 25.1 - Decision): *low* in saturated fatty acids, l*ow* in saturated and *trans* fatty acids, *reduced in saturated fatty acids*, and *reduced in saturated and trans fatty acids*.

The following nutrition content claims were permitted by virtue of the drafting provided in the Draft Assessment Report: *reduced in trans fatty acids, low in trans fatty acids, free in saturated fatty acids, free in trans fatty acids, x% free of trans fatty acids,* and similar claims such as *proportionately low in saturated fatty acids* however; specific conditions were not recommended for their use.

A number of stakeholders (from the industry and public health sectors) requested the use of an alternative condition for *low saturated fatty acid* claims of no more than 28% saturated fatty acids and *trans* fatty acids as a proportion of the total fatty acid content. One submitter suggested that for the *low* claims, an additional criterion of no more than 0.5 g of *trans* fatty acids per 100 g of food should be introduced to prohibit foods containing up to 1.5% *trans* fatty acids from carrying a *low saturated fatty acid* claim.

A public health submitter suggested that if the conditions for *low saturated fatty acids* could not be met, suppliers would instead make claims in relation to *trans* fatty acids, which takes the emphasis away from the public health message to reduce saturated fats and increase polyunsaturated fats in the diet. These submitters therefore recommended that claims about *trans* fatty acids be prohibited, until suitable daily intake reference values are available to determine conditions for these claims.

There was concern from some submitters that the definition in the Code of *trans* fatty acids does not take into account that the scientific literature reports different health effects from *trans* fatty acids from ruminant animals compared to *trans* fatty acids from industrial sources.

25.4 Preliminary Final Assessment Report – approach taken and submitter comments

The approach that saturated and *trans* fatty acids should be considered together when developing applicable conditions for claims was considered more broadly. As a result, conditions were developed for the following claims:

- *free of saturated fatty acids* (the food must be free of *trans* fatty acids);
- *free of trans fatty acids* (the food must meet the conditions for a *low saturated fatty acid claim*, i.e. no more than 0.75 g of saturated and *trans* fatty acids per 100 ml of liquid food or 1.5 g of saturated and *trans* fatty acids per 100 g of solid food);
- *reduced in trans fatty acids* (with the same conditions as those recommended in this Final Assessment Report);
- *x% free of trans fatty acids* (prohibited); and
- *low trans fatty acids* (prohibited).

In addition, it was clarified in the Preliminary Final Assessment Report that the *trans* fatty acid content of the food could be voluntarily declared in the nutrition information panel (this would constitute a nutrition content claim).

A number of submitters noted their support of the proposed approach.

Some submitters objected to the conditions for *free of trans fatty acid* claims, for the following reasons:

- as the claim must meet the conditions for *low saturated fat* claims, this permits a certain level of *trans* fatty acids in the food, whereas there is no tolerance level for other *free* claims;
- the approach is inconsistent with the conditions for *gluten free* and *lactose free* claims which state there is 'no detectable gluten/lactose';
- the proposal supports manufactured food over natural food, as some natural foods cannot be totally free of *trans* fatty acids (or saturated fatty acids) whereas products like confectionery can;
- the conditions need to state that 'the food must be free of *trans* fatty acids'; being silent will make it particularly difficult to enforce (this also applied to the *free saturated fatty acid claim)*;
- the proposed restrictions may reduce the incentive for industry to continue to eliminate *trans* fatty acids because this claim will be restricted to foods with a low fat content; and
- foods that contain no *trans* fatty acids, e.g. nuts and avocadoes, should be able to make the claim even if they are not 'low' in saturated fatty acids.

Regarding the *reduced trans fatty acids* claim conditions, it was suggested that there should also be a requirement for a reduction in saturated fatty acids because foods that are high in saturated fatty acids (harmful to health) may still be eligible for this claim. It was also questioned why the conditions for making a *low saturated fatty acid* claim did not apply to this claim.

Permission for a *low trans fatty acid* claim was requested with the following conditions recommended:

- the food meets the conditions for a *low saturated and trans fatty acid* claim; or
- as a proportion of the total fatty acids content, there is no more than 28% saturated fatty acids and *trans* fatty acids; and

- an additional condition that the food contains no more *trans* fatty acids than 1% of the total fatty acid content.

Some submitters objected to the permission for voluntary declaration of *trans* fatty acids in the nutrition information panel because this was inconsistent with permissions for voluntary declaration of other nutrients. Other submitters considered that mandatory declaration of *trans* fatty acids in the nutrition information panel nutrition information panel would enable consumers to make informed choices.

Submitters once again requested the use of an alternative condition for the *low saturated fatty acid* and the *low in saturated and trans fatty acids* claims. They also raised similar concerns about the definition of *trans* fatty acids in the Code as those raised in response to the Draft Assessment Report.

One submitter considered that saturated and *trans* fatty acids claims should be considered separately so that consumers who wish to distinguish between the two types of fat should not be hindered by the fear that because a choice is made to reduce intake of one type of fat, that another will be increased.

25.5 Key changes from proposed approach in the Preliminary Final Assessment Report

The requirement that foods carrying *free of saturated fatty acids* claims must not contain any detectable saturated fatty acids has been inserted into the drafting in response to submitter comments to clarify this requirement. Although technically not necessary (due to the role of fair trading provisions in *free* claims), it was potentially confusing if only 'free of trans fatty acids' was presented as the sole qualifying criteria in respect of *free of saturated fatty acid* claims.

For the *trans fatty acid free* claim, FSANZ concurs with submitters that the conditions proposed in the Preliminary Final Assessment Report were inconsistent with the general approach for other *free* claims, in that the food must be free of the claimed nutrient. To resolve this, the conditions for *trans fatty acid free* claims were amended so that the food cannot contain any detectable *trans* fatty acids and must contain no more than 0.75 g of saturated fatty acids per 100 ml of liquid food or 1.5 g of saturated fatty acids per 100 g of solid food. This replaced the requirement that the food carrying a *trans fatty acid free* claim meet the conditions for *a low saturated fatty acid* claim (which inadvertently included the presence of *trans* fatty acids).

