

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

General Level Health Claims

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PART 1 – GENERAL ISSUES

1. Qualifying Criteria for General Level Health Claims

1.1 Decision

In relation to qualifying criteria for general level health claims, FSANZ recommends that:

- Qualifying criteria for certain general level health claims will be based on the applicable nutrition content claim criteria as follows:
 - general level health claims about dietary fibre, monounsaturated fatty acids, omega-3, 6 and 9 fatty acids, polyunsaturated fatty acids, potassium, protein, vitamins or minerals, the food must meet the requirements for making a *source* claim set for the applicable nutrition content claim; and
 - for general level health claims about cholesterol, fat, salt or sodium, saturated and *trans* fatty acids (combined), saturated fatty acids, sugar, and low energy, the food must meet the relevant criteria for a *low* nutrition content claim.
- For general level health claims relating to ingredients and nutrients without applicable criteria for making nutrition content claims, e.g. carbohydrate, high energy, it is the responsibility of the supplier to determine the appropriate level of the nutrient or ingredient that should be in the food before making the health claim. The claim would need to be substantiated according to the Scientific Substantiation Framework and not be misleading.
- Conditions prescribed in other standards of the Code for making nutrition content claims about certain foods, for example, Standard 2.9.2 – Infant Foods, would also apply to general level health claims on that food and these would override the conditions outlined above if inconsistent.
- For claims about biologically active substances and wholegrain, a serve of the food must contain at least 10% of the amount required to be consumed per day to achieve the claimed health effect.
- For weight loss and maintenance claims 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.
- For claims in relation to maternal folate consumption and normal foetal development the food must contain no less than 40 µg of folic acid per serving.

The general conditions relating to the first bullet point above are prescribed in paragraph 6(1)(d) of the draft Standard. The conditions for general level health claims about biologically active substances, weight loss and maintenance, and maternal folate consumption and normal foetal development are prescribed in the Table to clause 12 of the draft Standard.

1.2 Amendments to current standards/CoPoNC recommendations

As conditions for health claims (equivalent to a general level health claim) are not currently prescribed in the Code or included in CoPoNC, the conditions outlined above are new.

1.3 Draft Assessment Report – approach taken and submitter comments

Qualifying criteria are used to regulate the amount of the property of the food that must be contained in a food in order for a nutrition content claim to be made about that property. The approach in the Draft Assessment Report was that these conditions were then used as applicable as the minimum conditions for making a general level health claim. In the Draft Assessment Report it was stated that claims in relation to risk decreasing nutrients (such as vitamins and minerals, protein, omega-3 fatty acids and fibre) will need to meet the minimum criteria in relation to nutrition content claims, and claims in relation to risk increasing nutrients (such as fat, saturated fat, sodium, total sugars and energy) will be required to meet, as a minimum, the relevant *low* nutrition content claim criteria. However the draft Standard did not clearly reflect this intended approach.

At this stage in the consultation process, disqualifying criteria for the amount of saturated fat, sodium and sugars were proposed to apply as food vehicle eligibility criteria to determine the foods that would be eligible to carry health claims. It was therefore also proposed that where saturated fat, sugars or sodium were the subject of the health claim, the disqualifying criteria in relation to that nutrient would not apply. With the move in the Preliminary Final Assessment Report towards nutrient profiling to determine food vehicle eligibility criteria (rather than disqualifying criteria relating to the sodium, saturated fat and sugar content only of a food), that approach is no longer considered necessary and has been omitted from the draft Standard.

Some submitters noted the lack of clarity around which nutrition content claim qualifying criteria had to be met for the food to qualify to carry a general level health claim about a particular property. Some submitters were concerned that foods that met the qualifying criteria for a *reduced* nutrition content claim would not qualify to carry a general level health claim based on the qualifying criteria for the *reduced* claim. For example, to communicate the benefits of a product reduced in fat, it must meet the conditions for a low fat claim.

1.4 Preliminary Final Assessment Report – approach taken and submitter comments

The draft Standard was amended in the Preliminary Final Assessment Report to that outlined above in section 1.1 – Decision, in order to clarify the intent in relation to the requirement for general level health claims about certain risk increasing and risk reducing nutrients.

There were no submitter comments received in response to the revised drafting for qualifying criteria for general level health claims.

1.5 Rationale for final decision

The Policy Guideline states that the application of qualifying criteria should be considered for a food to be permitted to carry a claim. The use of qualifying criteria provides a standardised approach to the regulation of general level health claims. It ensures that the product must have a minimum or maximum amount of the property of the food that is the subject of the claim before a health claim can be made, which serves to prevent potentially misleading claims. It should be noted that this applies only to those health claims about nutrients for which specific qualifying criteria have been set.

For health claims about nutrients or other substances for which no qualifying criteria have been prescribed, the claim must still be substantiated according to the Scientific Substantiation Framework (refer to Chapter 8) and the claim is subject to fair trading legislation.

The use of qualifying criteria for nutrition content claims as the basis for establishing qualifying criteria for general level health claims:

- is consistent with Codex Guidelines for Use of Nutrition and Health Claims (Codex Alimentarius Commission, 2005); and
- provides consistency in the application of qualifying criteria across the nutrition content claim/general level health claim spectrum.

FSANZ does not consider it appropriate that foods can qualify to carry general level health claims when only meeting criteria for *reduced* claims. Whilst it may be appropriate to identify ‘healthier’ alternatives in some food categories through the use of comparative nutrition content claims as a means to provide wider consumer choice (e.g. *reduced fat* potato crisps), the food itself could still be relatively high in the risk increasing nutrient that is the subject of the claim. FSANZ recognises that not all foods carrying *reduced* claims will have high levels of the nutrient that is the subject of the claim however, it is not possible to regulate differently depending on the actual level of the nutrient in the food, except to use the *low* and *source* criteria as the generic cut-off points. This approach may also encourage industry innovation in order to meet the qualifying criteria.

Although there are no qualifying criteria for health claims about properties of the food with no qualifying criteria for nutrition content claims prescribed in the Code, e.g. carbohydrate claims, the claim would need to be substantiated and would also be regulated by fair trading legislation. The absence of qualifying criteria for these properties is based on a lack of evidence for a public health risk related to their consumption (refer to Attachment 5, Chapter 9 for further information).

For the rationale for qualifying criteria for general level health claims in relation to biologically active substances refer to Chapter 5, for wholegrains refer to Chapter 10, for weight loss and maintenance claims refer to Chapter 8, and for claims in relation to maternal folate consumption and normal foetal development refer to Chapter 6.

2. Nutrient Profiling Scoring Criteria

2.1 Decision

FSANZ recommends that a mostly across-the-board scoring system (based on the UK Food Standards Agency Nutrient Profiling Model) be used to determine the eligibility of foods to carry general and high level health claims. The scoring system is to be known as the Nutrient Profiling Scoring Criteria (NPSC). Key features of the NPSC include:

- The base unit of calculation is 100 g or 100 ml, whichever is used as the basis of expression in the nutrition information panel.

- ‘Baseline’ points allocated for increasing amounts of energy, saturated fat, sodium and total sugars are offset by ‘modifying’ points allocated for the increasing percentage of the product that is fruit, vegetables, nuts, legumes, coconut, spices, herbs, fungi and algae, and the amount of fibre, and in some cases protein.
- The final score determines whether or not a food is eligible to carry a general level health claim assuming that it also meets the qualifying criteria.
- There are three food categories (edible oils, spreads and certain cheeses; other foods; and beverages including milk) each with different cut-off points for determining eligibility to carry general level health claim.
- The NPSC are also the default criteria for determining the eligibility of foods to carry high level health claims.

The provisions for the NPSC are located in Schedule 1 of the draft Standard.

2.2 Amendments to current standards/CoPoNC recommendations

Notwithstanding foods carrying vitamin and mineral claims, there are currently no conditions imposed on the composition of foods which may carry claims which are not specifically prohibited by the Transitional Standard for Health Claims (Standard 1.1A.2). Therefore these provisions are new.

‘Claimable food’ criteria have been removed and foods carrying health claims about vitamins and minerals will now be subject to nutrient profiling scoring criteria.

2.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report, a simple approach was taken for generic eligibility criteria for health claims, based on the levels of total sugar, saturated fat, and sodium per serve. The cut-off points for the three components were based on intake recommendations for Australia and New Zealand which were subsequently converted to a ‘per eating occasion’ basis (see Attachment 5 of the Draft Assessment Report). The model was as follows:

- A product was eligible if it contained:
 - sodium \leq 325 mg/serve and
 - saturated fat \leq 4 g/serve and
 - total sugars \leq 16 g/serve.
- Specific criteria were applied to meals and main dish products. These products could carry a health claim if they contained:
 - sodium \leq 775 mg/serve and
 - saturated fat \leq 7 g/serve and
 - total sugars \leq 31 g/serve.

Because the basis was per serve, it was possible for a single product to be either disqualified or not depending on serve size. For example, a large apple was not eligible owing to the quantity of sugar per serve whereas a small apple was eligible to carry a claim.

There was widespread submitter opposition to the approach taken in the Draft Assessment Report. Comments were mainly focussed on:

- the appropriateness of the foods which would be prohibited or allowed to make claims;
- the choice of the nutrients chosen to set the disqualifying criteria (especially total sugars) including the omission of energy content;
- the use of a per serve model and that serve sizes are not defined in the food regulations;
- suggestions for alternative approaches for determining eligibility/ineligibility;
- concerns that many foods consistent with national nutrition guidelines would be excluded, for example some types of raw fruit; and
- the need for a system to take both risk-increasing and risk-decreasing components into account.

Several different approaches were suggested by submitters, including the system developed in the UK to determine eligibility/ineligibility for products to be advertised to children. A group of submitters suggested a category-based set of criteria that they had developed. A further suggestion was the approach of Drewnowski (2005) using the average of many micronutrients, expressed as a percent of the RDI, as the basis of a scoring system.

2.4 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report FSANZ proposed that a nutrient profiling system based on the UK Profiling System (UK Food Standards Agency, 2006) be used to determine the eligibility of foods to carry general level health claims. In summary, the approach included the following features:

- ‘baseline’ points allocated for increasing amounts of energy, saturated fat, sodium and total sugars are offset by ‘modifying’ points allocated for the increasing percentage of the product that is fruit/vegetables/nuts/legumes¹ and the amount of fibre, and in some cases protein;
- the final score determines whether or not a food is eligible to carry a general level health claim assuming that it also meets the qualifying criteria; and
- there were three food categories (edible oils, spreads and certain cheeses; other foods and milk; and beverages excluding milk) each with different cut-off points for determining eligibility to carry general level health claims.

Refer to Attachment 6 of the Preliminary Final Assessment Report for details on the development of the profiling system and the characteristics of the recommended NPSC.

In summary, FSANZ examined eight models in response to submitter comments (Table 1). To test these models a new database was compiled from AusNut 95, the New Zealand FOODCrop Files and a private database derived from labels in supermarkets in late 2005 (A. Barclay, personal communication). The advantages of including actual label data are that it reflects products currently in the market place and the variation among similar products whereas standard food composition tables contain average values.

¹ For purposes of the NPSC, the fruit/vegetable/nut/legume category also includes coconut, spices, herbs, fungi, seeds and algae.

Table 1: Models used to assess product eligibility

| Model | Base | Type | Classification | Approach |
|--|------------------------------|---|----------------|--|
| 1, 2, 3 (based on model in the Draft Assessment Report) | Per serve | Across the board | Threshold | Only 'risk increasing' nutrients included. |
| 4 | Per 100 g | Category based | Threshold | 'Risk decreasing' nutrients to offset the 'risk increasing' components are implicit in use of categories which have different cut offs for the 'risk increasing' components between categories; and explicit use of a positive nutrient in one category. |
| 5 | Per 100 g | Category based | Threshold | More categories than Model 4. 'Risk decreasing' nutrients to offset the risk increasing components are implicit in use of categories and explicit of risk decreasing nutrients for two categories. |
| 6 (UK Nutrient Profiling Model) (Rayner et al, 2005) | Per 100 g | Across the board (food and beverages separated) | Scoring | 'Risk decreasing' nutrients explicitly offset the risk increasing components in the scoring system. |
| 7 (FSANZ modification of model 6) | Per 100 g or ml | Mostly across the board | Scoring | 'Risk decreasing' nutrients explicitly offset the risk increasing components in the scoring system; an additional category is included for which the 'risk increasing' component criteria are less stringent. |
| 8 (based on Nijman et. al, 2007) | Energy density and per 100 g | Mostly across the board | Threshold | 'Risk increasing' components only; the small number of categories are defined because they have high levels of one risk increasing component and the criterion for that risk increasing component is less stringent. |

The approach of Drewnowski (2005) suggested by a submitter was not examined for the following reasons:

- it did not include the risk increasing components that are related to chronic disease;
- a decision had been made that all components relating to product eligibility to carry a claim would need to be declared on the label to improve the ease enforceability. Therefore a system requiring declaration of many micronutrients would have substantial implications for label design, and the cost of laboratory analysis of products;
- current regulations state that nutrients may only be voluntarily declared on the label if they meet the conditions for *source* claims (if any) and so declaring small or trace amounts would be a substantial shift from the view that declaration in the nutrition information panel is equivalent to a nutrition content claim; and
- FSANZ is yet to consider the incorporation of the 2006 NHMRC nutrient reference values into the Code, hence developing a system based on values that may be altered did not seem desirable.

Many comments from submitters in industry, jurisdictions and public health sectors received in response to the Preliminary Final Assessment Report indicated that the revised model was an improvement on that proposed in the Draft Assessment Report. There was support for the per 100 g or ml approach rather than per serve since this approach is not open to serve size manipulation.

There was a range of general comments criticising the NPSC as follows:

- the system does not allow micronutrients to be scored;
- the system is too lenient; and
- the system is too stringent.

A range of ‘improvements’ were suggested by submitters. Suggestions tended to be focused on a particular product type and related to methods that would allow more of certain product groups to be eligible to make health claims, assuming they could meet the qualifying criteria for an unspecified claim. Specific comments were as follows:

- Products with small serving sizes are disadvantaged because they are scored per 100 g which overstates their contribution to the diet, for example, breakfast cereals, confectionary including chewing gum, and yeast spreads. Adding an additional column of modifying points which allocated increasing points as the serving size decreased was suggested.
- Products with low moisture content are disadvantaged, for example, breakfast cereals are disadvantaged compared with bread.
- Comments received in relation to wholegrains included:
 - Need to clarify as to whether wholegrain cereals are classed as nuts/seeds and so could score modifying points.
 - Dietary guidelines recommend an increase in wholegrains therefore why are they not included in the percent fruit/vegetable/nuts/legumes etc set of modifying points?
- Comments received in relation to modifying points included:
 - The system is unfairly weighted towards the baseline points and each of the columns in the modifying points table should have a maximum score of 10.
 - The multiplier of two for dried fruit does not offset the sugar content of dried fruit adequately, for example in breakfast cereals.
 - Fibre points, in particular, should be extended up to ten points to favour products that had extra fibre added to them, for example, breakfast cereals.
 - The ‘tipping point’, i.e. the number of baseline points at which protein could be scored for a product, should be raised from <11 to <13.
- Comments received about the three product categories included:
 - The definition of milk which allows a milk to be classed as a category 2 product (and so be eligible if it had <4 total points) meant that milk with additions such as omega-3 fatty acids were classified as a category 1 product and had to score <1 total point to be eligible.

- The definition of cheese which allows a cheese to be classed as a category 3 product is such that if a particular cheese contained fruit or nuts, for example, then it would be a category 2 product.
- Comments received on specific products included:
 - Some eligible products should be ineligible including:
 - fruit juice;
 - whole milk;
 - hot chips;
 - all hard cheese (saturated fat content);
 - diet soft drink² (because they might make health claims about their added vitamin content).
 - Some ineligible products should be eligible including:
 - various breakfast cereals (small serve size, high fibre content for some);
 - all hard cheese (micronutrient content);
 - macadamia nuts (because nuts are healthy, and macadamia oil is eligible);
 - salty fish (omega-3 content is important);
 - yeast spreads (high salt content but small serve size);
 - processed cheese (the salt content is needed for food safety reasons so that the cheese does not need refrigeration);
 - various cereal bars and ice creams (allowed to be sold in school canteens with food-restriction policies);
 - sugar-containing chewing gum (small serve size); and
 - sugar containing soft drink (sugar has no adverse effects beyond its contribution to energy and so the baseline points inflate its score unfairly).

Some stakeholders have asked why there are different cut-points to classify beverages and foods. FSANZ notes that the original UK system it adapted contained this distinction. During the development of the UK system, different methods were explored to account for the variable moisture content, and hence nutrient density. These included scoring beverages per 200 g or per 300 g or per 400 g rather than per 100 g. An alternative approach explored was an additional set of modifying points that allocated increasing points for increasing percentage of the product that was water. The final model used a different cut-point rather than additional or different scoring for beverages and foods as the way to deal with the high quantity of water in most beverages (Rayner et al., 2005). The modelling undertaken by FSANZ did not indicate any reason to discard this aspect of the UK system and it is easier to implement than the other options of scoring drinks using a different base or requiring the percentage moisture to be declared on products.