25.6 Further consultation –approach taken and submitter comments

25.6.1 Low proportion of saturated fatty acid claims

Conditions for a new claim about *saturated fatty acids as a low proportion of total fatty acids* were proposed by FSANZ in a Consultation Paper released in December 2007. The use of this claim was not regulated by the draft Standard in previous Reports. However, in response to stakeholder requests, consideration was given to specific conditions for its use. In the Paper four options were considered by FSANZ and Option 2 was put forward as FSANZ's preferred option:

Option 2 – New category of claim to be made as an extension to the polyunsaturated/monounsaturated fatty acid claim

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

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

The majority of submitters supported option 2 outlined above. However a number of submitters (including some of those who supported Option 2) expressed concern that the wording of the claim would be too confusing for consumers and that the requirement for an additional claim about mono or polyunsaturated fatty acids added unnecessary complexity to the claim. There was concern that consumers would not understand the 'proportion' aspect of the claim and could get this confused with *low* or *reduced* saturated fat claims. It was suggested that alternative descriptors or claims be used, e.g. *favourable fatty acid ratio, healthier fatty acid ratio, higher proportion of healthier fats.*

Some submitters made other recommendations including that:

- the requirement for an associated claim about mono or polyunsaturated fatty acids should be removed;
- the conditions relating to the mono or polyunsaturated fatty acid content of the food should be removed;
- the *trans* fatty acid content of the food should be limited (e.g. 1% of total fat);
- there should be an additional requirement that the claim cannot be split; and
- the claim should be prohibited.

It was suggested by some submitters that the 28% criterion should be applied to all related claims, i.e. claims about cholesterol, and a claim about *low proportion of saturated and trans fatty acids*, as well as the high level health claim about blood cholesterol and saturated fatty acid intake.

25.6.2 Trans fatty acid free claims

New conditions for a claim about *trans fat free* were also proposed in the Consultation Paper. In the Paper two options were considered by FSANZ:

Option 1: *Status quo (i.e. as proposed in the Preliminary Final Assessment Report)*

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

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

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

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

Option 2 was put forward as FSANZ's preferred option.

The majority of submitters supported Option 2. Reasons for their support included; this approach will allow provision of more meaningful information for consumers, it provides incentives for manufacturers to develop healthier options, it allows the claim to be used in association with foods that have a healthier profile and is consistent with other fatty acid claims.

Some submitters suggested that a *low trans fatty acid* claim would be more useful than *free* as it would permit the claim on dairy ingredients, where traces of *trans* fatty acids remain and would encourage use of healthier oils. Another submitter suggested a *very low trans fat* claim (<0.5g TFA per 100g) would be useful, as this claim does not excessively discriminate against naturally occurring *trans* fatty acids. Some submitters considered that the *free* claim would only be useful if it refers to industrially produced *trans* fatty acids and allowing the claim on foods such as avocadoes and nuts does little to educate consumers as these foods do not contain significant amounts of *trans* fatty acids.

25.7 Rationale for final decision

Conditions for claims about saturated and *trans* fatty acids have been included in the draft Standard because of their potential for impact on public health (NHMRC and Ministry of Health, 2006). The conditions are similar to those in CoPoNC with some amendments as outlined below.

Saturated fatty acids are the predominant type of fatty acid in dairy products, in some meats, animal fats and in palm oil, palm kernel oil and coconut oil (NHMRC, 2003). *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.

The NHMRC Nutrient Reference Values for Australia and New Zealand do not make specific recommendations for intake of *trans* fatty acids but note that a combined limit of 8-10% of energy from saturated and *trans* fats together would be prudent (NHMRC and Ministry of Health, 2006). The World Health Organization (WHO) recommends that *trans* fatty acids do not contribute more than 1% of total energy intake.

Given the adverse effect of the intake of both saturated and *trans* fatty acids on the risk of developing cardiovascular disease and that these fatty acids are usually present together in the food supply, both have been considered together when developing the applicable claims and conditions.

The conditions for *low in saturated fatty acids* and *low in saturated and trans fatty acids* claims are consistent with those recommended in the Codex Alimentarius Guidelines for Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005). This Guideline does not specifically include *trans* fatty acids in the conditions for claims about saturated fatty acids but recommends that their inclusion be considered. A specific level of *trans* fatty acids, for example 0.5 g per 100 g as suggested by submitters, has not been included in the recommended conditions, because there are no bi-nationally agreed reference values upon which to base these conditions.

For the *reduced trans fatty acid claim* the conditions include that there is no increase in the amount of saturated fatty acids in the food compared to a reference food (along with the reduction of 25% of the *trans* fatty acids). These conditions are consistent with the conditions for the *reduced saturated fatty acids* claim, which require that there is no increase in *trans* fatty acids. The suggestion from a submitter that food carrying a *reduced trans* fatty acid claim is also reduced in saturated fatty acids was not applied because the claim relates specifically to a reduction of *trans* fatty acids, therefore a decline in saturated fatty acids is not warranted. The submitter suggestion that foods carrying *reduced trans fatty acid* claims have to be 'low' in saturated fatty acids has not been applied because this would essentially limit these claims to low fat foods where the *reduced trans* fatty acid claim has little relevance and would likely be superseded by a *low saturated (and trans) fatty acid claim.* This is not the intention as permission for a *reduced trans* fatty acid claim may encourage industry to continue to reduce *trans* fatty acids in the food supply. Refer to Chapters 11 and 12 in Part 2 of this Attachment for further information about *reduced* claims.

The potential for consumers to be misled and the potential impact on public health if claims are made regarding *trans* fatty acids on foods containing relatively high levels of saturated fatty acids means that the saturated fatty acid content of foods carrying claims about *trans* fatty acids must be taken into account.

Therefore, for the *free of trans fatty acids* claim the food must also be low in saturated fatty acids. For the *free of saturated fatty acids* claim the conditions include that the food must contain no detectable saturated fatty acids (as well as *trans* fatty acids), for clarity for enforcement as requested by submitters. The same applies to the conditions for the *free of trans fatty acids* claim. Refer to Chapter 16 – Free Claims, in Part 2 of this Attachment for further information.

Criteria have not been developed for *low trans fatty acid* claims due to lack of a suitable reference value upon which to base such criteria, therefore these claims have been prohibited. The *x% trans fatty acid free* claim has also been prohibited because, as there are no conditions for *low trans fatty acid* claims, the *x% trans fatty acid free* claim cannot be limited to a certain level of *trans* fatty acids in the way that the *x% sugar/fat free* claims are limited to foods that meet the conditions for *low* sugar/fat.