2.5 Investigation of further modifications to the NPSC

A range of modifications to the NPSC presented in the Preliminary Final Assessment Report were examined using either the ‘improvements’ suggested by submitters, or by developing a way to operationalise submitters’ comments.

² Note that diet soft drinks are not permitted to be fortified with vitamins and minerals

Because Category 2 (foods except those in Category 1 or 3) contains the majority of products, it was decided to examine various possible modifications using this category in the first instance. If any modification proved to be useful, then the implications for Category 1 (beverages) and 3 (cheese, edible oils and spreads, butter conforming to designated Standards in the Code) products were subsequently considered.

Modifications of the NPSC were developed to examine:

- two modifications to make the system more lenient overall;
- two modifications to make the system more stringent overall;
- three modifications investigating options around small serving size; and
- changes to the scoring of the modifying components.

Details of these modifications to the NPSC are discussed in the following sections. Except where noted, the same database was used as previously described in the Preliminary Final Assessment Report. All modifications were examined separately except for the final modification which examined a further modification to those which had been decided upon.

2.5.1 Modifications of the NPSC to examine the impact of making the NPSC either more stringent or more lenient on product eligibility

Modification 1 – Lowering the cut-off for eligibility from <4 to <3 total points for Category 2 (to make the NPSC more stringent)

More than 1000 products in the database scored three total points and would therefore be ineligible if this modification were implemented. Examples include:

- avocado;
- more than 100 seafoods including canned tuna;
- various ricotta and cottage cheeses;
- baked beans, chick peas, lentils;
- dried fruit;
- low sugar/salt peanut butter;
- 112 nuts and seeds e.g. almonds;
- various white and wholemeal breads, rice cakes;
- plain pasta;
- various lean meat cuts;
- four low carbohydrate ice creams;
- no added sugar fruit leather; and
- some pizzas and convenience foods.

This list contains many foods that would commonly be regarded as ‘healthy’ or are core foods. Given these results, this modification was discarded.

Modification 2 – Require Category 2 products to score <4 for each baseline component as well as <4 total points (to make the NPSC more stringent)

Using this modification Category 2 products which score <4 total points but which score ≥ 4 ³ for any of the four baseline components would become ineligible to carry health claims. This means that any product which contains >1340 kJ or >4 g saturated fat or >18 g sugars or >360 mg sodium per 100 g/ml would become ineligible. The submitter making this suggestion also cited hot chips as a food which should be ineligible.

More than 1000 products in the FSANZ database would become ineligible including:

- 49 fruits including dried fruits and avocado;
- 70 vegetable products including some potato chips/wedges and pickled products;
- 22 legume products (e.g. chick peas, lentils, baked beans);
- 112 nuts and seeds e.g. almonds;
- 119 breakfast cereals including many mueslis;
- 215 breads, including white, wholemeal varieties and rice cakes;
- 7 cheeses, including ricotta and cottage;
- 32 crackers including corn cakes and rice crackers;
- 5 egg products;
- 191 seafood products including canned tuna;
- 66 meal and main dishes;
- 160 meats and alternatives including a range of meat types and cuts;
- 90 pasta, rice and noodle products including cous cous and plain pasta;
- 83 sauces including tomato based pasta sauces;
- 20 soups;
- some cakes, cereal snack foods/bars;
- various convenience foods, including pizzas;
- 4 ice cream products;
- no added sugar fruit leather;
- 4 spreads including peanut butter, tahini, almond paste;
- 5 flavoured yoghurt products;
- 1 sweetener;
- 2 sandwich products; and
- 2 snack foods, both popcorn.

This modification causes many previously eligible foods to become ineligible because of their energy content (nuts, breakfast cereals), their sodium content (many breads), their saturated fat content (nuts, lean meat) or sugar content (dried fruit). This modification was discarded because it excludes many basic foods. Note that most types of frozen hot chips that were eligible scored less than 4 points for each of the baseline components, and so most remained eligible under this modification.

³ ≥ 4 : greater than or equal to 4. Although readers might be more familiar with ≥ 4 to express this concept, using an underline to symbolise 'equal to' becomes problematic when formatting headings etc with underlines. Hence ≤ 4 and ≥ 4 are used for clarity.

Modification 3 – Raise the cut-off for eligibility from <4 to <5 for category 2 (to make the NPSC more lenient)

Although less than 500 products scored 4 total points, this was an interim score for many products because the fibre and/or fruit/vegetable/nut/legume etc content was missing (because much of the information came from labels and this information is not always declared). Similarly, products with an interim score of 5, 6, 7 etc might have total score of 4 if more of the modifying points could be assigned. However, product types which definitely scored 4 total points and would become eligible if the cut-off was raised to <5 included:

- various types of smoked and other canned fish;
- a small number of cakes and bake mixes, pancake mix;
- crumbed fried chicken, chicken nuggets;
- reduced fat sour cream;
- fish paste;
- chicken burger, fried fish fillet;
- low fat ice cream;
- additional cuts of lamb chops;
- some types of roasted, salted nuts;
- coconut cream, coconut milk;
- additional types of hot chips; and
- additional types of regular, flavoured yoghurt, some full fat custard, packet mousse.

Owing to the missing composition data, it is not possible to determine what other products might become eligible. Therefore this model could not be assessed adequately and was discarded.

Modification 4 – Raise the tipping point for counting protein points from < 11 to <13 (to make the NPSC more lenient)

In the NPSC presented in the Preliminary Final Assessment Report, only two sets of products could score modifying points for protein: those scoring <11 baseline points and those which contain at least 80% fruit/vegetable/nuts/legumes etc regardless of the baseline points score. One submitter suggested that the ‘tipping point’ for scoring protein points should be raised to <13 baseline points as a method for making the system more lenient.

Table 2 shows the products which become eligible if the tipping point is raised from <11 to <13. The products that become eligible under this scenario are generally cereal-based products scoring 4-5 fibre points and which also become able to score 4-5 points for protein. This includes several types of breakfast cereal including some muesli, some products with added sugar (iced buns) or added fat (cheese-topped rolls, scones). Several breakfast cereals which could not be classified previously, owing to missing information regarding their exact fruit content, would be eligible owing to their protein content. In addition, some cereal and muesli bars become eligible.

A range of meat based foods could now score 4-5 protein points but these score few other modifying points because they have no fibre or fruit/vegetable/nut/legume etc content and so did not become eligible.

These products would need to reduce their baseline points to become eligible, for example, sodium levels (e.g. ham and bacon) or fat levels (various meats, fried chicken, etc) as it would not be possible for many of these foods to add substantial amounts of fibre or fruit etc. Other foods such as olives which have 11 - 12 baseline points do not contain appreciable amounts of protein and so do not score any protein points and remain ineligible. There is a further group of foods which score 11 - 12 baseline points and which are not eligible even when the protein tipping point is raised to <13 but could become eligible by either reducing baseline components or by increasing modifying components. These products include some pizzas, hamburgers, types of pre-prepared meals, breakfast bars and some additional breakfast cereals. Although some yeast spreads score <13 baseline points and would be permitted to score 5 protein points if the protein tipping point is raised to <13, they do not score other modifying points and would need to reduce baseline points to become eligible.

Table 2: Eligibility of products with 11-12 baseline points when the protein tipping point is increased from <11 to <13

| <i>Examples of products scoring 11-12 baseline points which become <u>eligible</u> if they can score their protein content</i> | <i>Examples of products scoring 11-12 baseline points still <u>ineligible</u> after protein points are scored</i> | <i>Examples of products scoring 11-12 baseline points that are <u>eligible</u> without this modification</i> |
|---|---|--|
| <p>Most breakfast cereals with a baseline score of 11-12</p> <p>Several types of cracker, generally low fat/higher sodium</p> <p>Dried breadcrumbs, some types of scones</p> <p>One pizza, an additional type of hot chips</p> <p>One wholemeal loaf with unusually high amounts of fruit, some other fruit breads (previously uncertain owing to missing fruit content information)</p> <p>Two breakfast bars with another ten unable to be classified owing to missing fruit content information</p> <p>One type of corn chips, Popcorn, salted</p> | <p>Olives and similar pickles</p> <p>Ham, bacon</p> <p>Various cuts of meat including lamb forequarter chops</p> <p>Various types of smoked fish, fish cake, fish paste</p> <p>Fried chicken</p> <p>Some hamburgers, pizzas, fish cakes, fruit pies, filled choux pastry,</p> <p>Various convenience foods, breakfast bars, cake-style muffins, crumpets</p> <p>Salad dressings, coconut cream/milk, fruit spreads, some yeast spreads</p> <p>Ice cream, cream, mayonnaise, salad dressings, ice cream toppings</p> | <p>A range of nuts and seeds</p> <p>Various hot chips, including frozen</p> <p>Green olives</p> |

The majority of products that become eligible under this modification are cereal-based and low in moisture. The breakfast cereals which become eligible tend to be higher in fibre and moderate in sugar and sodium, although it does not allow all higher fibre cereals to become eligible because some of these score 13 or more baseline points.

The impact of this modification on Category 1 and 3 products was also considered. Of the beverages, only concentrated cordials, milk powders and sweetened condensed milk score more than 10 baseline points. Cordial does not contain protein and gains no additional points. As milk scores only 1-2 points for protein, and no other modifying points, sweetened full cream milk is not eligible.

The milk powders are likely to be eligible after reconstitution, although this depends on their sugar and saturated fat content. Category 3 products are eligible if they score <28 points and so are unaffected by this change.

Overall this modification appears to be useful because the products which become eligible generally conform to dietary guidelines such as moderation in sugar and sodium and therefore FSANZ is recommending that this change is made to the NPSC.

2.5.2 *Modifications of the NPSC to examine the eligibility of products with small serving sizes*

Modification 5 – Use of an additional column of modifying points

A submitter proposed that products with small serving sizes should be given additional modifying points as shown in Table 3, because products with small serving size were considered to be disadvantaged since the system does not reflect the amounts of risk increasing nutrients actually consumed.

Table 3: Additional modifying points based on energy content for products with a serving size of less than 100 g/ml

| Energy content of serving | Additional modifying points |
|---------------------------|-----------------------------|
| <150 kJ | 6 |
| <300 kJ | 5 |
| <600 kJ | 4 |
| <900 kJ | 3 |
| <1200 kJ | 2 |
| <1500 kJ | 1 |

Of the 5000 products in the FSANZ database with a serving size of <100 g, just over 2000 were ineligible both before and after the extra set of points was allocated, and another 2000 were eligible before (and after) the extra set of points was allocated leaving approximately 1000 to be considered.

Submissions relating to the need to take small serving size into account did not specify how small the serve size should be. Hence the results are presented for three different cut-offs for serving size: <20 g, <50 g and <100 g (Table 4). Notable absences from this Table are the yeast spreads and most types of meat paste, jam and confectionary because these products remain ineligible after the serving size points are assigned. A number of products are now eligible whereas previously they were uncertain owing to missing information about fruit/vegetable/nut/legume etc content.

The range of breakfast cereals that become eligible using a serving size of <50 g are similar to those that become eligible if the tipping point for protein is changed (as in Modification 4). However, with the current modification, a range of ice creams, hams and salty foods also become eligible. Due to the eligibility of these ‘less healthy’ foods, the non-specification of serving sizes in the Code and the strong criticism received in response to the model proposed in the Draft Assessment Report which was based on serving size, this modification to the NPSC was not examined further.

Table 4: Eligible foods for different serving size cut-offs (Modification 5)

| <i>Serving Size</i> | <i>Examples of category 2 products which become eligible</i> |
|---------------------|---|
| Less than 20 g | Pickles – olives, capers, relish etc Soy sauce, oyster sauce etc Fish paste Reduced fat cream Various plain, lower fat crackers Desiccated coconut Chewing gum (some), liquorice, carbohydrate modified confectionary Artificial sweeteners Pine nuts, roasted salted nuts Peanut butter with salt &/or sugar Spreadable fruit (50% fruit) Small number of sweet biscuits One type of potato crisp, one type light corn chips |
| Less than 50 g | <i>As above including similar items with larger serving sizes plus:</i> Ham Various ice creams, tofu-based ice confection Some breakfast cereals – high fibre types (not high salt or high sugar types) Some cakes Smoked mussels and oysters |
| Less than 100 g | <i>As above including similar items with larger serving sizes plus:</i> Some types of canned fish Strudels Some fried chickens and lamb chops |

Modification 6 – Profiling criteria calculated per serving size for products with serving size less than 100 g

In this modification to the NPSC, the same point scoring system is retained but it is applied per serve, rather than per 100 g or 100 ml, to products with a small serving size. This was applied to all products with a serve size of less than 100 g in the first instance.

Of the 5000 products in the FSANZ database that had a serving size <100 g, nearly 1300 products were ineligible both before and after the modification was applied, and another 2000 were eligible both before (and after) the modification was applied. Table 5 shows the results for the remainder, which changed classification and became eligible, according to three different definitions of small serving size (<20 g, <50 g, <100 g). The results are similar to the previous modification (Modification 5) except that some additional items such as potato crisps, more confectionary, chocolate, sweet biscuits, high fat crackers become eligible. These products would be eligible even if the modification were limited to products with a serving size of < 20 g. Therefore this modification to the NPSC was discarded for the same reasons as Modification 5.

Table 5: Eligible foods for different serving size cut-offs (Modification 6)

| <i>Serving Size</i> | <i>Examples of category 2 products which become eligible</i> |
|---------------------|---|
| Less than 20 g | Pickles – olives, capers, relish etc Soy sauce, oyster sauce etc Salad dressings, tomato sauce (ketchup) Yeast spread, fish paste Cream, reduced fat and regular Crackers, including high fat varieties Plain sweet biscuits, shortbread, chocolate coated or chocolate chip biscuits Desiccated coconut Chewing gum Many types of confectionary, liquorice, carbohydrate modified confectionary Fruit bars & roll-ups Some chocolates and chocolate bars Artificial sweeteners Pine nuts, roasted salted nuts, peanut butter with salt &/or sugar Spreadable fruit (50% fruit), jam, cream cheese One type of potato crisp, one type light corn chips Salami, corned silverside, chicken nuggets Sugar, honey |
| Less than 50 g | <i>As above including similar items with larger serving sizes plus:</i> Potato crisps Ham Various ice creams, tofu-based ice confection Breakfast bars, muesli bars Iced or jam filled biscuits, some fruit-filled biscuits Many breakfast cereals – high fibre types, high salt types and high sugar types A number of cakes and baking mixes Smoked mussels and oysters, crumbed fried prawns Popcorn – salted and sugar coated |
| Less than 100 g | <i>As above including similar items with larger serving sizes plus:</i> Some types of canned fish Strudels, cake-style muffins Some fried chickens and lamb chops Pizza Some iced fruit buns, cheese topped bread Toasted muesli |

Modification 7 – Products with a small serving size contributing a small proportion of the percentage daily intake (%DI) per serving scoring zero for that component

A submitter suggested that where a product with a small serving size contains only a small amount of one of the baseline components per serve, it should receive a score of zero for that component regardless of what it might score for that component per 100 g. The reference values for the four baseline items specified in the Code were used to operationalise this idea (Table 6). Three different proportions of the reference value were examined. Although not articulated by the submitter, FSANZ interpreted the submitter as meaning that the modifying points should still be allocated per 100 g/ml.

Table 6: The three cut-offs used for four nutrients to define ‘small contribution to intake’ in Modification 7

| Component | Reference value from Standard 1.2.8 | <1% of the reference value in the Code | <2.5% of the reference value in the Code | <5% of the reference value in the Code |
|-------------------|-------------------------------------|--|--|--|
| Energy (kJ) | 8700 | <87 | <217.5 | <435 |
| Saturated fat (g) | 24 | <0.24 | <0.6 | <1.2 |
| Sugars (g) | 90 | <0.9 | <2.25 | <4.5 |
| Sodium (mg) | 2300 | <23 | <57.5 | <115 |

For example, sugar-containing chewing gum contains 1547 kJ energy (4 points) and 97 g sugar (10 points) per 100 g and no appreciable amounts of saturated fat or sodium, yielding a score of 14 baseline points and 14 total points (as it does not score any modifying points); thus it is ineligible to carry health claims. If a modification allowing products which contain <1% of the reference value of a baseline nutrient per serve to score 0 for that component, and using a serving size of three grams, this gum which contains 42 kJ energy per serve would score 0 for energy, but its sugar content would be scored per 100 g as 2.6 g sugar per serve is above the sugar criterion of <0.9 g/serve. It would still be ineligible in this scenario. However if 5% of the reference value is used as the criterion, then this gum would receive 0 points for sugar as well as energy and have a total score of 0 points (eligible).

Table 7: Eligible foods for different serving size cut-offs (Modification 7)

| <i>Serving Size</i> | <i><1% of reference value in the Code</i> | <i><2.5% of reference value in the Code</i> | <i><5% of reference value in the Code</i> |
|------------------------|--|--|---|
| <i>Less than 20 g</i> | Candy coated chocolate, some chewing gum Some ricotta cheese Some water biscuits Oil roasted sunflower seeds Fish paste Some rice crackers Artificial sweeteners | <i>As at left plus:</i> Jelly beans, fruit gums, peppermints Carbohydrate modified confectionary Plain sweet biscuits Pickle, marinated sundried tomatoes Fried, battered chicken nuggets | <i>As at left plus:</i> Fruit spread, lemon butter Meat and fish pastes, salami Plain sweet biscuits, some chocolate biscuits, shortbread Boiled lollies, marshmallows, liquorice, toffee Fancy filled chocolates Sugary chewing gum Sugar |
| <i>Less than 50 g</i> | - | <i>As above plus:</i> Smoked mussels and oysters Battered deep fried scallops Salted roasted peanuts | <i>As above and at left plus:</i> roasted salted nuts Some ice creams Peanut butter regular Some potato crisp One type of breakfast cereal Olives, banana chips |
| <i>Less than 100 g</i> | - | <i>As above plus:</i> Chicken fried with skin | <i>As above and at left plus:</i> Low fat ice cream |

Table 7 shows the results assuming three different definitions of small serve size and three different proportions of the reference value. Products which become eligible include a range of confectionary, fried food, sugary and salty spreads and pickles. FSANZ interpreted the Policy Guideline statement *the claim ...does not promote irresponsible food consumption patterns* as referring to this type of food. Notable absences from this table are yeast spreads and breakfast cereal. This modification also greatly increases the complexity of the scoring system and so it was discarded.

2.5.3 *Modifications of the NPSC to examine possible changes to the scoring for modifying components*

Various alterations to the modifying points were suggested. It was stated that having a scoring range of 0-5 for each of the modifying characteristics meant that the system was unfairly weighted towards the baseline components and each modifying component should have a scoring range of 0-10. However, given the prevalence of chronic disease, FSANZ believes that any profiling system should tend to encourage a reduction of risk-increasing components in food products rather than the addition of other components to products with very high levels of risk-increasing components.

Modification 8 – Permitting the scoring of modifying points for wholegrain cereal content

In this modification to the NPSC the fruit/vegetable/nuts/legume category was expanded to include wholegrain as a scoring item. Wholegrain content was not originally in the FSANZ database. However in response to a request some manufacturers of breakfast cereals and breads supplied additional ingredient information.

It should be noted that wholemeal bread and some breakfast cereals are eligible under the NPSC model proposed in the Preliminary Final Assessment Report. Therefore the focus was on any change in eligibility of some breakfast cereals and cereal bars from Modification 8.

Of the 20 breakfast cereals examined, only eight products are currently ineligible. Of these, six remain ineligible and 2 become eligible when wholegrain content is counted towards points from the fruit/vegetable/nut/legume category. It should be noted that not all breakfast cereal contains any wholegrain content and so these do not change classification. In addition, the higher fibre content of some cereals may be due to the addition of bran. Bran is not a wholegrain under the definition of wholegrain in the Code (it is only part of the grain). Some of the higher fibre cereals also contain higher levels of sugar and/or saturated fat and/or sodium and score more baseline points than their lower fibre counterparts.

All of the six cereal bars tested remain ineligible when wholegrain content is counted towards points from the fruit/vegetable/nut/legume category.

In summary, this modification has little impact on classification. The allocation of points for fruit, nuts and legumes is to offset the baseline points that products score for sugar, energy and saturated fat, and energy. The inclusion of vegetables in this category comes from the original UK profiling system where legumes were considered to be a type of vegetable. Wholemeal bread scores few baseline points so it can score for its protein content and is therefore eligible without needing to score for its wholegrain content. As noted, scoring for wholegrain does not substantially increase the range of breakfast cereals that become eligible.

If the intention is to increase the number of breakfast cereals that are eligible to carry health claims, then a different method is required.

Therefore including wholegrain cereal in the fruit/vegetable/nut/legume category would have little impact on product classification and so this possible modification was discarded.

Modification 9 – Extending the fibre points

A submitter suggested that the fibre points could be extended up to 10 as indicated in Table 8.

Table 8: Extension of the scoring system for fibre

| Points | Current scoring system: Fibre content g/100 g | Suggested modification: Fibre content g/100 g |
|--------|--|--|
| 0 | <= 0.9 | <= 0.9 |
| 1 | >0.9 | >0.9 |
| 2 | >1.9 | >1.9 |
| 3 | >2.8 | >2.8 |
| 4 | >3.7 | >3.7 |
| 5 | >4.7 | >4.7 |
| 6 | - | >5.7 |
| 7 | - | >6.7 |
| 8 | - | >7.7 |
| 9 | - | >8.7 |
| 10 | - | >9.7 |

This modification will only alter the classification of products which are currently ineligible and contain more than 4.7 g fibre/100 g. Forty products in the FSANZ database became eligible including:

- breakfast cereals with higher fibre content;
- certain low fat crackers;
- roasted salted nuts, a small number of dry roasted nuts without added salt;
- some peanut butter with salt and/or sugar;
- desiccated coconut;
- one type of potato crisp;
- unsalted popcorn, popped in oil; and
- light corn chips.

Although the higher scoring for fibre allows some breakfast cereals to become eligible, nuts with added fat, sugar or salt become eligible, as do some snack foods including one type of potato crisp and various fatty popcorns.

Most of the breakfast cereals and all of the crackers that become eligible under this modification also become eligible if the tipping point for protein is changed to <13 (Modification 4). The modelling was done with foods currently in the marketplace. Expanding the fibre points in this way would also encourage manufacturers to add bran, inulin or other fibre sources to food to offset the baseline scoring of a range of other products. As the primary focus is on reducing the risk-increasing nutrients in products this would not seem a desirable outcome. Therefore this modification was discarded.

Modification 10 – Increasing the multiplier for dried fruit

Several submissions suggested that the points for fruit, and dried fruit in particular, did not offset the amount of sugar in the fruit adequately. For dried fruit, a multiplier is applied to allow for the equivalent non-concentrated amount. At present a multiplier of two is used (except where this is in conflict with the characterising ingredient provisions of the Code).

Higher values of three and four for the multiplier were examined using a subset of 300 foods for which there was information about percentage of fruits, vegetables, nuts and legumes in the product.

When a multiplier of 3 was used a type of sweet biscuit containing dried fruit became eligible and when a multiplier of 4 was used one type of breakfast cereal containing dried fruit became eligible in addition to the biscuit. Neither multiplier allowed a wholemeal bread product with unusually high amounts of dried fruit to become eligible.

Changing the tipping point for protein to <13 (Modification 4) results in the same breakfast cereal and wholemeal fruit bread becoming eligible and so is a more useful modification than Modification 10. However there were few products containing large amounts of dried fruit in the FSANZ database and so this option could not be thoroughly tested.

Modification 11 - Redistributing fruit/vegetable/nuts/legume points

Another possibility would be to redistribute the fruit/vegetable/nut/legume points so that there is no gap in the scoring as shown in Table 9.

Table 9: Alternative scoring scale for fruit/vegetable/nut/legume points

| Points | Current scoring system: | Suggested modification: |
|--------|-------------------------|-------------------------|
| 0 | <= 40% | <= 40% |
| 1 | >40% | >40% |
| 2 | >60% | >50% |
| 3 | - | >60% |
| 4 | - | >70% |
| 5 | >80% | >80% |

Five products – a low saturated fat and low sodium potato crisp, a simmer sauce, a no added salt tomato sauce (ketchup), and two types of frozen chips containing unsaturated oils became eligible under this modification. However, the information in the FSANZ database regarding the content of fruit, vegetables, nuts, and legumes is lacking for many products and so it was not possible to test this option on a wide range of products with differing ingredient percentages. This modification was not pursued.

In summary, Modifications 8 -11 did not achieve significantly worthwhile changes to the eligibility of foods beyond that achieved by Modification 4 (changing the tipping point for protein to <13 baseline points). As noted previously, the FSANZ database does not contain information on the fruit/vegetable/nut/legume content for many products and so even with additional information supplied by some manufacturers it is not possible to do a thorough evaluation of some of the modifications.

2.5.4 *Modifications to the product definitions*

Modification 12 – The categorisation of milk

In response to the Preliminary Final Assessment Report, submitters commented that milks with added substances such as omega-3 fatty acids would not be captured by the definition of milk (Category 2) and therefore would be in Category 1. As Category 1 products must score <1 total point to be eligible, but Category 2 products are eligible if they score <4 total points, this was regarded as inequitable. In response to this FSANZ investigated how this discrepancy might be removed.

The original UK system scored products per 100 g. The decision to allow products which declare their nutrition information panel in ml to be scored in ml meant that some whole milk products which had previously scored 0 points for sugar then scored 1 point because they contained 4.6 g lactose per 100 ml but only 4.5 g lactose per 100 g (since the first cutpoint is at 4.5 g per 100 ml or 100 g). As a result, this extra point combined with their saturated fat points was enough to change the classification from eligible to ineligible. (Although the same effect on lactose was also seen in low fat milks, they had lower saturated fat scores and so their classification was not affected.) The decision to move milk from Category 1 to Category 2 was made to reverse the effect on classification of the decision to allow milk to be scored per 100 ml. Further consideration led to the realisation that if the cutpoint between the first two steps in the sugar scale was changed from ≤ 4.5 g to ≤ 5.0 g, then the baseline points score of whole milks would generally reflect their saturated fat content. Table 10 shows the classification of cow milks in the database with lactose content >4.5 g under Model 7 presented in the Preliminary Final Assessment Report (with milk meeting the definition classed as Category 2) and under the modification of all milk classed as Category 1 but using a higher cutpoint between the first two steps in the sugar scale. Although some products would be ineligible, they would tend to be the higher fat whole milks.

Examination of a number of branded whole milks currently available in supermarkets (but not included in the database) indicated that some contain only 3.2 g protein per 100 ml and consequently score only one point for protein whereas whole milks containing 3.3g protein per 100 ml score two protein points. Consequently milks with 3.2 g protein would be ineligible even if their lactose and saturated fat content is the same as a whole milk with 3.3 g protein. Therefore the location of the equals sign in the protein column was altered i.e. previously products with >3.2 g protein scores 2 points and this was changed to products with ≥ 3.2 protein. Modelling of Category 2 foods in the database showed that no food which had previously been ineligible changed classification. It is still possible for whole milks containing certain combinations of lower protein (e.g. 3.1g/100 ml), and higher lactose and saturated fat to be ineligible.

Table 10: Examples of classification of milk products in the database containing more than 4.5 g lactose

| Product name | Energy (kJ/100ml) | Saturated fat (g/100 ml) | Sugars (g/100 ml) | Sodium (mg/100 ml) | Protein (g/100 ml) | Model 7 baseline points | Modified baseline points | Protein points | Model 7 total points | Modified model total points | Model 7 | Modified Model 7 |
|--|-------------------|--------------------------|-------------------|--------------------|--------------------|-------------------------|--------------------------|----------------|----------------------|-----------------------------|------------|------------------|
| Lactose free skim milk | 144 | 0.01 | 4.8 | 35 | 3.4 | 1 | 0 | 2 | -1 | -2 | Eligible | Eligible |
| Skim milk | 148 | 0.1 | 4.9 | 51 | 3.5 | 1 | 0 | 2 | -1 | -2 | Eligible | Eligible |
| Skim milk UHT | 145 | 0.1 | 4.9 | 45 | 3.4 | 1 | 0 | 2 | -1 | -2 | Eligible | Eligible |
| Slim skim milk | 148 | 0.1 | 5 | 58 | 3.5 | 1 | 0 | 2 | -1 | -2 | Eligible | Eligible |
| Brand A low fat milk | 191 | 0.8 | 4.9 | 58 | 3.4 | 1 | 0 | 2 | -1 | -2 | Eligible | Eligible |
| Brand B low fat milk UHT | 191 | 0.8 | 4.9 | 58 | 3.4 | 1 | 0 | 2 | -1 | -2 | Eligible | Eligible |
| Brand C low fat milk | 193 | 0.9 | 5 | 50 | 3.3 | 1 | 0 | 2 | -1 | -2 | Eligible | Eligible |
| Brand D low fat milk | 197 | 1 | 4.9 | 58 | 3.4 | 1 | 0 | 2 | -1 | -2 | Eligible | Eligible |
| Milk composite | 238 | 1.5 | 4.7 | 50.6 | 4.2 | 2 | 1 | 2 | 0 | -1 | Eligible | Eligible |
| Organic full cream UHT milk | 266 | 2 | 4.8 | 58 | 3.4 | 2 | 1 | 2 | 0 | -1 | Eligible | Eligible |
| Brand E Milk, with calcium | 289 | 2.2 | 4.9 | 34 | 4.2 | 3 | 2 | 2 | 1 | 0 | Ineligible | Eligible |
| Brand F Full cream UHT Milk | 271 | 2.3 | 4.8 | 58 | 3.3 | 3 | 2 | 2 | 1 | 0 | Eligible | Eligible |
| | 273 | 2.3 | 4.8 | 49 | 3.4 | 3 | 2 | 2 | 1 | 0 | Eligible | Eligible |
| Brand G Full cream UHT Milk, Fluid, Whole | 264 | 2.4 | 4.6 | 47 | 3.3 | 3 | 2 | 2 | 1 | 0 | Eligible | Eligible |
| Milk, Fluid, Whole, Lactose Reduced | 280 | 2.6 | 4.8 | 42.2 | 3.4 | 3 | 2 | 2 | 1 | 0 | Eligible | Eligible |
| Pure organic (unhomogenised) full cream milk | 280 | 2.6 | 4.8 | 42.2 | 3.4 | 3 | 2 | 2 | 1 | 0 | Eligible | Eligible |
| Full cream milk | 288 | 2.7 | 4.8 | 58 | 3.2 | 3 | 2 | 1 | 2 | 1 | Eligible | Ineligible |
| Brand H extra creamy milk | 271 | 2.8 | 5 | 48 | 3.1 | 3 | 2 | 1 | 2 | 1 | Eligible | Ineligible |
| Milk, Fluid, Whole, High Fat(Fat>4%) | 315 | 3.1 | 4.9 | 41 | 3.2 | 4 | 3 | 1 | 3 | 2 | Eligible | Ineligible |
| | 316.2 | 3.3 | 4.7 | 59.7 | 3.4 | 4 | 3 | 2 | 2 | 1 | Eligible | Ineligible |

Table 11: Examples of classification of other cow milks and milk alternatives in the database

| Product name | Energy (kJ/100 ml) | Saturated fat (g/100 ml) | Sugars (g/100 ml) | Sodium (mg/100 ml) | Protein (g/100 ml) | Model 7 baseline points | Modified baseline points | Protein points | Model 7 points | Modified model total points | Model 7 | Modified model 7 |
|--------------------------------------|--------------------|--------------------------|-------------------|--------------------|--------------------|-------------------------|--------------------------|----------------|----------------|-----------------------------|-------------|------------------|
| Brand A fat free soy drink | 150 | 0.0 | 2.0 | 50 | 3.5 | 0 | 0 | 2 | -2 | -2 | Eligible* | Eligible |
| Brand B enriched rice drink | 210 | 0.0 | 4.6 | 37 | 0.4 | 1 | 0 | 0 | 1 | 0 | Ineligible* | Eligible |
| Brand C light soy drink | 188 | 0.1 | 2.1 | 37 | 3.4 | 0 | 0 | 2 | -2 | -2 | Eligible* | Eligible |
| Brand D rice drink | 275 | 0.1 | 4.2 | 62 | 0.6 | 0 | 0 | 0 | 0 | 0 | Eligible* | Eligible |
| Vanilla flavoured rice drink | 223 | 0.1 | 4.8 | 43 | 0.2 | 1 | 0 | 0 | 1 | 0 | Ineligible* | Eligible |
| Rice drink | 192 | 0.1 | 5.0 | 65 | 0.3 | 1 | 0 | 0 | 1 | 0 | Ineligible | Eligible |
| Brand E light soy with added calcium | 220 | 0.2 | 3.0 | 60 | 2.2 | 0 | 0 | 1 | -1 | -1 | Eligible | Eligible |
| Brand F vanilla soy drink | 257 | 0.3 | 1.8 | 36 | 3.2 | 0 | 0 | 1 | -1 | -1 | Eligible | Eligible |
| Brand G soy drink with calcium | 257 | 0.3 | 1.8 | 36 | 3.2 | 0 | 0 | 1 | -1 | -1 | Eligible | Eligible |
| Milk with calcium and fibre | 202 | 0.3 | 2.1 | 44 | 3.0 | 0 | 0 | 1 | -2 | -1 | Eligible | Eligible |
| Brand H soy drink, chocolate | 306 | 0.3 | 9.2 | 102 | 3.0 | 3 | 3 | 1 | 2 | 2 | Ineligible | Ineligible |
| Milk, Low Fat, Chocolate, Commercial | 224 | 0.3 | 6.8 | 66 | 5.2 | 1 | 1 | 3 | -2 | -2 | Eligible | Eligible |
| Organic oat drink | 179 | 0.4 | 0.4 | 30 | 1.4 | 0 | 0 | 0 | 0 | 0 | Eligible | Eligible |
| Brand I vanilla soy drink | 350 | 0.4 | 4.9 | 44 | 3.1 | 2 | 1 | 1 | 1 | 0 | Ineligible | Eligible |
| Brand J strawberry soy drink | 310 | 0.4 | 5.0 | 43 | 3.1 | 1 | 0 | 1 | 0 | -1 | Eligible | Eligible |
| Brand K chocolate soy drink | 310 | 0.4 | 5.6 | 42 | 3.1 | 1 | 1 | 1 | 0 | 0 | Eligible | Eligible |
| Milk, UHT, chocolate flavour | 308 | 1.5 | 9.9 | 38 | 3.5 | 3 | 3 | 2 | 1 | 1 | Ineligible | Ineligible |
| Brand L iced coffee UHT | 354 | 2.4 | 9.3 | 56 | 3.3 | 5 | 5 | 2 | 3 | 3 | Ineligible | Ineligible |
| Milk, fluid, whole ** | 285 | 2.5 | 4.5 | 39 | 3.4 | 2 | 2 | 2 | 0 | 0 | Eligible | Eligible |

* also scores 1 point for fibre content ** Category 1 at Preliminary Final Assessment.