Voluntary declaration of the *trans* fatty acid content of a food in the nutrition information panel is permitted and this is the status quo. This voluntary declaration would be considered a nutrition content claim and hence the polyunsaturated and monounsaturated fatty acids content of the food would also need to be declared in the panel (under subclause 5(4) of Standard 1.2.8). Consideration of the need for mandatory declaration of *trans* fatty acids in the nutrition information panel is not within the scope of Proposal P293. The Review Report entitled Trans Fatty Acids in the New Zealand and Australia Food Supply[4] concluded that national non-regulatory approaches to further reducing the levels of *trans* fatty acids in the Australian and New Zealand food supply should be implemented and that immediate regulatory intervention was not required. The report recommended that a review would commence in early 2009 of the outcome of non-regulatory measures to reduce *trans* fatty acids in the food supply and assess the need to consider regulatory action commensurate with the ongoing risk posed by trans fatty acid intakes, such as additional labelling or compositional requirements.

The definition of *trans* fatty acids will remain as it is currently in the Code at this stage, i.e. *the total of unsaturated fatty acids where one or more of the double bonds are in the trans configuration acids and declared as trans fat.* While FSANZ acknowledges that arguments have been put forward to suggest that ruminant-derived *trans* fatty acids may have different health effects than manufactured *trans* fatty acids, there is a lack of definitive evidence to support this view. To change this definition is beyond the scope of Proposal P293 and a separate application to FSANZ would be required for this to be considered.

25.7.1 Low proportion of saturated fatty acid claims

It is recommended that the *low proportion of saturated fatty acids of total fatty acids* claim continue to be permitted. In addition, the same conditions will be prescribed for a claim about *low proportion of saturated and trans fatty acids of total fatty acid content*. Provision of conditions for making these claims provides certainty around the use of the claims and may encourage innovation in certain foods. The recommended conditions ensure the claims can only be used on foods with an appropriate fatty acid profile.

[4] http://www.foodstandards.gov.au/_srcfiles/Transfat%20report_CLEARED.pdf

Although a small number of submitters suggested that the *low proportion of saturated fatty acids* claim be prohibited, their reasoning for this was based on potential for consumer confusion from the claim, that the claim would be permitted on foods that are not consistent with dietary guidelines, and that the information should be conveyed through education instead. FSANZ considers there are insufficient grounds for prohibiting this claim, as under Proposal P293 deliberations, nutrition content claims have only been prohibited when there are health and safety concerns associated with the claim (e.g. *reduced gluten*). It is also not consistent with the Council of Australian Governments (COAG) principles of minimal effective regulation to prohibit these claims. Where there are clear cases of misleading labelling, fair trading legislation can be utilised.

The criterion of 28% saturated and *trans* fatty acids of total fatty acids has been applied to other claims about fatty acids, both currently in the Code and in draft Standard 1.2.7, e.g. claims about polyunsaturated fatty acid content. It is therefore consistent across all conditions for claims about fatty acids, where applicable. Submitters did not object to the use of this criterion.

FSANZ notes submitter concerns that the total level of *trans* fatty acids in foods carrying these claims would not be limited and agrees that this is of concern. However the suggestion of additional criteria of 1% *trans* fatty acids of total fatty acids or of total energy is not supported by any Australian or New Zealand reference values. Submitters who suggested this criterion did not provide any evidence that a value of 1% is relevant or practical for regulatory purposes. To provide this additional criterion would be inconsistent with the approach FSANZ has taken in prohibiting *low trans fatty acid* claims because there is no relevant reference value upon which to base conditions for these claims. It should also be noted that the Australia New Zealand Collaboration on Trans Fats, established in early 2007, was set up to work cooperatively in reducing the amount of *trans* fatty acids in the New Zealand and Australian food supply through non-regulatory means. The group's objective is to promote wide implementation of current industry and public health initiatives for reducing the levels of *trans* fatty acids in food and increasing consumer awareness and understanding. FSANZ considers that this work will assist in limiting, or at least reducing, the percentage of *trans* fatty acids in foods carrying the *low proportion of saturated fatty acids* claim and that this avenue should be given time to take effect before considering more restrictive criteria for nutrition content claims.

FSANZ acknowledges submitter concerns about the complexity of the claim when expressed as an extension of a nutrition content claim about mono or polyunsaturated fatty acids. FSANZ that agrees the claim is potentially too complex and now recommends that a nutrition content claim about mono or polyunsaturated fatty acids is no longer required.

If a claim about saturated fat is made on a label, the monounsaturated fatty acids, polyunsaturated fatty acids, cholesterol, and *trans* fatty acid content are required to be declared in the nutrition information panel. In line with this, there will be no requirement that the mono or polyunsaturated fatty acid content is at least 40% of total fatty acids. This is because as a result of the 28% criterion applying to saturated and *trans* fatty acids, the remaining 72% will be unsaturated fatty acids, thus by default the food will contain an appropriate fatty acid profile.

Some submitters suggested that there be a requirement that the claim not be split. This has less relevance now that the requirement for an additional claim (about the mono or poly unsaturated fat content) has been removed. In addition, without being more prescriptive about the actual wording of the claim, this requirement would be impractical.

As with all nutrition content claims, the wording of the claim is not prescribed and suppliers can use synonyms for the descriptor of the claim and to describe the property of the food. Claims regarding fatty acids are well established in the market place and consumers are familiar with them however, it will be up to suppliers to determine what they consider to be the best the wording for *low proportion* claims in terms of consumer understanding, within the boundaries of the claim conditions.

The 28% saturated and *trans* fatty acid criterion will not be applied to cholesterol claims, or to the high level health claim about blood cholesterol and saturated fatty acid intake as suggested by some submitters. These amendments fall outside of the scope of the Consultation Paper. In addition, the Scientific Advisory Group (SAG) would need to be reconvened in order to consider amending the conditions previously proposed for high level health claims.

25.7.2 Trans fatty acid free claims

FSANZ considers that the optional criterion of no more than 28% saturated fatty acids as a proportion of the total fatty acid content is appropriate in the conditions for *trans fatty acid free* claims. This is consistent with the conditions for other fatty acid claims, which include a disqualifying criterion of no more than 28% saturated and *trans* fatty acids as a proportion of the total fatty acid content. In addition, it allows the claim on foods with a healthier fatty acid profile instead of limiting the claim to low fat foods.

FSANZ notes submitter suggestions that claims of *very low* or *low trans fat* would be more useful than *free* claims, however, there is no appropriate reference value for *trans* fatty acid intake and hence no readily available basis on which to establish regulatory criteria for such claims.

26. Unsaturated fatty acids

26.1 Decision

FSANZ recommends the following conditions for nutrition content claims about unsaturated fatty acids:

Claim	Conditions
Source (of polyunsaturated and/or monounsaturated)	Saturated fatty acids and trans fatty acids must be no more than 28% of the total fatty acid content of the food. The claimed fatty acid must make up at least 40% of the total fatty acid content of the food.
All omega fatty acid claims	The type of omega fatty acid must be specified in the wording of the claim, immediately after the word ‘omega’.
All omega-3 fatty acid claims	For all foods except fish and fish products with no added saturated fatty acids:

i) saturated fatty acids and trans fatty acids must be no more than 28% of the total fatty acid content of the food; or

ii) there must be no more than 5 g of saturated fatty acids and trans fatty acids per 100 g of food.

The nutrition information panel must indicate the source of omega-3, i.e. alpha-linolenic acid, eicosapentaenoic acid and/or docosahexaenoic acid.

Source of omega-3 The food must contain at least 200 mg alpha-linolenic acid per serving or 30 mg total eicosapentaenoic acid and docosahexaenoic acid per serving.

Good Source of omega-3 The food must contain at least 60 mg total eicosapentaenoic acid and docosahexaenoic acid per serving.

Source of Omega – 6 and
Source of omega-9 Saturated fatty acids and trans fatty acids must be no more than 28% of the total fatty acid content of the food.

The claimed fatty acid must make up at least 40% of the total fatty acid content of the food.

Increased The food must contain at least 25% more of [the claimed unsaturated fatty acid] as the same quantity of reference food.

The reference food must comply with the minimum conditions for a nutrition content claim in relation to [the claimed unsaturated fatty acid].

The claim must state the identity of the reference food, the difference between [the claimed unsaturated fatty acid] content of the food and the reference food. The claim must be presented so that all elements of the claim are together.

Conditions for claims relating to unsaturated fatty acids are included in the Table to clause 11 of the draft Standard.

26.2 Amendments to current standards/CoPoNC recommendations

There are no recommended changes from current provisions in relation to polyunsaturated and monounsaturated fatty acids. These claims are currently regulated in clauses 12 and 13 of Standard 1.2.8 of the Code. FSANZ proposes to retain the current criteria for these claims and intends to review these criteria and conditions when the NHMRC nutrient reference values are considered in respect of the Code.

26.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report FSANZ stated that it did not intend to review the criteria for polyunsaturated and monounsaturated (including omega) fatty acid claims. This was because the NHMRC Nutrient Reference Values for Australia and New Zealand were under development and it was deemed appropriate to await these values. These nutrient reference values would provide guidance for criteria relating to dietary fats, in particular essential fatty acids linoleic acid and alpha-linolenic acid (ALA), and the long-chain fatty acids docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), and docosapentaenoic acid (DPA).

Several submitters agreed with the proposed approach of waiting for the NHMRC nutrient reference values to be released. One submitter questioned the lack of provision for a *good source* claim for foods containing significant amounts of ALA per serve.

Another submitter queried the recommended intakes of ALA, EPA and DHA used to determine the source criteria for omega claims in the draft Standard.

26.4 Rationale for final decision

The approach proposed in the Draft Assessment Report for unsaturated fatty acid claims has been retained and the criteria for these claims are consistent with those presently prescribed in Standard 1.2.8.

The new NHMRC nutrient reference values were released in May 2006. FSANZ intends to undertake a review of the Code in light of these new reference values and will consider unsaturated fatty acids claims at this time. This project is currently being scoped.

Criteria for *source* claims for unsaturated fatty acids were developed by FSANZ as part of Proposal P213 - Labelling Requirements for Fatty Acids. During the assessment of Proposal P213 FSANZ convened an advisory group made up of individuals with expertise in the field of fatty acids. In response to submitter comments to the Draft Assessment Report for Proposal P293, the *good source* claim is not permitted for ALA (a short chain omega 3 fatty acid) because the expert advisory group for Proposal P213 considered that ALA did not have the same degree of beneficial health effects as the long chain omega 3 fatty acids. These criteria will be re-evaluated when the Code is reviewed in terms of the 2006 NHMRC nutrient reference values.

27. Sugar

27.1 Decision

FSANZ recommends the following conditions for nutrition content claims about sugar:

Claim	Conditions
% Free	The food meets the conditions for a nutrition content claim in relation to *low* sugar.
Low sugar	The food contains: • no more than 5 g total sugars per 100 g of solid food or; no more than 2.5 g total sugars per 100 ml of liquid food.
Reduced sugar	
Light/Lite claims in relation to sugar content	The food contains at least 25% less sugars than 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 the one place.
No added sugar	The claims cannot be made unless: (i) the food contains no added sugars as standardized in Standard 2.8.1, 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 or 2.6.2.
Unsweetened	(i) the food must meet the conditions for a nutrition content claim in relation to no added sugar; and

(ii) the food must not contain intense sweeteners, sorbitol, mannitol, glycerol, xylitol, isomalt, maltitol syrup or lactitol.

The provisions for nutrition content claims about sugar(s) are in the Table to clause 11 of the draft Standard.

27.2 Amendments to current standards/CoPoNC recommendations

Currently there are no provisions for claims about sugar(s) in the Code, however in CoPoNC conditions for various claims about sugar(s) are included. The key changes from the conditions in CoPoNC are that products with *no added* claims cannot contain concentrated fruit juice or deionised fruit juice unless that food is standardised under Standard 2.6.1 – Fruit Juice and Vegetable Juice or Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks. In addition, isomalt has been added to the list of prohibited sugars for products carrying an *unsweetened* claim. See Chapter 16 – Free claims, in Part 2 of this Attachment.

27.3 Draft Assessment Report – approach taken and submitter comments

The approach proposed in the Draft Assessment Report for *% free, low, reduced* or *light/lite* and *unsweetened* claims has been retained (see above). For *no added* claims it was proposed in the Draft Assessment Report that if the food contained naturally occurring sugars a disclaimer such as 'contains natural sugars' would also be required. This was based on research that indicated shoppers do not often use the nutrition information panel for interpreting *no added* claims and the potential for shoppers to misunderstand the claim.