Some submitters queried why milk alternatives had not also been placed in Category 2 in the model presented in the Preliminary Final Assessment Report. Table 11 shows the classification of milk alternatives and also cows milk with less than 4.5 g lactose or with added sugar by Model 7. Milk alternatives which were ineligible at that time had either higher sugar and/or higher saturated fat and/or lower protein. Some of these become eligible under the proposed modification.

There would be a number of advantages to making these modifications. Firstly, it reduces one of the exceptions in the system, i.e. the classification of milk into Category 2 rather than Category 1 with the other beverages. Secondly, most whole milk is eligible.

The other products which have a total sugar content between 4.5-5 g per 100 g/ml that would be affected by this alteration were examined. Table 12 shows the types of products that have sugar levels in this narrow range, for example, the higher sugar vegetables such as parsnips and the lower sugar fruits such as grapefruit. Most products do not change classification. Some products such as curry simmer sauces cannot be classified owing to missing information about their vegetable content. Among the few that become eligible are some types of salted roasted peanuts and a few types of white sauce. There are several different analyses for macadamia nuts available to FSANZ. By some analyses macadamia nuts are ineligible owing to a higher saturated fat content in conjunction with their energy content, whereas other analyses of macadamia nuts have less saturated fat. In the latter case the move from ≤ 4.5 to ≤ 5.0 g sugar before one point is scored for sugar content would make them eligible.

Table 12: Eligibility of products with 4.5-5.0 g sugar per 100 g when the first step for scoring total sugars in the baseline table is changed from ≤ 4.5 to ≤ 5.0

| <i>Examples of products previously <u>ineligible</u> that become <u>eligible</u></i> | <i>Examples of products previously <u>eligible</u> that remain <u>eligible</u></i> | <i>Examples of products previously <u>ineligible</u> that remain <u>ineligible</u></i> |
|---|---|---|
| Macadamias (some analyses) Cheese sauce, white sauce Yeast-free bread Salted roasted peanuts (some analyses) | Haricot beans, baked beans, canned spaghetti in tomato sauce Peas, parsnip, pumpkin, leeks, onions, beetroot, canned tomatoes Guava, raspberries, rockmelon, grapefruit, loquats Fruit canned in artificial sweetener Popcorn (no fat) Almonds, roast hazelnuts No added salt peanut butter A small number of soups Plain yoghurt Baked rice custard | Hot dogs Mayonnaise French onion cheese spread Some vinaigrette dressings High fat crackers |

2.5.5 Modifications involving more than one change

Modification 13 – Higher fruit/vegetable/nut/legume points for foods which are 100% fruit/vegetable/nut/legume

It will be noted from the above that there are references to a small number of products which are ineligible even though they are members of core foods, e.g. pine nuts, some analyses of macadamia nuts and some dry roasted nuts. FSANZ acknowledges the importance of foods such as fruits and vegetables as fundamental elements of a healthy diet and the logic for such foods to be able to make health claims. This was one of the primary drivers for developing a system beyond the ‘disqualifying criteria’ proposed in the Draft Assessment Report, which amongst other failings, did not allow large fruits (e.g. pears, apples) to qualify for health claims. For purposes of the NPSC, the fruit and vegetable category also includes nuts, legumes, coconut, spices, herbs, fungi, seeds and algae. One submitter however has noted that not all raw or fresh nuts were eligible through the NPSC as presented in the Preliminary Final Assessment Report. This remains true after both modifications of changing the first sugar step and raising the protein tipping point are applied.

In order to better address the attributes of this category per se, FSANZ has now introduced a higher point score for products which are 100% fruit/vegetables/nuts/legumes. This is shown in Table 13. Foods, or mixtures of foods, that are 100% fruit, vegetables, nuts or legumes will now qualify for 8 points.

Table 13: Alternative scoring scale for fruit/vegetable/nut/legume points

| Points | Current scoring system | Suggested modification |
|--------|------------------------|------------------------|
| 0 | <= 40% | <=40.0 |
| 1 | >40% | >= 40.0 |
| 2 | >60% | >= 60.0 |
| 3 | - | - |
| 4 | - | - |
| 5 | >80% | >= 80.0 |
| 6 | | - |
| 7 | | - |
| 8 | | = 100.0 |

When modelled in the FSANZ database the impact of this modification is that some nuts that were previously ineligible now become eligible if they are 100% nut. Those that may have other foods added, such as salt or fat, do not qualify for the 8 points, and therefore do not become eligible.

Table 14 shows the eligibility of some foods. Desiccated coconut was previously ineligible but under this modification becomes eligible. Olives pickled in brine are not a 100% product under this definition, and scores 5 points but not 8 points. By contrast, frozen peas and corn is a mix of two foods that each meets the 100% definition.

FSANZ recommends that this change is made to the NPSC .

Table 14: Classification of selected products under the modification allowing 8 points to be scored if the product is 100% fruit/vegetable/nut/legume

| Product | Energy (kJ/100g) | Saturated fat (g/100g) | Total sugars (g/100g) | Sodium (mg/100g) | Baseline score | Protein (g/100g) | Protein Points | Fibre (g/100g) | Fibre Points | Fruit/vegetable/nut/legume points | Total Points | Classification |
|--|------------------|------------------------|-----------------------|------------------|----------------|------------------|----------------|----------------|--------------|-----------------------------------|--------------|----------------|
| Macadamias Brand A: unsalted dry roasted | 3068 | 10.3 | 4.5 | 3 | 19 | 7.6 | 4 | 6 | 5 | 8** | 2 | E |
| macadamias Brand B: | 3130 | 11.8 | 4.3 | 150 | 20 | 10.4 | 5 | * | 5* | 8 | 2 | E |
| Macadamias Brand C: | 3070 | 10.3 | 4.5 | 3 | 19 | 7.6 | 4 | * | 5* | 8 | 2 | E |
| Macadamias Brand D: salted dry roasted | 3020 | 10.3 | 4.5 | 3 | 19 | 7.6 | 4 | * | 5* | 8 | 2 | E |
| macadamias | 3020 | 12.4 | 5.5 | 340 | 23 | 9.5 | 5 | * | 5* | 5 | 8 | NE |
| Pine nuts Brand E: Dry | 2520 | 7.8 | 9.5 | 4 | 16 | 24 | 5 | 1.9 | 1 | 8** | 2 | E |
| roasted almonds | 2418 | 3.9 | 4.8 | 27 | 10 | 21.3 | 5 | 11.8 | 5 | 8 | -8 | E |
| Desiccated coconut | 2772 | 57.7 | 6.6 | 15 | 19 | 6.6 | 4 | 15.4 | 5 | 8 | 5 | E |
| Peanuts, salted, oil roasted | 2510 | 9.2 | 4.3 | 433 | 20 | 26.4 | 5 | 6 | 5 | 5 | 5 | NE |
| Peanut butter, salt & sugar added Brand F: Honey | 2526 | 7.4 | 9.8 | 319 | 19 | 26.5 | 5 | 9.8 | 5 | 5 | 4 | NE |
| roasted cashews (71% cashew) | 2230 | 6.0 | 29.5 | 11 | 17 | 12.2 | 0 | * | 4* | 2 | 13 | NE |
| Dried apricots | 1101 | 0 | 60.5 | 5 | 13 | 1.4 | 0 | 9.1 | 5 | 8 | 0 | E |
| Seedless raisins Olive, black, sweetened, pickled in brine, drained | 1259 | 0.3 | 69.1 | 58 | 13 | 2.3 | 1 | 4.9 | 5 | 8 | -1 | E |
| Beans, mixed, in brine, drained | 434 | 0.2 | 22.4 | 654 | 12 | 0.7 | 0 | 1.2 | 1 | 5 | 6 | NE |
| | 700 | 0.1 | 2.5 | 310 | 4 | 6.4 | 3 | 5.2 | 5 | 5 | -12 | E |

* fibre value not declared in the NIP, so food composition tables value assumed
E: eligible, NE: not eligible

** data from database, result assumes that no other ingredients are present

2.6 Consideration of other submitter comments

2.6.1 Eligibility of fruit juice

Some submitters expressed the view that fruit juice should not be eligible. The draft Standard attached to the Preliminary Final Assessment Report stated the following:

- *Fruits, vegetables, nuts and legumes that are fresh, cooked, frozen, preserved, pickled, pureed or dried and have undergone minimal processing (e.g. sliced, tinned, frozen, pure juices included concentrated juices and purees) can be included for the purpose of counting V points. Fruits, vegetables including potatoes and root vegetables and nuts which are whole, roasted, chopped, grated and ground can also be included for counting towards V points.*
- *Fruit and vegetables that have been subject to further processing (e.g. deionised fruit juice sugars, powders which do not meet the definition of a fruit or vegetable, protein isolates, leathers or oils) cannot be used for V points. For example, a 100% spreadable fruit jam (ingredients figs (55%), deionised grape juice, fruit pectin and lemon juice) cannot score the maximum V points, as deionised juice and fruit pectin cannot be used for V points.*

National dietary advice considers juice as fruit, although there are qualifiers. The New Zealand guidelines specify that only one serve of juice can be counted (Ministry of Health, 2003) and the [Australian Guide to Healthy Eating](#)⁴ says “choose fruit more often than juice”

Therefore, FSANZ has not removed the exception that allows fruit juice to score fruit/vegetables/nuts/legumes points and so become eligible. However the words ‘pure juices’ have been clarified to specify that only juices which meet the definition in Standard 2.6.1 – Fruit Juice and Vegetable Juice⁵ may score fruit/vegetables/nuts/legumes points. The proposed Standard in the Preliminary Final Assessment Report indicated that extracts could not score fruit/vegetables/nuts/legumes (V) points but also that pure fruit juice is exempted from this and may score as a fruit. As a result any drink containing 80% or more fruit juice becomes eligible by virtue of the five fruit/vegetables/nuts/legumes points it is able to score whereas another drink with the same sugar content but a lower percentage of fruit juice is ineligible.

2.6.2 Scoring of coconut products

The proposed Standard in the Preliminary Final Assessment Report stated the following:

‘Oils derived from fruits or vegetables (e.g. walnut oil, peanut oil)’

In addition it stated that:

⁴ <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pubhlth-strateg-food-guide-practical.htm>

⁵ **fruit juice or vegetable juice** means the liquid portion, with or without pulp, obtained from –

- (a) fruit or vegetables respectively; and
- (b) in the case of citrus fruit, other than lime, the endocarp only of the fruit;

and includes products that have been concentrated and later reconstituted with water to a concentration consistent with that of the undiluted juice from which it was made.

‘Coconut should be treated as follows:

- (i) The fresh coconut flesh should be scored as fruit;
- (ii) The water in the centre of the coconut should be scored as 100% fruit juice;
- (iii) The juice squeezed from the flesh (coconut cream) is comparable with fruit juice and should be scored as 100% fruit juice;
- (iv) Coconut milk that is coconut cream diluted with water should be scored based on dilution;
- (v) Desiccated and dried block coconut are equivalent to dried fruit and should be scored as dried fruit; and
- (vi) Coconut which is processed beyond the original product being juiced or dried cannot be used for V points (e.g. coph).

This section of the Schedule has been amended since the release of the Preliminary Final Assessment Report. It has been modified so that the flesh of a coconut is defined as a nut (which does not use the multiplier that would apply to dried fruit). As such, (v) as stated above is redundant. For consistency with the provisions in Schedule 1 of the draft Standard that state, for example, that peanut oil cannot score fruit/vegetables/nuts/legumes points (as it is an extract of the peanut), it has been decided that parts (iii) and (iv) which were adopted from the UK Profiling System should be altered. Hence coconut milk and cream will be treated as extracts of the coconut flesh, like coph, and can not score fruit/vegetable/nut/legume points, thereby making (iii) and (iv) redundant. However, in view of the unusual nature of coconut, the flesh and water from the centre are still regarded as two separate products which are eligible to score fruit/vegetable/nut/legume points.

2.6.3 Inclusion of herbs and spices in the fruit/vegetables/nuts/legumes category for scoring V points

Some submitters suggested that herbs and spices should be removed from the list of products that could score fruit/vegetables/nuts/legumes points. FSANZ notes two uses of this type of product. Firstly, they are used in very small amounts as flavouring agents. As rounding to the nearest percentage point is allowed in the ingredient list, it is unlikely that the quantity used would alter the scoring points. Secondly, some herbs are used as an important ingredient in foods such as pesto and tabouli. Basil and parsley in larger quantities would contribute the same range of nutrients as the same quantity of other green leaves. Therefore, no change has been made to fruit/vegetables/nuts/legumes category which allows herbs and spices to score fruit/vegetables/nuts/legumes points.

2.6.4 Eligibility of ‘hot’ chips

Whether a particular hot chip product is eligible or not depends on whether it is fried in saturated or unsaturated oil, the amount of fat absorbed and how much salt is added to it. Many chip manufacturers have reformulated their products extensively such that 100 g chips now has much the same profile as a boiled potato with one teaspoon of polyunsaturated margarine. FSANZ notes that one of the reasons given for having a profiling system is to encourage manufacturers to make changes to their products. Therefore FSANZ believes that a product which has made an extensive change should be assessed according to its current composition and not assessed against perceptions based on its former composition.

2.7 Submitter comments relating to application of food vehicle eligibility criteria in general

In addition to comments about the specific model proposed, submitters to the Preliminary Final Assessment Report commented in general on the inclusion of a set of generic eligibility criteria as part of the Standard. Comments in support of the approach included:

- the model is consistent with FSANZ's objectives and ministerial guidelines;
- the system incorporates 'positive' as well as 'negative' nutritional characteristics which is desirable;
- the model is a positive tool to determine whether a food is 'healthy/less healthy', which also encourages the food industry to innovate and develop 'healthier' food products along with providing a clear guide to the advertising industry, self-regulatory organisations and regulators;
- the system has strengths in terms of being consistent with the Australian Dietary Guidelines and provides provisions for core food groups; and
- the system is user friendly, with easy calculations from information that is readily available.

There were also comments opposing the approach:

- the system is too complex;
- there is no scientific basis for the model or for the approach of having a vehicle-related set of criteria. Dietary recommendations apply to whole diets and so it is incorrect to apply the recommendations to individual products;
- there is no scientific basis for compensating risk increasing components with risk-decreasing components; and
- the vehicle-related criteria should align with international criteria.

FSANZ agrees that the NPSC is more complex than the system proposed at Draft Assessment and notes the interest from some submitters in category-based systems. However, FSANZ considers that category-based systems are also complex. Category-based systems need complex definitions to delineate the categories and also have different criteria for each category. Such systems can also be 'high maintenance' in a constantly changing food supply. Therefore FSANZ believes that a system that has the least number of categories is more manageable, and more in keeping with the Policy Guideline which states the regulatory approach should *allow for effective monitoring and appropriate enforcement*, than is a category based system.

FSANZ notes that the Policy Guideline also states that the regulatory approach should *be consistent with and complement Australian and New Zealand national policies and legislation including those relating to nutrition...* The Policy Guideline includes the concept of 'disqualifying criteria' and since individual products carry health claims, it is reasonable to apply vehicle related criteria at the individual product level where these criteria draw on nutrition related national policy and guidelines.

The Policy Guideline states that claims can be made providing *the claim is socially responsible and does not promote irresponsible food consumption patterns*.