The majority of submitters who commented on sugar claims generally supported the conditions for the claims. However some submitters suggested that:

- provision should be made for split claims, i.e. for *reduced sugar* claims;
- the *reduced sugar* claim should only be allowed on foods that also have a reduction of 25% or more in energy; and
- *reduced sugar* claims should be accompanied by a statement as to whether the product is also reduced in energy as consumer research shows that consumers do not look for or understand nutrient trade-offs.

Some submitters commented on the criteria for *sugar-free* claims. The rationale for FSANZ not specifying criteria for *sugar-free* claims is the same for other *free* claims (refer to Chapter 16 – Free Claims, in Part 2 of this Attachment).

The *no added sugar* claim received the most comment from submitters. Some submitters suggested that the requirement for the disclaimer 'contains natural sugar' be removed since there is no scientific basis for distinguishing between naturally occurring and added sugar and because there is no evidence base supporting the use of the disclaimer. Submitters also suggested that if the requirement for a disclaimer continues, a threshold needs to be established and products containing only natural lactose should be exempt. There was also disagreement over the proposal to prohibit the addition of malt, concentrated fruit juice or deionised juice to products with the *no added* claim. Submitters stated that concentrated and deionised juices are a superior choice to sugar as they offer nutrition beyond energy and that prohibition of these ingredients may lead manufacturers to replace fruit juices with sugar.

In addition submitters stated that different forms of fruit juice are not distinguishable by analysis and therefore it would be difficult to enforce proposed restrictions.

27.4 Preliminary Final Assessment Report – approach taken and submitter comments

In response to opposition to the requirement for the disclaimer on products with the *no added sugar* claim, FSANZ commissioned research investigating the impact of the disclaimer on consumer understanding of the claim following the release of the Draft Assessment Report (TNS Social Research, 2006). Results from this study indicated that the disclaimer 'contains natural sugar' was of little benefit to consumers in interpreting the *no added sugar* claim (refer to section 5.5.6 in the Preliminary Final Assessment Report). Consequently FSANZ proposed in the Preliminary Final Assessment Report that the disclaimer would not be required. Other conditions for the *no added* claim proposed in the Draft Assessment Report were retained.

Although not sought in the Preliminary Final Assessment Report, submitter comments were also received on *sugar-free* claims (see Chapter 16 – Free Claims in Part 2 of this Attachment).

Overall industry supported the proposal to not require the disclaimer for *no added* claims whereas public health and government agencies did not. Reasons for supporting the mandatory requirement for the disclaimer included:

- the claim can be on high sugar products which could be misleading;
- FSANZ research has indicated 58% respondents incorrectly thought canned peaches with a *no added claim* had no/low sugar levels;
- FSANZ research indicating consumer misunderstanding does not support FSANZ objectives of providing information for informed choice and preventing misleading/deceptive conduct;
- there is concern about the claim on fruit juice promoting juice consumption; and
- it is likely that had a greater number of young people and those in low income groups been included in the FSANZ research that a greater proportion of respondents would have incorrectly interpreted the claim.

Other comments received on the *no added* claim included:

- the use of the claim should be restricted to products *low* in sugar;
- the definition of sugar in Standard 2.8.1 should be updated to include new natural sweetener products such as rice syrups;
- foods with concentrated fruit juice should not be prohibited from carrying the claim because fruit juices contribute points in the nutrient profiling criteria, they can be added for flavouring purposes, and it is inconsistent with permitting dried fruit in products with *no added* claims;
- compositional criteria should be used for deciding which products can carry the claim; and
- it is unlikely that fair trading laws would be enforced on this issue as the claim is literally true.

27.5 Rationale for final decision

FSANZ recommends that the restrictions on the type of sweeteners that can be added to products carrying *no added* claims are retained. While malt and malt extracts, concentrated fruit juice and/or deionised fruit juice are not sugars, they are largely made up of sugar and used for sweetening purposes. Because FSANZ's consumer research (FSANZ, 2003a) 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, FSANZ considers 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 comparable regions. For instance, the European Union has proposed that a product with the *no added sugar* claim must not contain any added mono- or disaccharides or any other food used for its sweetening properties. In Canada, added sugars or other ingredients containing added sugars or ingredients that contain sugars that functionally substitute for added sugars are not permitted in products with the *no added* claim.

In the United States, the requirements are slightly different since the claim is allowed if no sugar or sugar-containing ingredient is added during processing, however, if the food is not *low* or *reduced calorie* a statement to this effect is required on the label.

In the Preliminary Final Assessment Report FSANZ considered the option of only permitting *no added* claims on products which meet the criteria for the *low* sugar claim. Although this approach might reduce possible consumer confusion with products which carry the claim but have medium/high sugar levels it was considered that this approach was not justified since the extent to which *no added* claims affect consumer purchase behaviour is uncertain and it would remove 'factual' information from some product labels.

In 2007, FSANZ carried out additional research on the impact of nutrition content claims on consumer intent to purchase and evaluations of the products' nutritional value (Roy Morgan Research, 2008) (refer to Attachment 10). This study included the *no added sugar* claim and it was found that the presence of this claim on a sweet biscuit product did not influence the self-reported likelihood to purchase the product nor the evaluation of the products' nutritional value. A second study (Colmar Brunton Social Research, 2008) investigated the use of nutrition content claims and their influence in purchase decisions in a supermarket setting. Results indicated that of the 20% (n=32) of shoppers interviewed who reported having read a nutrition content claim (when present on the label), 69% purchased the product (see Attachment 10). However, due to the small sample size definitive conclusions about the impact of a nutrition content claim on purchase intention cannot be made. Other label elements were used by a significantly greater percentage of consumers in their decision to purchase the product or not, such as brand/product/flavour (58%), the ingredient list (36%) and the nutrition information panel (34%) than nutrition content claims. The findings from these two studies support the recommendation to not require additional regulatory risk management measures for the *no added sugar* claim. While FSANZ acknowledges that earlier FSANZ studies suggest some consumers may misunderstand the *no added* claim, FSANZ considers that results from the recent studies do not provide any indication that nutrition content claims (including the *no added sugar* claim) result in consumers purchasing a product because of believing it to be 'healthier' than it really is. As a result, the nutrient profiling scoring criteria is not being applied to products with nutrition content claims (refer to Chapter 1 – Regulatory Approach for Nutrition Content Claims, in Part 1 of this Attachment).