FSANZ believes that this principle means that the focus for vehicle related criteria should be on affecting chronic disease and therefore believes that placing the emphasis of the vehicle-related system on energy, saturated fat, sugar and sodium is appropriate. FSANZ also notes that the modifying points use various surrogates to take a range of micronutrients into account to some extent.

To date there has been no evaluation of the impact on consumer dietary intake of currently used logos such as the National Heart Foundation Tick. Therefore the choice of a model cannot be based on this important outcome. In the absence of such substantive science, FSANZ notes that the model it has adopted draws on national dietary guidelines. As described in the Preliminary Final Assessment Report, the quantitative amounts in the steps of the model are also underpinned by dietary recommendations very similar to those used in Australia and New Zealand.

FSANZ notes that there are different systems in each of the US and Canada and that work on defining vehicle-related criteria has only recently commenced in Europe. Therefore, there is no single system to align to, and emerging approaches and their effectiveness will only be tested through time and application.

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

As a result of the examination of various modifications to the NPSC as presented in the previous sections, FSANZ recommends the following four key changes to the NPSC that was presented in the Preliminary Final Assessment Report:

- the first step for total sugars in the baseline table be changed from ≤ 4.5 to ≤ 5.0 ;
- milk is deleted from Category 2 and placed in Category 1 with the other beverages;
- the tipping point at which protein can be counted even if the product does not score 5 for fruit/vegetable/nut/legume content is raised from < 11 baseline points to < 13 baseline points; and
- the scoring range for fruit/vegetable/nut/legume content is extended to 8 points for foods that are 100% fruit/vegetable/nut/legume.

2.9 Rationale for final decision

The rationale for the first two changes is inter-linked. The reason for changing the original UK Profiling System and creating a definition for milk to fall into Category 2, was that the cutpoint between the two lowest sugar steps was very close to the average lactose content of whole milk and so some milks scored 0 sugar points and some 1 point. This was exacerbated by the decision to score products per 100 ml if their nutrition information panels were expressed on this basis and the extra point was enough to make them ineligible. As described in the original UK documents, total sugars were used in the baseline points table, rather than non-milk extrinsic sugars, because total sugars are measurable and the modifying points were used to account for the lactose content of milk and the intrinsic sugar in fruit.

The definition of milk that applied when milk was placed in Category 2, is such that if a milk product has, for example, omega-3 added to it, then it no longer met the definition of milk under Category 2 and became a Category 1 product. By raising the cutpoint between the first and second step to ≤ 5.0 , whole milks generally score 0 sugar points.

This means that most whole milks become eligible. The exceptions are a small number of higher fat milks and some milk products manufactured by concentrating lower fat milks. Milks with less protein than usual may not score enough modifying points to become eligible. Thus changing the step for sugar means that:

- instead of expanding the definition to allow milks with added substances to be classed as category 2, milk can be returned to category 1 (beverages);
- the milks which are ineligible are a small proportion of those with higher saturated fat as well as lactose; and
- reducing the number of variations to the system should make it easier to implement the system and will help reduce requests for exemptions.

The third change, raising the ‘tipping point’ for protein to <13 baseline points, was suggested by a submitter specifically to allow some additional breakfast cereals to become eligible. Several other modifications to increase the number of eligible breakfast cereals were also suggested by various submitters such as allowing for small serving sizes and increasing the number of points for dried fruit or fibre. There were similarities and differences in the range of additional eligible products that these various modifications yielded. Changing the tipping point had the advantage that left the focus of the system on the baseline components and caused least change in the system. Although breakfast cereal is the type of product most advantaged by this modification, some other products also benefit (a small number of breakfast bars and some of the lower fat/sodium crackers) It should be remembered that breakfast cereals are a low moisture food, compared to bread for example, and so score more energy points per 100 g because of this. Therefore this alteration somewhat offsets the extra energy points they score resulting from their low moisture. The additional points allow some products with unusually high amounts of dried fruit to become eligible (e.g. bread with higher amounts of dried fruit).

The fourth change is to extend the scoring range for fruit/vegetable/nut/legume content for foods that are 100% fruit/vegetable/nut/legume. This change was suggested by a submitter to allow all raw or fresh nuts to become eligible. FSANZ modelled various extensions of the scoring range and it was concluded that by extending the points to 8 for 100% fruit/vegetable/nut/legume content, such foods would be eligible to carry a health claim. FSANZ considers that this approach brings consistency to the application of the nutrient profiling scoring criteria for products which are 100% fruit/vegetable/nut/legume content.

In the NPSC presented in the Preliminary Final Assessment Report, foods that scored 11 (now increased to 13) or more baseline points could only score protein (P) points if they scored the ‘maximum’ fruits/vegetables/nuts/legumes points (which was 5 points). As a result of extending the maximum fruits/vegetables/nuts/legumes points from 5 points to 8, the requirement to score the ‘maximum’ points has been amended so that foods that score 13 or more baseline points are still required to score at least 5 fruits/vegetables/nuts/legumes points rather than the ‘maximum’ points, in order to also score protein points.

2.10 Overall conclusions

FSANZ recognises there are highly diverse views as to whether food eligibility criteria should be applied at all, and if so, which foods should be ‘in’ or ‘out’. We also acknowledge that diets are made up of a variety of foods and no one food can be considered as ‘good or ‘bad’.

However, health claims are made on single foods and it is FSANZ's view they must therefore be reflective of the suitability of that food for healthier dietary choices. The line drawn between the foods that are eligible or not is inevitably arbitrary to some extent due to the complexity and changing nature of the food supply, and individuals and organisations widely differing and subjective views as to what constitutes a 'healthy' food. FSANZ has taken many factors and many view points into account to arrive at scheme of best fit that is transparent, and objectively as possible considers the policy guidelines, national dietary guidance, and the practical implications of implementation and enforcement.

FSANZ recognises that some specific foods with small serve sizes, e.g. yeast extracts, honey, may be disadvantaged by the per 100 g approach and as such not be eligible under the approach proposed. If manufacturers of individual foods which are ineligible but are consumed in small quantities can demonstrate that the foods offer net health benefits, then this could be considered on a case-by-case basis as part of the usual application process.

In summary, the approach being proposed is that presented in the Preliminary Final Assessment Report, with small but meaningful changes to the scoring approaches for sugars and protein, and the re-categorisation of milk to 'beverages'. These changes have been made in order to fine-tune the impacts of the cut-off scores on certain foods from a public health perspective.

FSANZ notes that there has been interest from others regarding whether the NPSC can be used for other purposes. The original UK system is used to assess foods for an advertising purpose. FSANZ tested the system extensively and then modified it to suit the current purpose. It is noted that the NPSC is only half of the criteria that a food product must meet before the label can carry a health claim. The other half of the system is the qualifying criteria. Not all foods which are eligible under the NPSC would be able to meet a qualifying criterion and carry a health claim. Those who seek to extend the use of the NPSC to other arenas would have to assess for themselves whether the NPSC can function as a stand-alone criterion for other purposes.

3. Exemptions from Nutrient Profiling Scoring Criteria

3.1 Decision

FSANZ recommends that:

- the nutrient profiling scoring criteria will not apply to general level health claims about gluten and lactose; and
- foods standardised under Part 2.9 – Special Purpose Foods that carry general level and high level health claims will not be required to meet the nutrient profiling scoring criteria.

These exemptions are provided in paragraph 6(1)(a) of the draft Standard.

3.2 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report the exemption from the nutrient profiling scoring criteria (referred to then as disqualifying criteria) for general level health claims about gluten and lactose was proposed.

Foods carrying claims about vitamins and minerals were also proposed to be exempt from the nutrient profiling scoring criteria, however, the food had to meet the definition of a 'claimable food'. The only foods exempt from the nutrient profiling scoring criteria in Part 2.9 of the Code were those standardised under Standard 2.9.2 – Foods for Infants. As the draft Standard does not apply to foods standardised under Standard 2.9.1 – Infant Formula Products, specific exemption for these foods was not necessary.

There was very little specific comment from submitters; however, a small number of submitters expressed agreement with the intended approach. Other submitters made comments in relation to the eligibility of formulated supplementary foods to make claims because they did not meet the disqualifying criteria (now referred to as nutrient profiling scoring criteria). It was suggested that these foods be exempt from the disqualifying criteria because they require specific energy levels and hence the deliberate addition of sugars and fats.

There were no amendments to the proposed exemptions in the Preliminary Final Assessment Report and no additional submitter comments

Since the release of the Draft Assessment and Preliminary Final Assessment Reports, FSANZ has decided to exempt foods standardised under Standards 2.9.3 and 2.9.4 from the nutrient profiling scoring criteria, in addition to foods for infants which were already exempt.

3.3 Further consultation – approach taken and submitter comments

Subsequent to the Preliminary Final Assessment Report, FSANZ considered that the 'claimable food' approach for claims about vitamins and minerals could be reviewed under Proposal P293, rather than in a proposal that would consider the 2006 nutrient reference values for the Code.

The application of different food vehicle eligibility criteria for health claims about vitamins and minerals, and health claims about other nutrients ('claimable food' criteria and nutrient profiling scoring criteria, respectively), would result in some foods being eligible to carry a health claim about a vitamin or mineral but not about another nutrient, or vice versa.

In the Consultation Paper, FSANZ proposed three options for the food vehicle eligibility criteria for nutrition content claims and general level health claims about vitamins and minerals. These options were:

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 that ‘claimable food’ criteria be removed for foods carrying nutrition content claims and general level health claims about vitamins and minerals (Option 3) and that foods carrying general level health claims about vitamins and minerals would no longer be exempt from nutrient profiling scoring criteria.

Overall, submissions 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. 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, the majority 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. Option 2 was supported by one submitter who suggested additional measures to strengthen the approach, for example mandatory balanced diet statements whenever health claims are made.

A number of industry submitters provided an alternative option (Option 3a only) which supported the removal of claimable foods but opposed general level health claims about vitamins and minerals being subject to nutrient profiling scoring criteria. The rationale underpinning this view was that:

- the Scientific Substantiation Framework provides adequate protection for the consumer;
- it would limit industry innovation;
- it would reduce the vitamin and mineral intake of the population, as industry would decide not to fortify if they could not make a claim; and
- it would be illogical to propose that certain foods may be ‘claimable foods’, yet they would be prevented from providing structure-function statements that inform the consumer of the benefit of the nutrient concerned simply because the food does not meet nutrient profiling scoring criteria.

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. It was also considered that Option 3 is not consistent with the intent of Standard 1.3.2 or with the intent of the Policy Guideline.

3.4 Rationale for final decision

A system of nutrient profiling, referred to as ‘nutrient profiling scoring criteria’ has been developed to determine the eligibility of foods for making health claims according to their nutrient profile (refer to Chapter 2 of this Attachment for further information). The nutrient profiling scoring criteria will apply generally to most foods carrying health claims, however some specific exemptions are recommended.

Foods standardised under Standards 2.9.2, 2.9.3 and 2.9.4 carrying general level and high level health claims will be specifically exempted from the nutrient profiling scoring criteria. The rationale for this is that these foods are specially formulated for specific dietary purposes, for the specific needs of infants, a supplement to the normal diet, or to aid with sports performance, respectively. Foods standardised under Standards 2.9.2, 2.9.3 and, depending on the claim(s) made, Standard 2.9.4, must meet certain compositional requirements prescribed under the Part 2.9 standards. For example, maximum levels for the sodium content of foods for infants are prescribed, and formulated supplementary foods must meet certain energy requirements. It is not considered appropriate for these foods to also meet the nutrient profiling scoring criteria that have been developed for general purpose foods.

FSANZ recommends that the nutrient profiling scoring criteria will also not apply to general level health claims that refer to gluten or lactose. This is because consumers who rely on these products should be able to choose from a full range of suitable products (based on the need to avoid undesirable reactions to gluten/lactose) rather than being restricted to choosing from only those that meet nutritional criteria based on different and additional objectives (i.e. the 'healthy' diet). It is therefore important that messages on *low lactose*, *lactose free*, *gluten free* or *low gluten* foods aimed at people who are required to restrict their intake of lactose or gluten are not restricted by the generic nutrient profiling scoring criteria applicable to general level health claims about other properties of the food. It should be noted that if a food carries a health claim about gluten or lactose and also about another property, e.g. fat, the food would need to meet the nutrient profiling scoring criteria.

At the time of developing the concept of 'claimable foods', FSANZ devised the 'claimable food' definition to act as a criterion that ensured claims made in relation to vitamins and minerals were placed only on foods that were given related permissions to fortify; or in the case of naturally occurring vitamins and minerals that met qualifying levels and were limited to foods broadly consistent with healthy eating guidelines. Therefore the 'claimable food' definition has served as a food vehicle eligibility criterion, as does the generic nutrient profiling scoring system that has been developed for general level health claims.

FSANZ now recommends that 'claimable food' criteria be removed and foods with general level health claims about vitamins and minerals will now be subject to nutrient profiling scoring criteria. An advantage of this approach will be greater consistency in the regulation of all general level health claims about different nutrients. A consistent approach will be less confusing for industry, consumers and enforcement agencies.

The Consultation Paper included a comparison of foods that would be eligible to make general level health claims under 'claimable food' criteria with foods eligible through the application of nutrient profiling scoring criteria. Eligibility was assessed using food products from a database of more than 10,000 foods. It was reported by FSANZ that the nutrient profiling scoring criteria are more effective at restricting health claims to foods consistent with dietary guidelines and more consistent with the Policy Guideline, than the 'claimable food criteria'. Health claims are therefore being more logically presented on 'healthier foods'.

In response to a submitter comment, mandatory balanced diet statements are already a requirement for health claims. General level and high level health claims must be made in the context of a healthy diet consisting of a variety of foods as appropriate to the type of food and specific health effect claimed. This must be expressly stated as part of the claim.

FSANZ has found no evidence for treating general level health claims about vitamins and minerals differently to other nutrients, and considers a consistent approach to be more logical and pragmatic. Generic claim conditions will now be the same across all nutrients, including wording conditions, substantiation requirements and food vehicle eligibility criteria. It is recognised that some foods will be able to be fortified but not be eligible to carry a general level health claim under the nutrient profiling scoring criteria. These foods will, however, still be able to carry nutrition content claims and as health claims have not been expressly permitted to date, this change should not impact negatively to any great extent.

4. Conditions around presentation and wording of general and high level health claims

4.1 Introduction

The following sections relating to wording conditions, advisory or warning statements, positioning of claim elements and small packages have been written in the context of general level health claims. However, the application of the principles discussed to high level health claims is determined on a case-by-case basis. Attachment 7 of this Report identifies the particular criteria and conditions relating to the high level health claims that have already been pre-approved by FSANZ.

Nutrition content claims state only the presence or absence of the ‘property of the food’, and, where applicable, need to meet any compositional criteria for use of descriptor terms such as *low* or *high* etc. Once a health effect is also stated, the claim becomes a general level or high level health claim, and depending on the nature of the stated health effect, will need to meet further requirements, as outlined below.

4.2 Wording conditions for general level health claims

4.2.1 Decision

FSANZ recommends that general level health claims must state:

- the property of the food⁶;
- the specific health effect claimed in relation to that property of the food;
- the specific population group, where the evidence used to substantiate the claim indicates that the health effect cannot be attributed to the general population but to specific population groups only; and
- that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods. The actual wording of the healthy diet context must be appropriate to the type of food bearing the claim, the property of the food and the specific health effect claimed.

⁶ Where ‘property of the food’ means any of the following that is associated with a nutrition or health purpose, -

- (a) energy, a nutrient, or a biologically active substance; or –
- (b) a component, ingredient; or any other feature or constituent of the food; or
- (c) glycemic index.

If the substantiation for the health claim can only be based on the food itself rather than the property of the food, then the claim must state that food and the specific health effect in relation to that food (refer to Chapter 9 of this Attachment, for more information).

For general level health claims these conditions are prescribed in clause 6 of the proposed Standard.

4.2.2 *Draft Assessment Report – approach taken and submitter comments*

The general approach recommended in the Draft Assessment Report has been retained.

In response to the Draft Assessment Report there was opposition by one industry submitter to the requirement to state the specific health effect. Their concern was that this prohibits the claim ‘red meat for wellbeing’ which has been scientifically proven and used since 2002.

Although some submitters noted support of the requirement to express health claims in terms of a varied and healthy diet, there were a number of concerns, mainly from industry submitters, with this approach. Specific comments included that:

- it is restrictive, unnecessary and ineffective or confusing for consumers;
- overseas research does not support a skew in consumption as a result of claims;
- it will not resolve the problem of unbalanced dietary habits;
- FSANZ have not demonstrated harm with the current system or that consumers will be better informed with additional information;
- the role of the specific nutrient still occurs irrespective of what else is consumed;
- stating ‘variety of foods’ is untrue in terms of the health effect and it forces the provision of dietary advice unrelated to the product; and
- the word ‘nutritious’ should be required with respect to variety of foods, to reflect dietary guidelines and because ‘variety’ could mean a variety of confectionary etc.