Rice syrup type products that are produced using a malting process would be captured under 'malt extracts' and therefore not be permitted in products carrying the *no added* claim. Other rice extracts such as rice bran extracts may contain constituents other than sugars and therefore be used for purposes other that 'sweetening'. Therefore it would not be appropriate to include 'rice extracts' as a separate group of ingredients in the definition of sugar.

FSANZ considers the nutrient composition of dried fruit to be significantly different to concentrated fruit juice due to the fibre content and therefore dried fruit is permitted to be present in products with the *no added sugar* claim. Although the nutrient profiling scoring criteria do permit concentrated fruit juice to be included in 'V' (fruit/vegetable/nuts/legumes) points, the profiling criteria includes sugar content in the baseline points to which fruit sugars will contribute.

For the rationale for *reduced sugar* claims, refer to Chapters 11 and 12 in Part 2 of this Attachment.

28. Vitamins and minerals

28.1 Decision

FSANZ recommends the following conditions for nutrition content claims about vitamins and minerals on general purpose foods:

Claim	Conditions
*Sourc*e and *good source*	The vitamin or mineral must be listed in column 1 of the Schedule to Standard 1.1.1. Claims about potassium are also permitted.
Source	A serving of the food must contain at least 10% of the RDI or ESADDI for the vitamin or mineral.
Good source	A serving of the food must contain at least 25% of the RDI or ESADDI for the vitamin or mineral.
Comparative claims	Not permitted

These conditions are prescribed in the Table to clause 11 of the draft Standard. The draft Standard will include a cross reference to Standard 1.3.2 which provides conditions for the maximum amount of a vitamin or mineral that can be claimed on foods permitted to be fortified under that Standard.

28.2 Amendments to current standards/CoPoNC recommendations

Claims in relation to vitamins and minerals on general purpose foods are currently regulated by Standard 1.3.2 – Vitamins and Minerals. The 'claimable food' definition in this Standard will be removed and foods will no longer be required to meet the 'claimable food' definition in order to carry nutrition content claims about vitamins or minerals. Conditions for nutrition content claims in relation to vitamin and mineral content will be prescribed in the draft Standard. The basis for the qualifying criteria will be changed from per *reference quantity* to *per serve*. The reference quantity definition includes specific quantities that have been developed for foods permitted to be fortified, e.g. cheese has a reference quantity of 25 g. The amendment to the basis for qualifying criteria from per *reference quantity* to *per serve* therefore only impacts on foods that are permitted to be fortified under Standard 1.3.2.

Some vitamin and mineral claims are also permitted and subject to separate conditions under other Standards in the Code, for example Part 2.9 – Special Purpose Foods. These permissions and conditions will continue as per the status quo.

28.3 Draft Assessment Report – approach taken and submitter comments

The approach recommended in the Draft Assessment Report was the same as recommended in this Report, except that general purpose foods carrying nutrition content claims and health claims about vitamins or minerals had to be 'claimable foods' as defined in the draft Standard. The basis for the qualifying criteria for nutrition content claims about vitamins and minerals was changed from per *reference quantity* to *per serve.*

There were conflicting views with respect to the change from a per reference quantity to a per serve amount as the basis for the qualifying criteria, with some submitters (industry and government) in support of this change but others (industry) opposing it. Specific issues around the use of a per serve basis were:

- Standard 1.3.2 was not under discussion;
- there was no previous consultation or regulatory impact analysis carried out;
- elsewhere FSANZ has accepted that there will not be changes to requirements in Standard 1.3.2 'until the standard can be reviewed';
- the Draft Assessment Report states that criteria for vitamins and minerals will be considered as part of future fortification work and review of the Code with respect to 2006 NHMRC nutrient reference values; and
- products in smaller packs will be prevented from making claims, resulting in reformulating or relabelling costs.

It was considered that if standard serve sizes were not prescribed, then a reference quantity should be used.

It was requested that comparisons of vitamins or minerals are permitted within a food group.

Comments were received about the claimable foods concept including that they are prescriptive, limiting and outmoded; and that consistency in regulation of health claims is needed. Some submitters considered that the review of the claimable foods criteria would be more appropriate once the Code has been reviewed to take account of the 2006 NHMRC nutrient reference values.

28.4 Preliminary Final Assessment Report – approach taken and submitter comments

The general approach for the regulation of claims in relation to vitamin and mineral content as proposed in the Draft Assessment Report was retained, with some minor clarification of the clause regulating the maximum quantity of a vitamin or mineral that can be claimed when foods are fortified with those vitamins or minerals.

An Editorial note to clause 7A of amended Standard 1.2.8 – Nutrition Information Requirements, was inserted to clarify that a percent RDI declaration is not required for vitamins and minerals which have an Estimated Safe and Adequate Daily Dietary Intake (ESADDI) prescribed in the Code.

This is the current approach, however, FSANZ considered that since this requirement in draft Standard 1.2.7 differed to the wording currently in Standard 1.3.2, further clarification was necessary.

Although not specifically consulted on, submitters once again commented about the change in approach to a per serve basis for the qualifying criteria for vitamin and mineral claims. Some submitters were in support of a per serve approach as this would provide a more accurate reflection of the declared *source* or *good source* claim, and because the current 'reference quantity' definition was confusing and only worked for certain foods.

Some submitters noted that under Proposal P230 – Consideration of Mandatory Fortification with Iodine, it was mentioned that claims about iodine would be considered under Proposal P293 however there has been no mention of iodine under Proposal P293. There was concern that because of the 'claimable foods' criteria, manufacturers are prevented from informing consumers about iodine and there is limited incentive to switch to iodised salt in products such as gravies, sauce mixes, and salad dressings.

28.5 Further consultation – approach taken and submitter comments

In the Consultation Paper, FSANZ noted that there are differing 'food vehicle eligibility criteria' for foods carrying nutrition content claims, depending on whether the claim was about a vitamin or mineral, or about a macronutrient or other substance. Three options covering the regulation of both nutrition content claims and general level health claims were proposed:

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

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

Option 2: Amend claimable food approach (hybrid):

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

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

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

FSANZ recommended Option 3 as the preferred approach.

There was considerable comment from submitters on this topic. A number of submitters also took the opportunity to express their strongly held views regarding the application of food vehicle eligibility criteria generally (that is, not specifically relating to vitamins and minerals).

Overall, submitters fell into three broad categories: those who supported one of the specific options outlined in the Consultation Paper, those who suggested alternative options and those who opposed all options, mainly because they considered that foods carrying nutrition content claims should be subject to nutrient profiling scoring criteria or a similar risk management measure. A number of submitters also provided additional commentary on issues which were beyond the scope of the Consultation Paper.

Of those submitters who supported one of the specific options put forward by FSANZ, most favoured FSANZ's recommended approach (Option 3). Only one submitter supported Option 1 (status quo) although they noted that there was some merit in applying the nutrient profiling scoring criteria to both nutrition content and health claims. A number of industry submitters supported the removal of 'claimable food' criteria from nutrition content claims (Option 3a) but were opposed to general level health claims about vitamins and minerals being subject to nutrient profiling scoring criteria.

While one jurisdiction supported the retention of the 'claimable foods' criteria for vitamin and mineral content claims (Option 1a) this was made in conjunction with further suggestions relating to the nutrient profiling scoring criteria that could not be addressed within the scope of the Consultation Paper.

Several submitters provided commentary on the specific options but indicated no preferred option. The remaining submitters (government agencies and public health professionals) were generally opposed to all options (noting all nutrition content claims should be subject to the nutrient profiling scoring criteria or similar risk management). The rationale for this view centred on a perceived need for adequate consumer protection and the lack of evidence (and doubts about the quality of evidence) on how consumers interpret vitamin and mineral content claims. They also considered that Option 3 is not consistent with the intent of Standard 1.3.2 or with the intent of the Policy Guideline.

28.6 Rationale for final decision

Nutrition content claims in relation to vitamin and mineral content on general purpose foods will be permitted in accordance with claim requirements for nutrition content claims, as prescribed in the draft Standard. Qualifying criteria will be based on a per serve amount rather than per reference quantity. In addition, general purpose foods that carry nutrition content claims about vitamins or minerals will not be subject to food vehicle eligibility criteria (i.e. nutrient profiling scoring criteria). This approach is the same as for other macronutrients or biologically active substances.

Currently, these claims are allowed only where a minimum specified percentage of the RDI or ESADDI of the vitamin or mineral is contained in a prescribed *reference quantity* for a fortified food. However, this requirement will now be based on a *serving* as it currently is for all other 'claimable foods'. The amendment is designed to prevent nutrition content claims being made on foods containing less than 10% RDI or ESADDI per serving, even though such foods contain at least 10% RDI or ESADDI per reference quantity. Currently, this can occur where the reference quantity is relatively large (e.g. 600 ml) and the package and therefore serving size is small (e.g. 200 ml); in these circumstances, a serving of the food as labelled could contain less than 10% RDI or ESADDI and still carry a nutrition content claim.

Calculating on the basis of a serving of the food rather than its reference quantity ensures that foods that bear a *source* nutrition content claim always contain at least 10% RDI per serving, and foods that bear a *good source* nutrition content claim always contain at least 25% RDI per serving. This amendment will only result in relabelling of foods that have both smaller serving sizes than their prescribed reference quantity and where the vitamin or mineral has been declared when the food contains less than 10% of the RDI per serve. Foods that have greater serving sizes than their prescribed reference quantity are not affected by this amendment. FSANZ notes concern from submitters regarding the potential for manufacturers to benefit from increasing the serving sizes of their products and will therefore monitor the marketplace as necessary.

The conditions currently prescribed in Standard 1.3.2 relating to maximum claims will remain on a per reference quantity basis, consistent with current provisions. These conditions will remain in Standard 1.3.2 because they refer to the table containing the permissions in that Standard to fortify food with vitamins and minerals.

Given that the Schedule to Standard 1.1.1 includes an RDI for iodine, nutrition content claims about iodine would be regulated in the same way as claims about other minerals, as outlined in this Chapter. The qualifying criteria for a nutrition content claim about iodine would also need to be met for a food to carry a general level health claim about iodine. A nutrient function statement about iodine and normal brain development in the unborn child, babies and young, has been included in the Scientific Substantiation Framework (See Attachment 1).

FSANZ has considered whether food vehicle eligibility (i.e. 'claimable food' criteria) is necessary for the regulation of vitamin and mineral nutrition content claims. In particular, it was queried whether there was any basis for prescribing a different regulatory approach for nutrition content claims about vitamins and minerals in comparison with other nutrition content claims about other nutrients.

Existing FSANZ and international consumer research suggests that fat, sugar, saturated fat and calories are of more interest and importance to consumers and tend to be used more than micronutrients in purchase decisions (Scott and Worsley, 1997; Paterson, 2001; FSANZ, 2007b; FSANZ, 2003b; Garretson and Burton, 2000; Keller et al., 1997; Neuhouser, 2002; AC Nielsen, 2005; Muller, 1985; Russo et al., 1986). Therefore, recent FSANZ consumer research has not focussed on the impact of nutrition content claims about vitamins and minerals on consumer purchase decisions.

In response to concerns raised over consumer understanding of nutrition content claims on foods, recent FSANZ consumer research focussed on the effect of nutrition content claims about macronutrients (e.g. fat, sugar, fibre) on consumer purchase intentions and product evaluations. Results revealed no significant enhancement of consumer purchase intentions and product evaluations of a mock product carrying a macronutrient nutrition content claim (e.g. low in fat, reduced sugar), compared with the same mock product but without the claim (Roy Morgan Research, 2008). Given the lower salience of vitamin and mineral claims to consumers, it is likely that any effects on product evaluations and intention to purchase would be less than those for macronutrient content claims. Qualitative FSANZ research on vitamin and mineral supplementation of food further supports this since findings suggested that most consumers held neutral views towards vitamin and mineral nutrition content claims, reporting claims such as these make no difference to their purchase decisions (FSANZ, 2003b).

In conclusion, the removal of the 'claimable foods' approach for nutrition content claims about vitamins and minerals ensures a consistent regulatory approach for these claims. Consumer research findings suggest that, as there is less consumer interest in vitamin and mineral claims compared with macronutrient claims, it is unlikely that consumers will be misled by vitamin and mineral nutrition content claims appearing on a broader range of foods.

29. Wholegrain

29.1 Decision

FSANZ recommends that the general conditions for nutrition content claims will apply to claims about wholegrain, for example:

- **'**presence' type nutrition content claims are permitted, for example, *source of wholegrain, contains wholegrain, with wholegrain etc;* and
- as there is no reference value or specific conditions for making claims about wholegrain in the Code, descriptors that indicate a certain level of wholegrain in a food are not permitted, for example, *rich* in wholegrain.