It was queried whether the reference to the wording condition about the appropriate total diet in the Policy Guideline should apply to general level health claims or just to high level health claims.

One submitter suggested that the requirement to state a ‘healthy diet’ is inconsistent with Standard 1.1A.2 (which prohibits the word health or similar, on a label as a part of or in conjunction with, the name of the food).

It was questioned whether consumers understand ‘varied and healthy diet’, and it was suggested that ‘diet’ may be misinterpreted as meaning to restrict food intake, and that it needs to be clear whether ‘diet’ refers to a balanced diet or modified diet with fortified or specific foods.

4.2.3 *Preliminary Final Assessment Report – approach taken and submitter comments*

Although the general approach for the wording of general level health claims remained the same as that proposed in the Draft Assessment Report, in the Preliminary Final Assessment Report (Section 9) FSANZ recommended a simplification to the drafting to clarify that it was not a requirement (but is optional) to include in the health claim a descriptor (such as *good source*) to describe the level of the property of the food that is the subject of the claim. There were no comments received from submitters in relation to this.

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

The drafting of the proposed Standard was amended following the release of the Preliminary Final Assessment Report to reflect the intent that the dietary context statement must be appropriate to the property of the food that is the subject of the claim, in addition to being appropriate to the food carrying the claim and the claimed health effect.

4.2.5 Rationale for final decision

4.2.5.1 Property of the food and specific health effect

Certain wording conditions have been developed to form the mandatory elements of health claims. These are the requirements to explicitly state the specific health effect and the property of the food that attributes that health effect. These wording conditions have been determined as a strategy to minimise the use of implied health claims.

The requirement for the claim to refer to the specific health effect is supported by the Policy Guideline which states that *claims must communicate a specific rather than broad benefit*. FSANZ interpretation of this principle is that general wellbeing claims and general performance claims e.g. *has a positive effect on wellbeing*, should not be permitted (unless a related health claim with a specific health effect is present). The requirement for the claim to expressly state the specific health effect, and the definition of health effect itself, will prohibit the use of such claims.

Rather than referring to the terminology used in the Policy Guideline (i.e. *specific benefit*) the proposed Standard will refer to the *specific health effect* as this will align with the definition of health effect that is included in the proposed Standard. As per the definition of health effect, the wording of the claim must include reference to an effect, such as *reduce the risk of* or *improves, maintains, enhances etc.*

The wording pre-requisites, including reference to a specific health effect rather than a broad or non-specific benefit, are required in order to provide consumers with adequate information about the claim and to assist in preventing misleading or deceptive claims, including implied claims.

4.2.5.2 Healthy diet context statement

The recommended approach, that the claim must state that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods, is supported by the Policy Guideline which states that *claims.....may only be made in the context of the appropriate total diet (that must be described)*. The Policy Guideline also provides further support for the inclusion of a requirement relating to a healthy and varied diet. It states that *claims about a food or component can describe a health benefit for the population but must not:*

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

FSANZ has interpreted the reference to the *context of the appropriate total diet* in the Policy Guideline as meaning that the claim should communicate that the specific health effect is achieved from consuming a healthy diet that has adequate amounts (or low amounts in the case of risk increasing nutrients) of the claimed nutrient or property of the food from a variety of foods, so that consumers do not perceive that the claimed food alone will provide the specific health effect.

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

FSANZ's (2005a) qualitative consumer research also provides evidence to suggest that the term *total diet*, as referred to in the Policy Guideline, is not well understood by consumers. The drafting of the Standard therefore includes reference to a 'variety of foods' and 'healthy diet' to ensure terminology to this effect is used in the wording of health claims, instead of 'total diet'.

As the substantiation requirements for general level health claims are based on the total diet-health relationship, it is also important to emphasise this relationship in the claim. For example, if a supplier makes a claim about strong bones and teeth (specific health effect) and calcium (property of the food related to the specific health effect), the claim could be worded in the following way to convey the total diet context:

A healthy diet including a variety of foods rich in calcium helps to achieve strong bones and teeth. Milk is a good source of calcium.

As the phrase *variety of foods* is to be presented within the context of a healthy diet, FSANZ considers that *nutritious foods* is implied and use of the word nutritious, as suggested by a submitter, is optional rather than mandatory in the interests of not being overly prescriptive.

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

- the food bearing the claim is for a specific population group whose diet does not normally consist of a wide variety of foods, for example, infants;
- the property of the food that is the subject of the claim is not widely available in the food supply, for instance, some biologically active substances may not be naturally occurring in a variety of foods (further information on the regulation of health claims about biologically active substances is discussed in Chapter 5 of this Attachment); or
- the claim relates to a dietary interaction such as *A good source of vitamin C. Vitamin C increases the absorption of iron from the diet.* Consumption of Vitamin C is only going to assist in the absorption of iron from the diet, if foods containing iron are consumed.

This aspect is addressed in the drafting by requiring that dietary context statements be appropriate to the type of food and specific health effect claimed.

For instance, including age appropriate statements may satisfy the healthy diet context requirement where claims are made in relation to infant foods. e.g....*when consumed as part of a varied and healthy diet appropriate for children under two years*. This helps to address the submitter comment that the wording of the claim needs to be clear as to whether the ‘diet’ is a balanced or modified diet.

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

In the case of dietary interaction claims, it may be appropriate for the statement to be modified. For the claim example *A good source of vitamin C. Vitamin C increases the absorption of iron from the diet*, the healthy diet statement could be worded *when consumed as part of a healthy diet involving the consumption of a variety of foods, including iron rich foods such as red meat [etc]*.

The prohibition of the use of the word *health* in the name or in conjunction with the name of the food under Standard 1.1A.2, has a different context and rationale than the use of the term *healthy diet* in the proposed Standard. In Standard 1.1A.2 the intent is to reduce the risk of consumers being misled into believing that an individual food is healthy in its own right. In the proposed Standard the reference to *healthy* is in relation to the whole diet, so that consumers interpret the claim in the context of the whole diet rather than relying purely on the food carrying the claim to deliver the claimed health effect.

The requirement for claims to be made in the context of a healthy diet also assists in differentiating claims in relation to food from claims in relation to therapeutic goods. This is because claims in relation to therapeutic goods are generally framed without reference to diet, as a therapeutic good has an impact in and of itself. In contrast, foods can only have a sustained health effect when supported by an appropriate diet.

International regulations highlight the necessity of ensuring that claims are expressed in terms of the total diet context and have worked this concept into regulation in various ways. Refer to Attachment 12 for further detail.

4.2.5.3 Population subgroup

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

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

The recommended approach maintains effective minimal regulation by requiring additional wording in the claim in relation to the population subgroup only when indicated by the evidence used to substantiate the claim.

The proposed approach can be demonstrated using the hypothetical claim example *A healthy diet consisting of a variety of foods rich in calcium helps to achieve strong bones and teeth. Milk is a good source of calcium.* If the evidence supported that the consumption of a calcium rich diet provided the benefit of strong bones and teeth to children and adolescents only, this must be communicated as part of the claim. Therefore the claim would be worded as follows: *A healthy diet consisting of a variety of foods rich in calcium helps to achieve strong bones and teeth in children and adolescents. Milk is a good source of calcium.*

4.3 Advisory or Warning Statements

4.3.1 Decision

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|---|
| FSANZ has not recommended any specific requirements for advisory or warning statements in draft Standard 1.2.7. |
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4.3.2 Draft Assessment Report – approach taken and submitter comments

No advisory or warning statements were recommended in relation to the proposed Standard in the Draft Assessment Report. No submitter comments were received in response.

4.3.3 Rationale for final decision

The Policy Guideline states that, *where advisory or warning statements in relation to the claim are required, they must appear in close proximity to the claim in the same communication medium.*

Warning or advisory statements in addition to those currently required under the Code have not been considered necessary in relation to any of the claims possible under the proposed Standard. Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations currently has requirements for specific warning and advisory statements to be on the labels of certain foods or foods containing certain ingredients, for example bee pollen, guarana, and propolis. Another example is foods containing added phytosterol esters and foods containing added tall oil phytosterols, which require advisory statements indicating that:

- the product should be consumed as part of a healthy diet;
- the product may not be suitable for children under the age of five years and pregnant or lactating women; and
- plant sterols do not provide additional benefits when consumed in excess of three grams per day.

If other warning or advisory statements are determined to be required in relation to the proposed Standard in the future, the Policy Guideline recommendation outlined above would be taken into account when considering the specific requirements for such statements.

4.4 Positioning of Claim Elements (split claims)

4.4.1 Decision

FSANZ recommends that:

- there is an option to shorten the wording of health claims by stating the property of the food and the health effect only, providing the health claim in its entirety is stated elsewhere on the label of the package or in the advertisement;
- an additional directive statement is required in conjunction with the shortened health claim, to direct consumers to the health claim in its entirety; and
- the directive statement is not required if the property of the food (as a nutrition content claim) is stated separately and in addition to the health claim in its entirety.

These requirements are outlined in the draft Standard in paragraph 6(1)(f) and subclause 6(2) for general level health claims and paragraph 7(1)(d) and subclause 7(2) for high level health claims.

4.4.2 Draft Assessment Report – approach taken and submitter comments

The approach in the Draft Assessment Report was similar to that recommended in this Report, except that the directive statement was also required on a label when the property of the food was presented separately to the health claim.

Some submitters to the Draft Assessment Report were in support of allowing part of the claim to be presented separately however, there were also some objections to this approach in terms of potential misinterpretation of the claim by consumers. Conversely, other submitters did not agree with the requirement for the entire claim to be presented in one place. There were some objections to the requirement to include a directive statement indicating where the complete claim is, as it is cumbersome and unnecessary. It was suggested that the requirement for all of the elements of the claim to be ‘in the one place’ was open to interpretation and could be taken to mean that the claim only had to be located on the label, but not necessarily in the one place on the label.

4.4.3 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report, the requirement for the directive statement when the property of the food is presented separately (as a nutrition content claim) from the health claim was removed.

The drafting was also clarified with respect to the meaning of ‘in one place’ in terms of the positioning of the claim elements, by the addition of the words ‘on the label’ (see Section 9 of the Preliminary Final Assessment Report).

There were no new comments received from submitters in relation to positioning of the health claim elements, in response to these amendments.

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

The requirement that all of the elements of the claim are located in the one place *on the label* has been amended to read *the entire claim is presented together*. This is because the proposed Standard applies to health claims that appear on advertisements in addition to those on food labels. The conditions should be applied equally across both, hence labels should not be singled out in these clauses.

4.4.5 Rationale for final decision

The property of the food, the specific health effect and the healthy diet context are considered to be essential elements of the claim that must always be presented together in order to assist consumers to make an informed choice. Furthermore, there may be additional wording conditions (on a case-by case basis) such as the requirement to communicate that the specific health effect only relates to certain population groups. The intended context of the claim may be lost if these essential elements are permitted to be separated.

However, if all these elements are presented together, the claim may mean the total message becomes long and wordy. The food industry has emphasised to FSANZ the importance that claims be succinct, user friendly and flexible. In order to allow flexibility for the wording and positioning of claims, it is recommended that the property of the food and the specific health effect can be presented together but separately from the entire health claim, as long as there is a statement that directs the consumer to the health claim in its entirety.

FSANZ have attempted to strike a balance between ensuring the full context of the claim is provided, and that the information has an effective impact for consumers. Whilst it is considered that the essential elements of the claim should always be stated together, the recommended approach allows the provision of information in a location on the package that is separate to the claim in its entirety. These claim elements would be accompanied by an additional statement to direct the consumer to the health claim in its entirety, such as *see back of pack*. This directive statement would need to be positioned near the claim elements in order for it to be noticed by the consumer however, there is flexibility as to the wording and format of the statement. As the wording of this directive statement is not prescribed, the user guide will provide examples of suitable additional statements.

The recommended approach applies to both high level and general level health claims and is provided to allow succinct claim statements on the main panel of a package, such as *rich in calcium for strong bones and teeth*.

The directive statement is not required when the property of the food is presented separately from the health claim. This is because it was considered unnecessary and inconsistent with the regulation of nutrition content claims, when the property of the food (as a nutrition content claim) is stated in isolation from a health claim. For example, if *good source of calcium* is stated on the front of the label and a health claim about calcium is stated in full on the back of the label, then the directive statement is not required. This helps to address submitters concerns around ‘unnecessary text’.

FSANZ considers that if a number of claims are made on the label of a package or in an advertisement, the healthy diet context could be stated only once, as long as it was appropriate to all the health claims and made clear to the consumer that the healthy diet context applied to each claim. This will be further explained in an interpretive user guide.

Several consumer research studies support this approach. Research studies suggest that shorter claims are preferred and are more effective than longer claims (Levy, 1995; Levy *et al.*, 1997; National Consumer Council, 1997; Paul *et al.*, 1999).

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

4.5 Small Packages

4.5.1 Decision

Nutrition content claims

Small packages⁷ are exempt from:

- including a full nutrition information panel (this is the status quo, and is currently regulated by clause 8 in Standard 1.2.8); and

Small packages are required to declare:

- the amount of the claimed nutrient/energy/biologically active substance and, depending on the claim, other specific nutrients, per serving;
- the serving size in g or ml;
- the percentage of the RDI per serve of any claimed vitamin or mineral;
- the source and amount per serving of omega 3 fatty acids when claims regarding omega 3 are made;
- potassium content when a claim about salt or sodium is made;
- sodium content when a claim about potassium is made;
- galactose content if a claim about lactose is made; and
- for comparative claims, the reference food and difference in claimed nutrient.

Health claims

Small packages are exempt from providing:

- the additional statement about regular exercise for weight management claims;
- the 'dietary context' information for health claims; and
- the information required relating to nutrient profiling scoring criteria, i.e. percentage of fruit etc, dietary fibre content, calcium content of cheese.

⁷ *Small packages* are defined in the Code as a package with a surface area of less than 100 cm².

Small packages are required to declare:

- any applicable requirements for the associated nutrition content claim (as outlined above);
- the appropriate population group, if applicable;
- the substantiated daily amount to achieve the health effect for claims in relation to biologically active substances; and
- the required disclaimer for cause-related marketing statements.

If applicable, the health claim may be split, but the statement indicating where the complete health claim is located must be on the label.

Any advertising material associated with the food in a small package must comply with all of the requirements for advertising associated with normal sized packages.

If %DI is declared on a small package, this must be carried out according to amended clause 7 of Standard 1.2.8.

Clause 8 of amended Standard 1.2.8 sets out the requirements for nutrition information when nutrition content claims and health claims are made on a food contained in a small package.

Clause 10 of the draft Standard sets out the exemptions for small packages from certain labelling requirements when claims are made on a food contained in a small package. All requirements in Standard 1.2.7 that are not listed in clause 10, apply to food in small packages that carry nutrition content claims or health claims (except those overridden by clause 8 of Standard 1.2.8).

4.5.2 Amendments to current standards/CoPoNC recommendations

The approach recommended above is similar to the current approach in the Code for the labelling of small packages. Currently in the Code, small packages are exempt from certain labelling requirements, including the requirement for a nutrition information panel, a statement of ingredients, and characterising ingredient declarations. Under present conditions in the Code, when nutrition content claims are made on a small package, the average quantity of the claimed nutrient or biologically active substance per 100 grams or 100 millilitres must be declared on the label. The main difference from the current approach is therefore that nutrients must instead be declared on a per serve basis.

4.5.3 Draft Assessment Report – approach taken and submitter comments

Special consideration was given to the labelling requirements for small packages at Draft Assessment. Due to limited labelling space on small packages it was proposed that in this special case exemptions from some of the labelling requirements in draft Standard 1.2.7 would be appropriate. There were specific exemptions from:

- the requirement to identify the reference food where a comparative nutrition content claim was made;
- mentioning the population sub-groups to which the health effect relates; and
- providing the healthy diet context for a health claim.

There was some lack of clarity in the drafting around whether small packages were exempt from other labelling requirements, such as the declaration of potassium when a sodium claim is made, the disclaimer for cause-related marketing statements and the %RDI declaration when a vitamin or mineral claim is made.

Some submitters supported the lessening of information requirements for small packages when claims are made whereas others felt that food in small packages should not be given further exemptions from labelling requirements.

Specific comments with regard to small packages were:

- if room is ‘found’ for health claims then other existing statutory requirements should have been given preference;
- legibility issues could be a problem where claims are made, with the more complex the claim, the more space it will take up on small packages; and
- small packages should not have wording exemptions as they are able to provide additional information in the form of a fold out label or shelf information.

4.5.4 Preliminary Final Assessment Report – approach taken and submitter comments

After the release of the Draft Assessment Report it was noted that the drafting of the clause relating to small packages in draft Standard 1.2.7 was inaccurate. After analysing the submitter comments above and taking into account the mistakes in the drafting, we completely reviewed the approach for small packages in terms of labelling requirements for small packages when nutrition content claims and health claims are made. The revised approach was provided for consultation in the Preliminary Final Assessment Report.

In the Preliminary Final Assessment Report, the exemptions for small packages carrying nutrition content claims or health claims were revised to ensure that the adequate information is required to be provided to consumers on the label of a small package carrying a claim, particularly in terms of public health risks. Consistency with the current provisions in the Code was also considered in this review.

As a result of this review, it was decided that small packages should not be exempt from the requirement to identify the reference food where a comparative nutrition content claim was made or from mentioning the population sub-groups to which the health effect relates, if applicable, as these labelling requirements provide the necessary context to the claim in order for it to be informative and not misleading to consumers. An additional exemption was provided from the requirement to state the regular exercise statement as part of a weight management claim, which provides consistency with the exemption from stating the healthy diet context for a health claim. The drafting was clarified in terms of the requirement to declare certain nutrients when some nutrition content claims are made, for example, when a claim about lactose is made on a small package, the galactose content should be declared.

Support for the proposed approach was expressed by some industry and government submitters. Other submitters did not support any labelling exemptions for small packages, for similar reasons to those expressed in response to the Draft Assessment Report.

4.5.5 *Key changes from proposed approach in the Preliminary Final Assessment Report*

These divergent submitter views were considered however, we have chosen to retain the same approach in terms of exemptions from certain labelling requirements for small packages. However, since the Preliminary Final Assessment Report was released, the conditions for declaring the claimed nutrient or biologically active substance have been amended, such that instead of this declaration being on a per 100 gram or 100 millilitre basis, the declaration is on a per serving basis, and the serving size in grams or millilitres is also declared on the label.

Another amendment is that the percentage of the RDI of claimed vitamins and minerals must also be declared on the label of a small package.

4.5.6 *Rationale for final decision*

The rationale for the specific requirements for labelling on small packages carrying nutrition content claims and health claims provides information to consumers particularly where public health risks associated with certain claims have been identified e.g. for the requirement to declare potassium when a claim about sodium content is made due to implications for dietetic management. When deemed necessary, information is also required to be provided in order for the claim not to mislead or be deceptive, for example, statement of reference food and the difference in claimed nutrient for comparative claims. The requirements also provide consistency with current provisions in the Code, for example, the source of the omega-3 fatty acids is currently required to be declared on small packages by clause 8 in Standard 1.2.8.

Given that the substantiation for certain health claims may only apply to certain groups of the population, it is considered that the population group must be specified as part of the claim, if applicable, and that this requirement should be extended to small packages.

FSANZ's (2005b) quantitative consumer research investigated perceived health benefits communicated by the cause-related marketing statement '*Proceeds from this product will go to the Royal Society for Diabetes*'. The results indicated that respondents were significantly more likely to feel that a product with a cause-related marketing statement was more beneficial to health than a product with no claim. FSANZ considers that this result supports the use of a disclaiming statement in conjunction with a cause related marketing statement on all food packages and cannot justify an exemption from this requirement based on the size of the package.

Furthermore, the exact wording of statements such as the cause-related marketing disclaimer and the comparative claims declarations is not prescribed. This gives industry the option to develop short statements that will fit legibly on the labels of small packages, whilst fulfilling labelling requirements.

The longer health claim statements relating to the dietary context statement that may be difficult to fit onto small packages are not required, unless they relate to specific public health risks.

Requiring the declaration of the nutrients on a per serve basis provides more relevant and useful information to the consumer, particularly for small packages where the servings are considerably less than 100 g or 100 ml and/or the package contains more than one serving, for example, chewing gum.

This requirement, combined with the declaration of the serving size in grams or millilitres allows for calculations to be made to determine compliance of the food with qualifying criteria that are on a 100 g or 100 ml basis.

The rationale for requiring the declaration of %RDI of a claimed vitamin or mineral is that, for consumers who are not familiar with the recommended intakes for vitamins and minerals, a statement of the content of the vitamin or mineral alone will not have much meaning, especially given that vitamin and mineral content is normally provided in amounts that consumers are not familiar with (mg or µg). Therefore the requirement for the %RDI declaration gives further context and meaning to the claim.

If %DI values are declared on the label of a small package, in order to ensure that the relevant information is provided (serving size and the 8700 kJ statement) in a consistent manner with that on other packages, it is considered that the general requirements applying to %DI labelling should also apply to small packages.

It is outside the scope of Proposal P293 to consider the other mandatory labelling requirements of the Code (for example, ingredient lists) on a small package when space is found for a health claim, or to prescribe the use of a fold out label or shelf information as suggested by some submitters, as these recommendations relate to a broader set of labelling requirements than just those associated with nutrition, health and related claims.

PART 2 – ADDITIONAL CONDITIONS FOR CERTAIN GENERAL LEVEL HEALTH CLAIMS

5. Regulatory Approach for General Level Health Claims based on Biologically Active Substances

5.1 Decision

FSANZ recommends the following approach for regulating general level health claims about biologically active substances:

- general level health claims about biologically active substances must meet the general conditions for such claims;
- claims must declare the level of the substance in the food;
- the supplier must have records substantiating the amount of biologically active substance that is required to be consumed per day to achieve the claimed health effect;
- the supplier must declare this amount as part of the claim; and
- a serve of the food must contain at least 10% of the amount required to be consumed per day to achieve the claimed health effect.

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

In the draft Standard, clause 6 and the Table to clause 12 regulate general level health claims about biologically active substances.

5.2 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. Health claims about biologically active substance claims are currently subject to the broad prohibitions of Standard 1.1A.2 Transitional Standard – Health Claims. The permission and associated conditions for making general level health claims about biologically active substances in the proposed Standard will be new.

5.3 Draft Assessment Report – approach taken and submitter comments

The approach taken in the Draft Assessment Report was the same as the approach described in the box above, with the addition of the requirement for the claim to also state the basis from which the total daily efficacious amount had been determined.

The major comments from submissions focused on the following key issues:

- the regulatory approach;
- the amount of biologically active substance required to make a health claim;
- substantiation of claims; and
- the adequacy of information on labels.

Most submitters supported the proposed approach in principle, and agreed that general level health claims based on biologically active substance should be permitted, but raised a number of objections to the regulatory approach.

Some submitters, predominantly from the food industry, suggested biologically active substance claims should be regulated the same as other claims. They felt the additional conditions set for general level health claims about biologically active substances were not necessary and argued that a less prescriptive approach would be more appropriate. In contrast, some stakeholders from the public health and government sectors argued that the approach to regulating general level health claims about biologically active substances was too permissive and suggested that such claims should be treated as a separate category of claim.

Most industry stakeholders agreed with a 10% threshold for making general level health claims based on biologically active substances, while others argued there should be no specified minimum for such claims. However, many government and public health stakeholders were concerned that a 10% threshold could result in a food carrying a general level health claim without containing meaningful amounts of the biologically active substance. Some thought that 25% was a more reasonable amount to ensure that enough of a specified component is consumed. Others suggested that the amount present to make a claim should suit each individual substance and food.

Industry submitters emphasised that the substantiation requirements for general level health claims based on biologically active substances must be robust and clear to be effective. They supported the proposed substantiation regime, but some felt that having to include the effective level of the biologically active substance in the claim could be onerous. Similarly, there were concerns that having to also include the basis from which the total daily level had been determined was overly onerous.

Stakeholders from the public health and government sectors were apprehensive given manufacturers could determine the effective level of a biologically active substance required to achieve a claimed health effect and felt that in some cases there may not be enough evidence to establish effective levels. Most of those who were concerned about substantiation argued that FSANZ should determine effective levels, but acknowledged that this would be difficult. Some suggested additional guidance was needed for industry regarding how much constitutes a meaningful amount of a biologically active substance on which to base a general level health claim.

Consumer representatives and some stakeholders in the public health sector argued the proposed regulatory regime does not give adequate protection to consumers and that deceptive conduct has the potential to do serious harm to consumers. Concerns were raised that health claims based on biologically active substances might mislead consumers in relation to the healthiness of a food and that some biologically active substances may be unsafe for certain consumers.

5.4 Preliminary Final Assessment Report – approach taken and submitter comments

The approach taken in the Preliminary Final Assessment Report is the same as the approach described in the Draft Assessment Report, however, in the section on minor changes to drafting (Section 9 of the Preliminary Final Assessment Report), FSANZ removed the requirement to describe the basis for the substantiation of the claim on the label and replaced the word ‘benefit’ with ‘health effect’ to clarify the meaning of this term and be consistent within the draft Standard.

Issues raised by submitters were similar to those raised in response to the Draft Assessment Report. All stakeholder comments were considered by FSANZ before deciding on the final approach.

5.5 Rationale for final decision

The approach taken at Final Assessment is essentially the same as that proposed in the Draft Assessment Report. The general requirements for general level health claims about biologically active substances are the same as those for other general level health claims, and follow the same rationale (see Part 1 of this Attachment). In addition, FSANZ is proposing specific requirements for such claims because:

- at this time, establishing food-health relationships for biologically active substances is an emerging science and substantiation of general level health claims is complex;
- pre-approved function statements or authoritative sources are not available;
- claims are not underpinned by recommended intakes or national guidelines;
- information on biologically active substances available to consumers is more limited than information on nutrients that is widely available from government and other trusted sources; and
- the substances themselves are less familiar to consumers, food suppliers and the scientific community and it is therefore more difficult for consumers to make a judgement on the credence of claims based on such substances.

FSANZ proposes that the supplier of the food must clearly identify the amount required to achieve the health effect and how much of the substance is in a serve of food because general level health claims based on biologically active substances are not based on reference values in the Code. Consumers must be provided with adequate information about the amount of claimed biologically active substance present in the food to make an informed purchasing decision. Disclosure in the claim of the amounts contained in the food and the daily amount required to achieve the claimed health effect reduces the likelihood of spurious or misleading claims. However, the requirement to state in the claim the source (i.e. referenced material) of the substantiated basis for the daily amount has been removed because it is considered too cumbersome and potentially impractical.

FSANZ has taken a pragmatic approach in mandating that a serve of the food must contain at least 10% of the amount required to be consumed per day to achieve the claimed health effect. Biologically active substances are very diverse and reference values are not available. Therefore, it is not feasible for FSANZ to provide specific qualifying criteria for each individual biologically active substance. The 10% approach is consistent with the basis used for vitamin and mineral claims, i.e. a general level health claim based on the vitamin content of the food is only permitted if the food contains 10% of the RDI or ESADDI for that vitamin.

FSANZ recognises the ‘per day’ amount may differ between claims and that the assessment of the evidence by suppliers could be translated differently onto different products. Furthermore, some biologically active substances may be less widespread in the normal diet than some nutrients and hence a fully effective amount may not be readily achievable though the diet if the minimum amount of 10% is used and a consumer consumes only a limited number of serves of products containing the biologically active substance per day. However, all relevant information will be on the label and transparent to consumers, competitors and enforcement agencies.

As for all general level health claims, records that substantiate a general level health claim based on biologically active substances are to be held by the supplier of the food. The Scientific Substantiation Framework requires that claims be based on evidence and show consistent associations (see Chapter 8). To demonstrate this for biologically active substances requires a structured scientific approach, including evidence of suitable quality, and evidence substantiating the amount of substance required to be consumed per day to achieve the specific health effect.

Compositional and safety aspects are not managed by the proposed Standard as the Standard regulates claims rather than permission to add substances. Refer to Chapter 8 of Attachment 5 – Nutrition Content Claims, for the further information.

6. General Level Health Claims about Maternal Folic Acid Consumption for Normal Foetal development

6.1 Decision

FSANZ recommends the following conditions for general level health claims about maternal folic acid consumption for normal foetal development:

- the food must contain no less than 40 µg of folic acid per serving;

- the food must be eligible to carry a claim under the nutrient profiling scoring criteria;
- the claim must state words to the effect that the context is a varied diet including food sources of folate and a recommendation that women consume at least 400 µg of folic acid per day, at least the month before and three months after conception; and
- the claim is not permitted on soft cheese, pate, liver or liver product, foods containing added phytosterol esters or added tall oil phytosterols, foods standardised in Part 2.7 and foods standardised in Standards 2.9.1, 2.9.2, 2.9.4 and Division 2 of Standard 2.9.3 (formulated meal replacements).

The general conditions applying to all general level health claims are outlined in Clause 6 and the additional specific conditions applying to this claim are prescribed in the Table to clause 12 of the draft Standard.

6.2 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report, the compositional and wording conditions for the dietary context for this claim were the same as those for the folic acid and neural tube defect high level health claim, as follows:

- the food must contain no less than 65 µg folate and/or folic acid per serve;
- the food had to meet the disqualifying criteria (now referred to as nutrient profiling scoring criteria);
- certain foods were not permitted to carry the claim (as outlined in the Decision section above); and
- the wording of the claim had to include a recommendation that women consume at least 680 µg of dietary folate equivalents per day or 400 µg of folic acid per day, at least the month before and three months after conception.

Very few submitters commented on this approach. One of the jurisdictions considered it inconsistent that this claim must comply with the requirements of a high level health claim when other claims such as claims about a healthy heart or strong bones, do not. Another submitter considered that this approach meant that the claim had to be substantiated in the same manner as a high level health claim, even though the substantiation process for other general level health claims should suffice.

6.3 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report, the wording conditions for the folic acid and neural tube defect high level health claim was amended to a recommendation that women consume at least 670 µg of dietary folate equivalents per day (rather than 680 µg). This amendment also applied to the folate/folic acid and foetal development general level health claim.

There were no submitter comments received specially in relation to this amendment. One industry submitter made comments regarding the general conditions for the folic acid high level health claim. These would also apply to the general level health claim. These included that the qualifying criteria of 65 µg of folic acid per serving meant that some breads, particularly heavy grain breads that are often marketed to women of childbearing age, would not qualify to carry this claim under the required level for mandatory fortification.

They also considered that the required wording of the claim was not consumer friendly and therefore of limited use to industry.

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

Since the Draft and Preliminary Final Assessment Reports were released, FSANZ has revised the conditions for the folic acid neural tube defect high level health claim and the folic acid and foetal development general level health claim. The qualifying criteria have been amended so that the food must contain no less than 40 micrograms folic acid per serve, with no reference to folate. The wording of the dietary context in both health claims must refer to 400 µg folic acid with no reference to the amount of folate recommended, and must be in the context of a varied diet including food sources of folate.

6.5 Rationale for final decision

Claims referring to the food-health relationship of maternal folic acid consumption and normal foetal development would not normally be classified as a high level health claim because they do not reference a serious disease or condition, e.g. *This [food] contains folic acid. As part of a healthy diet consisting of a variety of foods, folic acid assists in normal foetal development during pregnancy.* They would therefore not normally be subject to the specific criteria and conditions that relate to the pre-approved high level health claim. However FSANZ recognises that suppliers may choose not to use the pre-approved high level health claim, because the reference to the serious disease or condition may attribute negative connotations to the product. This was given as one of the primary reasons regarding the slow uptake of the permitted pilot health claim regarding maternal folate consumption and a reduced risk of foetal neural tube defects on products and associated advertising. However, FSANZ considers that general level health claims relating to maternal folic acid consumption for normal foetal development should be regulated in the same way as the pre-approved high level health claim.

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

- The claim is directed at a specific population sub-group that could be particularly vulnerable to the information conveyed.
- A level of 400 µg of folic acid is the minimum daily protective amount to achieve the health effect. Therefore, general level health claims that communicate the health effect in a positive way should only be on foods that meet the high level health claim qualifying criteria. This criterion takes into account a reasonable number of serves of food that can be consumed on a daily basis to reach the required daily level.
- The claim relates to a very specific period in which the consumption of folic acid will achieve the health effect, that is, one month prior to conception and three months after conception. This is unlike the other food-disease relationships reviewed, which more often relate to permanent changes in the diet. This is important information that should be communicated by the general level health claim.

The drafting provides clarity for suppliers in terms of substantiation and the conditions that should be met for such a claim.

Analysis of the folic acid content of certain breads as a result of fortifying at the minimum level for mandatory fortification with folic acid in both Australia and New Zealand indicates that at this revised level for the qualifying criteria and using serving sizes recommended on product packaging, these breads, including heavy grain breads, meet the qualifying criteria to carry this claim.

Refer to Section 2.4 of Attachment 7 for further rationale for the conditions for this claim.

7. Life Stage Claims

7.1 Decision

FSANZ recommends the following in relation to claims about life stages:

- life stage claims will not be considered as a separate category of claim but will be regulated as for other general level or high level health claims, according to the health effect referred to in the claim.

7.2 Draft Assessment Report – approach taken and submitter comments

The approach for claims in relation to specific life stages taken in the Draft Assessment Report has been retained.

Very little comment was received from submitters regarding life stage claims, with one submitter noting their support of the intended approach.

7.3 Rationale for final decision

Life stage claims can be considered in a continuum of claims ranging from those that refer to different life stages, such as puberty, menopause and old age and associated symptoms, through to serious diseases associated with different life stages. For example, puberty can be associated with minor skin conditions through to severe acne, while old age can be associated with conditions such as hair loss through to serious diseases such as age-related macular degeneration. FSANZ considers that these claims should be permitted as they simply target a product to a particular population group to provide positive health effects.