These claims are regulated by clause 5 of the draft Standard. 'Wholegrain' is defined in Standard 2.1.1 – Cereals and Cereal Products.

Note: When wholegrain ingredients are presented as characterising ingredients on the label of a food, Standard 1.2.10 – Characterising ingredients and components of foods, also applies.

29.2 Amendments to current standards/CoPoNC recommendations

Although nutrition claims about wholegrain are currently permitted, conditions for their use are not specified in the Code or in CoPoNC; these conditions are therefore new.

29.3 Draft Assessment Report – proposed approach and submitter comments

In the Draft Assessment Report, FSANZ proposed specific qualifying criteria of at least 8 grams per serve and 15 grams per serve of food for *source* and *good source* of wholegrain claims respectively.

Submitters who made specific comments regarding wholegrain claims were not in support of these proposed conditions. It was considered that there should not be specific qualifying criteria for the two levels of claims because there is no reference value for wholegrain upon which to base these criteria. Some submitters noted that the requirements for percentage labelling of characterising ingredients provides information for consumers and that permission for this declaration should continue with respect to wholegrain ingredients. Various conditions for wholegrain claims were suggested by submitters as alternatives to those proposed by FSANZ, for example, a single claim of *good source* with a criterion of 7.5 g of wholegrain (dry weight) per serve (equivalent to about 12.5 g 'as is' in a serve of bread), based on a daily intake target of around 50 g.

29.4 Preliminary Final Assessment Report – approach taken and submitter comments

The proposed approach was amended in the Preliminary Final Assessment Report, with the intention that nutrition content claims about wholegrain be regulated in the same way as nutrition content claims about biologically active substances, i.e. 'presence' type claims could be made but descriptors, such as *good source* could not be used to indicate the level of wholegrain ingredient that is present.

Some submitters interpreted, and expressed concern, that FSANZ had it seemed, defined wholegrain as a biologically active substance, when it is actually a whole food or an ingredient, and this made the regulation of these claims unclear. In addition, some submitters noted that it does not make sense to declare a wholegrain ingredient such as brown rice in the nutrition information panel. They considered that wholegrain ingredients would be characterising ingredients under Standard 1.2.10.

Submitters objected to the proposed approach to the regulation of wholegrain claims for a variety of reasons including that:

- there will be no differentiation in the marketing of products containing, for example, 10% wholegrain compared to products with 50%, and consumers could consider both products to be equally healthy;
- FSANZ does not recognise the evidence that supports consumption of wholegrain nor the emphasis in nutrition policies on promoting wholegrain;
- any mention of wholegrain would be considered a nutrition content claim, even when describing the food (e.g. wholegrain bread)
- the proposal will undo good work that has been done by industry in marketing beneficial wholegrain products; and
- the approach is inconsistent internationally.

Go Grains Health and Nutrition Limited (Go Grains), an independent advisor in Australia on the role of grain-based foods on human health, proposed that a daily target intake (DTI) of 48 g or more of wholegrain be established as the reference value. They recommended that foods carrying a wholegrain claim should:

- contain more than 10% wholegrain ingredients or contain more than 4.8 g of wholegrain per serve (10% of the daily value);
- state the daily target intake (48 g); and
- state the contribution the food makes towards the daily target (expressed as grams per serve or as a percentage).

The daily target intake of 48 grams was agreed upon at an expert Round Table discussion convened by Go Grains and the International Life Sciences Institute (ILSI) in March 2006. The evidence base for this level, as well as the implications for different food categories of the percentage and absolute criteria were provided in the Go Grains submission that was made in response to the Preliminary Final Assessment Report (see submission summary at Attachment 13). A number of submitters were aware of the Go Grains proposal and noted their support of it. Go Grains also agreed that 'presence' type claims be permitted but descriptors that indicate a certain level of wholegrain in the food, not be permitted.

Other submitters suggested approaches for regulation of wholegrain claims were:

- the food must contain at least 8 g wholegrain per serve for any claim; and
- for *source* claims, at least 7.5 g (dry weight basis) per serve or 28% of total weight of food; *good source* claims at least 15 g per serve or 50% total weight of food; *excellent source* claims at least 30 g per serve or 75% total weight of food.

29.5 Rationale for final decision

Wholegrain foods have been promoted over their refined counterparts via dietary guidelines and other authoritative advice for many years because of the increased nutrient content of wholegrain foods, particularly 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).

'Wholegrain' is defined in Standard 2.1.1 – Cereals and Cereal Products and means 'the intact grain or the dehulled, 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 definition will continue to apply to nutrition content claims about wholegrain.

'Wholegrain' is a term used to describe wholegrain ingredients or foods rather than a nutrient as such and does not readily fit within the conditions for nutrition and health claims. However claims about 'wholegrain' are commonly used to promote 'healthier' products. In order to only allow meaningful wholegrain claims, FSANZ considers that parameters are required. In many ways the issues around managing wholegrain claims are similar to those for biologically active substances, in particular the lack of a bi-nationally agreed reference value on which to base specific qualifying criteria for various levels of claims. FSANZ therefore maintains its recommendation that wholegrain claims be regulated using the same approach as for claims about biologically active substances.

Thus it is proposed that descriptors indicating that a certain level of wholegrain is present in the food be prohibited. This will not preclude the declaration on the label of the percentage of wholegrain present in a food irrespective of whether it is considered to be a characterising ingredient of that food (under Standard 1.2.10) or not. It will also not prohibit the use of presence claims such as *source of wholegrain,* and *contains wholegrain,* or the naming of foods such as 'Wholegrain Bread'.

FSANZ agrees with submitters that wholegrain is an ingredient or food in itself, and is not captured by the definition of biologically active substances. As wholegrain is not a nutrient or a biologically active substance, declaration in the nutrition information panel of the amount of wholegrain in a food carrying a wholegrain claim will not be required under Standard 1.2.8 (however the presence of the nutrition content claim would trigger the requirement for a nutrition information panel if not already required on the food). Current market practice indicates that dietary fibre is commonly declared in the nutrition information panel of foods carrying wholegrain claims.

To FSANZ's knowledge, no country has developed criteria for nutrition content claims about wholegrain to date.

The US Food and Drug Administration (FDA) have provided draft guidance advising that only factual statements about wholegrain can be made, for example, *10 grams of wholegrain.* The Codex Alimentarius Guidelines for Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005) does not include conditions for claims about wholegrain.

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