Classification as a general level or high level health claim would be based on whether or not the claim refers to a serious disease or biomarker of a serious disease, rather than the life stage mentioned in the claim. It is not considered appropriate to treat all life stage claims as, for example, high level health claims, given that life stage claims could potentially refer to a broad spectrum of conditions ranging from non-serious to serious diseases.

Claims that refer to a life stage will be required to comply with all conditions for making a general level health claim or high level health claim, as appropriate. For example, where the health effect relates to a specific population group, the health claim will be required to state the specific population group to which the health effect relates.

8. Weight Loss or Maintenance Claims

8.1 Decision

FSANZ recommends the following in relation to weight loss/maintenance claims:

- weight loss/maintenance claims will be considered as general level health claims and must meet the substantiation and wording conditions for such 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) applies, 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
- claims are required to state the importance of exercise.

Conditions for general level health claims, such as weight loss/maintenance claims are regulated in clause 6 of the draft Standard. Specific conditions for weight loss/maintenance claims are prescribed in the Table to clause 12 of the draft Standard.

8.2 Amendments to current standards/CoPoNC recommendations

Standard 1.1A.2 Transitional Standard – Health Claims of the Code currently prohibits foods bearing claims or statements that the food is a slimming food or has intrinsic weight reducing properties. Terminology relating to these types of claims has evolved in the development of the draft Standard. Slimming claims, along with other related claims, are now referred to as ‘weight loss/maintenance’ claims. While there will be no prohibition on weight loss/maintenance claims in the draft Standard, there will be conditions for these claims.

8.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report, FSANZ proposed that weight loss/maintenance claims be permitted and regulated in accordance with general level health claims. As further clarity, for regulatory purposes, FSANZ considered ‘obesity’ to be a serious disease and thus any claim referring to obesity would be considered a high level health claim. ‘Overweight’ was considered a non-serious disease and therefore related claims would be general level health claims.

The Draft Assessment Report proposed the following approach for weight loss/maintenance claims:

- weight loss/maintenance claims were permitted;
- weight loss/maintenance claims were general level health claims;
- disqualifying criteria (now referred to as nutrient profiling scoring criteria) for general level health claims applied;
- claims were required to state the importance of exercise; and
- foods were required to meet the qualifying criteria for ‘low energy’, namely, less than or equal to 80 kJ per 100 ml of liquid foods, or less than or equal to 170 kJ per 100 g of solid or semi-solid foods.

Following the release of the Draft Assessment Report, submitters raised a variety of concerns about the proposed approach for regulating weight loss/maintenance claims. In particular, there was concern that only products meeting ‘low energy’ criteria would qualify to make weight loss/maintenance claims. This meant that some healthy options, such as low fat dairy products and fruit, would not qualify to make such claims because of their energy content.

After further consideration, FSANZ considered the general approach to weight loss/maintenance claims in the Draft Assessment Report to be appropriate however, the qualifying criteria set for such claims were reviewed.

8.4 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report, FSANZ considered it appropriate that the criteria for making a *diet* content claims should also apply to general level health claims referring to weight loss/maintenance. This change is intended to make the qualifying criteria for energy claims more consistent and flexible. It was proposed that foods making weight loss/maintenance claims be required to:

- a) meet the qualifying criteria for *low energy* claims (i.e. less than or equal to 80 kJ per 100 ml of liquid foods, or less than or equal to 170 kJ per 100 g of solid or semi-solid foods); or
- b) meet the qualifying criteria for *diet* claims (i.e. have 40% less energy as the same quantity of a reference food).

In addition, the food making the claim must also:

- c) state the importance of exercise; and
- d) comply with wording conditions that put the food in the context of an overall diet; and
- e) meet the eligibility criteria for a general level health claim under the nutrient profiling scoring criteria; and
- f) be fully substantiated in relation to the weight loss/maintenance claim.

FSANZ received mixed comments from submitters in response to the Preliminary Final Assessment Report in relation to weight loss/maintenance claims. Some submitters believed the proposed approach was too lenient while others thought it to be too restrictive. Several submitters thought there was a need to incorporate a measure of satiety into the regulation of weight loss/maintenance claims and thus allow products that enhanced satiety to make these types of claims. A number of submitters believed that weight loss/maintenance, in particular weight loss claims, should be prohibited because no one food has intrinsic weight loss properties.

Incorporating the option for foods to meet the conditions for making a *diet* claim means that foods that are reduced in energy (compared to a reference food), such as low fat dairy products, may now be eligible to make a weight loss/maintenance claim.

8.5 Rationale for final decision

The Policy Guideline is silent on weight loss/maintenance claims. In the context of the draft Standard, weight loss/maintenance includes measurement reduction, clothing size loss and weight control/maintenance; it does not include weight gain. An example of a weight loss/maintenance claim is: *This food is low in energy. A diet that is low in energy can assist in weight loss as part of a weight reduction program and combined with regular exercise.* Should claims based on intrinsic weight reducing properties of a food eventuate, these would be required to comply with the general conditions for weight loss or maintenance claims and be substantiated in accordance with the Scientific Substantiation Framework. FSANZ is not currently aware of any products that would be able to substantiate such a claim.

FSANZ has maintained the more flexible approach presented in the Preliminary Final Assessment Report. The overriding factor in weight management is overall energy balance. The proposed approach allows foods that may assist to reduce overall energy intake to make a weight loss/maintenance claim. The combination of risk management strategies proposed in the Preliminary Final Assessment Report aims to protect consumers from misleading claims. Lower energy products that do not meet the strict criteria for *low energy* claims are still able to make weight loss/maintenance claims.

In response to submitter concern that fruit and vegetables may not be able to make weight loss/maintenance claims, FSANZ has verified that many fruits and vegetables do meet the *low energy* criteria and therefore will be able to make claims. Foods that do not meet the qualifying criteria can make a variety of other claims assisting consumers in making healthy choices, including other energy based claims, such as *reduced energy* or *light*. Claims that refer to satiety are not weight loss/maintenance claims within the context of this regulation. Satiety is the specific health effect of the food and must be expressed and substantiated as a general level health claim in its own right. This means the satiety claim must be expressed in connection to a specified property of the food, e.g. fat, protein, carbohydrate, fibre, biologically active substances, or the whole food. Further guidance in relation to satiety claims will be provided in the User Guide to Standard 1.2.7.

9. Whole Food Claims

9.1 Decision

FSANZ recommends the following approach for general level health claims in relation to 'whole foods':

- whole foods are not specifically defined;
- health claims in relation to whole foods must state the food itself and the specific health effect that is claimed for the food;
- to be eligible to carry a general level health claim, whole foods must meet the nutrient profiling scoring criteria and any other generic conditions for making a health claim that are set out in clause 6 of the draft Standard;
- they must be substantiated according to the Scientific Substantiation Framework; and
- the evidence must point towards the health effect being attributed to the whole food.

Claim conditions relating to whole food claims are set out in subparagraphs 6(1)(e)(i) and (ii).

9.2 Amendments to current standards/CoPoNC recommendations

Claims about whole foods are not specifically addressed by the Code, or by CoPoNC. Hence these requirements will be new.

9.3 Draft Assessment Report – approach taken and submitter comments

FSANZ proposed the following approach for general level health claims in relation to ‘whole foods’ in the Draft Assessment Report:

- whole foods are defined as foods that consist of at least 90% by weight of primary foods;
- health claims in relation to whole foods do not need to state the property of the food;
- generic disqualifying criteria and conditions apply;
- claims must refer to generic food types;
- they must be substantiated according to the Substantiation Framework; and
- the evidence must point towards the health effects being attributed to the whole food.

In the Draft Assessment Report, the approach taken to define a whole food as a food that consists of at least 90% by weight of primary foods was considered to provide greater flexibility for making whole food general level health claims. Under Standard 1.3.2, primary food means fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish. In addition, it was acknowledged that general level health claims about whole foods could not refer to a specific component or property of the food, which is a pre-requisite for health claims, and was recognised that sufficient substantiated evidence of a health effect for a whole food might be available, where there is no such evidence for the specific component or property of the food responsible for the effect. FSANZ proposed to treat whole food general level health claims as a special case whereby the claim would be exempt from the requirement to state the property of the food. Such claims would still be required to meet generic disqualifying criteria and conditions for health claims.

Submitters (representing industry, academic and government stakeholders) expressed a number of concerns about the approach for ‘whole food’ claims proposed in the Draft Assessment Report. These included:

The definition of whole food and its application

- Strong opposition to the use of the definition of ‘primary foods’ as the basis for the definition of whole foods, given that the list of primary foods in Standard 1.3.2 is not exclusive, and therefore claims cannot be made about foods that are missing from the definition.
- The definition was considered to be overly restrictive and would limit information provided to consumers and restrict consumer choice.

- The 90% threshold is too high and would prohibit well recognised and meaningful claims. For example, low fat milk would be able to carry a claim ‘milk is good for healthy teeth and bones’, but sweetened fruit yoghurt (85% milk) would not be able to make a similar claim although it contains a similar level of calcium and protein.
- The proposed approach contradicts Australian Dietary Guidelines, which recommend eating wholegrain foods and that foods that contain 51% wholegrains be considered wholegrain foods. The guidelines do not specify that the foods should be made up of 90% primary foods.

Generic disqualifying criteria

- Concern that although many foods will meet the criteria for ‘whole food’, they may still be ineligible under generic disqualifying criteria to make a claim.

Claims must refer to generic food types

- Concern that the proposed approach would prohibit certain claims. For example, fruit varieties were noted to differ substantially in their phytochemical content, resulting in a health and nutritional value that can vary.

Substantiation of whole food claims

- Some opposition to the requirement for whole food general level health claims to be substantiated according to the substantiation framework.
- Proposed substantiation requirements for whole foods would prohibit some foods from making a claim. In many foods there can be a complex interaction between the different components in the food and it is not just one or a couple of components in the food that result in the benefit.
- Whole food claims should be permitted where there is a substantiated benefit; that claims should be permissible for any food, ingredient, nutrient, biologically active substance based on the scientific evidence for the claim and there should be no restrictions on particular types of foods, however defined.

Request for clarity

- It was queried whether the food product itself or the original product be subject to the 90% threshold. For example, would an orange juice claim be based on 90% by weight orange juice, or would the orange ‘fruit’ being regarded as the primary food.

9.4 Preliminary Final Assessment Report – approach taken and submitter comments

It was proposed in the Preliminary Final Assessment Report to remove the reference to primary food where it had been used in the context of defining whole foods.

The relevant clause was amended to reflect that the composition of the food is not the key feature, rather that the only circumstances in which a health claim can refer to a whole food is when substantiation is on the basis of the whole food (rather than a property of the food) providing the health effect.

The requirement for whole foods to meet generic conditions for making a health claim would remain. In addition, determining eligibility of a whole food to carry a health claim would be maintained, although the eligibility system has since changed from disqualifying criteria in the Draft Assessment Report to a requirement to meet nutrient profiling scoring criteria. Regardless of whether the claim is made about a whole food or a property of the food, the food on which the claim is being made will be subject to nutrient profiling scoring criteria. As this system evaluates the overall nutritional value of each food that intends to carry a health claim, the requirement for claims to refer to generic food types was deemed unnecessary and was removed.

No comments on the proposed approach taken for whole food general level health claims were received from submitters in response to the Preliminary Final Assessment Report.

9.5 Rationale for final decision

FSANZ acknowledges that the use of the pre-existing primary food definition in the Code was problematic for the reasons provided by submitters. The current recommendation is that the term ‘whole food’ is not specifically defined. This recommendation is made because of a change in approach from attempting to defining whole foods as specific types of foods that were captured under the primary food definition (for example, meat, eggs or fruit), to one which distinguishes between health claims made about the benefit of consuming any particular food (for example, tea) and claims made about a single property of the food (for example, the calcium content of milk). Health claims in relation to whole foods must explicitly state the food itself and the specific health effect that is claimed for the food. FSANZ considers that this approach addresses most submitter concerns and will provide consistency and certainty to suppliers and enforcement agencies.

With regard to submitter concerns about the substantiation requirements for whole food general level health claims, FSANZ maintains that such claims would be permitted subject to there being reasonable substantiating evidence that the health benefit is only derived from the whole food. By setting out the process and the requirements for suppliers to follow, FSANZ considers that the Scientific Substantiation Framework is sufficiently robust to ensure that inappropriate health claims are not made about whole foods.

It is also noteworthy that the approach to determining the eligibility of food has been superseded by the new nutrient profiling scoring criteria. Under this system, the overall nutritional benefit of a whole food will be assessed on the basis of its nutritional composition, taking into account both risk increasing and risk reducing nutrients. The vast majority of those foods seen as ‘natural’ whole foods (for example, milk or apples) will now be eligible for making claims.

10. General Level Health Claims about Wholegrain

10.1 Decision

FSANZ recommends the following conditions for general level health claims about wholegrain:

- for health claims on foods containing wholegrain ingredients, the food must meet the general conditions for making a general level health claim, and in addition:
 - the claim must state the level of the wholegrain ingredient in the food;
 - the amount of wholegrain that is required to achieve the claimed health effect must be stated in the claim and a serve of the food must contain at least 10% of that amount; and
 - the supplier of the food must have records substantiating the basis for the amount of wholegrain that is recommended to be consumed to achieve the claimed health effect.
- for health claims on foods composed entirely of wholegrain, the claim will be regulated in the same manner as other whole food claims.

General conditions for health claims about wholegrain are regulated in clause 6 of the draft Standard. Specific additional conditions for general level health claims about wholegrain are in the table to clause 12 of the draft Standard. Wholegrain is defined in Standard 2.1.1.

10.2 Amendments to current standards/CoPoNC recommendations

‘Wholegrain’ is currently defined in Standard 2.1.1 – Cereals and Cereal Products and this definition will be retained. Claims about wholegrain currently need to comply with Standard 1.1A.2 – Transitional Standard – Health Claims. The regulation of health claims about wholegrain as outlined above will be new to the Code.

10.3 Draft Assessment Report – proposed approach and submitter comments

It was intended that the qualifying criteria for general level health claims would be based on the minimum qualifying criteria for nutrition content claims, i.e. the food must contain at least 8 grams of wholegrain per serve.

Specific submitter comments regarding general level health claims about wholegrain were not received (for comments regarding the conditions for nutrition content claims about wholegrain see Attachment 5, Chapter 29 and for comments regarding the qualifying criteria for general level health claims in general, see Chapter 1 of this Attachment).

10.4 Preliminary Final Assessment Report – proposed approach and submitter comments

In the Preliminary Final Assessment Report the qualifying criteria of 8 grams of wholegrain per serve of food was omitted from the draft Standard. Instead, it was proposed that general level health claims about wholegrain be regulated in the same manner as general level health claims about biologically active substances, as follows:

- the claim must state the level of the wholegrain ingredient in the food;
- the amount of wholegrain that is required to achieve the claimed health effect must be stated in the claim and a serve of the food must contain at least 10% of that amount; and
- the supplier of the food must have records substantiating the basis for the amount of wholegrain that is recommended to be consumed to achieve the claimed health effect.

Concern from submitters was expressed around how the food industry will determine the substantiated level required to be consumed each day in order to achieve the health effect. It was considered that there is likely to be variation in the recommendations of the amounts of wholegrain required to be consumed by different suppliers and this could lead to consumer confusion and increasing difficulties with enforcement. Instead of industry determining the effective level, it was suggested that FSANZ should be responsible for determining this.

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

FSANZ agrees with submitters that ‘wholegrain’ does not meet the definition of biologically active substances and therefore health claims about wholegrain are not directly captured by the clauses relating to biologically active substances. The regulation of wholegrain general level health claims is now specifically articulated in the draft Standard to clarify that although wholegrain ingredients are not considered to be biologically active substances as such, the regulation of health claims about wholegrain ingredients is intended to be the same as that for biologically active substances.

10.6 Rationale for final decision

In the absence of a bi-nationally agreed reference value upon which to base the conditions for claims, FSANZ recommends that health claims about wholegrain ingredients be regulated as for claims about biologically active substances (refer to Chapter 5 of this Attachment for further rationale). In order to ensure that a meaningful amount of wholegrain underpins the claim, 10% of the amount of wholegrain that is required to be consumed per day to achieve the desired health effect will need to be present in a serve of food.

On foods where the whole food is composed entirely of wholegrain (thus meeting the definition in Standard 2.1.1), for example, a package of wholegrain oats, some of the specific conditions applying to wholegrain ingredients are not applicable to whole food claims. In order to maintain consistency with the regulation of whole food claims about other foods such as nuts and fruit, the conditions for making whole food claims will apply (see Chapter 9 of this Attachment). In this case the requirement to state the amount of wholegrain contained in the food and that the food must contain 10% of the amount required for the specific health effect would not apply.

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