ATTACHMENT 7

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

Regulatory Approach for High Level Health Claims

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1. INTRODUCTION

1.1 Decision

FSANZ recommends the following for the regulation of high level health claims:

- all high level health claims must be based on a food-disease relationship that has been pre-approved by FSANZ;
- use of the following pre-approved food-disease relationships to form the basis of high level health claims:

    - calcium, vitamin D status and osteoporosis;
    - calcium and enhanced bone mineral density;
    - folic acid and neural tube defect;
    - saturated fatty acids and *trans* fatty acids and serum LDL cholesterol;
    - saturated fatty acids and serum LDL cholesterol;
    - sodium and blood pressure; and
    - fruit, vegetables and coronary heart disease.
- an application to FSANZ must be made for approval to use any other food-disease relationships as the basis for a high level health claim;
- specific wording of the high level health claim will not be prescribed but the actual elements of the claim that must be included will be outlined in the draft Standard; and
- the same general wording conditions as prescribed for general level health claims will apply and include that the claim states:

    - the property of the food (if applicable) or food and the specific health effect claimed in relation to that property or food;
    - the specific population group to which the health effect relates (if applicable); and
    - that the health effect must be considered in the context of a healthy diet involving the consumption of a variety of foods, as appropriate to the type of food and the specific health effect claimed.

The conditions for high level health claims are outlined in clause 7 of the draft Standard. The specific conditions for high level health claims are prescribed in the Table to clause 7.

Note: refer to Attachment 3 for information about terminology relating to the regulation of high level health claims, for example, serious disease, biomarker, high level health claim.

1.2 Current situation regarding high level health claims

The Code currently permits one high level health claim for increased maternal folate consumption and reduced risk of foetal neural tube defects. A claim to this effect will continue to be permitted under the draft Standard, however the conditions for making the claim (qualifying criteria, food vehicle eligibility criteria and wording conditions) are not the same as those prescribed in Standard 1.1A.2 - Transitional Standard - Health Claims.

High level health claims based on the other pre-approved food-disease relationships listed above were prohibited under the Transitional Standard.

1.3 Submitter comments on high level health claims

While submitter comments about specific pre-approved food-disease relationships are addressed individually under each of the sections about the individual health claims, the following is a discussion of general comments in relation to high level health claims received in response to the Draft Assessment and Preliminary Final Assessment Reports and FSANZ's response to these comments.

1.3.1 Draft Assessment Report – submitter comments

There was general support for pre-approved food-disease relationships. However, there was concern that the wording criteria were unnecessarily strict. One submitter indicated that this may result in manufacturers choosing a general level health claim over a wordier high level health claim. In addition, there was concern that the stringent and highly prescriptive requirements to obtain approval was demanding and required substantial resources. There was also uncertainty about the logic underpinning certain disqualifying criteria.

There was a request for FSANZ to consider that high level health claims describe the relationship between the food or an ingredient in a food, as a contributing causal factor for a disease outcome e.g. a claim that describes the relationship between a high sugar food and dental caries.

One submitter noted that clarification is needed as to whether the population group needs to be referred to in the claim if the claim relates to the general public.

There were a number of comments about the scope for innovation by industry and the degree of commercial confidentiality associated with the approval process for high level health claims. It was considered that manufacturers would be very reluctant to apply for new high level health claims permissions if the process is fully open to public scrutiny and there is no guarantee to exclusive rights to the claims for a defined period. Some submitters endorsed the proposed approach to the management of high level health claims, providing the proposed amendments to the FSANZ Act to protect innovation are in place prior to gazettal of the Standard. Other submitters were concerned about the Food Regulation Ministerial Council recommended changes to the FSANZ Act which would allow the food industry to seek pre-market approval of food-disease relationships upon which to base high level health claims with no public consultation.

1.3.2 Preliminary Final Assessment Report – submitter comments

There was general support for the framework proposed for pre-approval of the food-disease relationships for high level health claims in the draft Standard. From an industry perspective it removes the cost burden on industry, particularly small industry. However, there were still some outstanding issues.

Some submitters expressed concern that FSANZ was not applying a consistent approach to assessing the evidence for the food-disease relationships.

They stated that this is most evident between food-disease relationships that FSANZ has pre-approved and those that it has not. One submitter felt that claims involving whole foods appear to require a lower level of evidence. In addition, there was concern about potential conflict of interest issues and a lack of transparency among members of the SAG. By contrast, other submitters noted the important role of the SAG in reviewing the evidence, although FSANZ needed to ensure that public health and consumer interests were strongly represented in the Group.

One submitter questioned the need to include the context of a 'healthy diet', stating that this is the responsibility of health professionals. In addition, it may add too many words to the claim making it difficult to fit the statements on a label without overwhelming the consumer with text. They suggested that the 'healthy diet' message be voluntary rather than mandatory.

One submitter questioned the reasoning behind applying specific qualifying criteria for each high level health claim carried over from nutrition content claims, then overlaying this with the nutrient profiling scoring criteria. The nutrient profiling scoring criteria have only recently been developed and have not formed part of the substantiation process for high level health claims.

There were several other specific comments:

- that there be an annual review of emerging food-disease relationships to assess whether there is enough evidence available to add new substantiated food-disease relationships to Standard 1.2.7;
- plant sterols are not mentioned in the substantiated diet-disease relationships but these ingredients have been shown to reduce cholesterol absorption; and
- it was recommended that the issue of bioavailability is thoroughly considered to ensure that the use of a high level health claim applies to all foods for which it is approved.

1.3.3 FSANZ's response to the submitter comments on high level health claims

FSANZ notes the concerns regarding the 'wordiness' of high level health claims but the rationale for each element of the health claim that must be included are described in Section 2. Manufacturers may instead prefer to use a less wordy general level health claim as a result.

The Policy Guideline provides the basis for the stringent process that must be adhered to regarding substantiation of a food-disease relationship. The inbuilt rigour is necessary to ensure that the relationship is based on an appropriate level of evidence so as not to mislead the consumer.

Chronic diseases are typically multifactorial, and so there may be several independent factors that lead to disease. Hence it is possible that several different diet relationships for a single disease outcome/biomarker, might be substantiated. Substantiation of, for example, a sodium-blood pressure relationship does not preclude the possibility that another food-blood pressure relationship might be substantiated in the future.

FSANZ notes the concern of some submitters that an inconsistent approach was applied to assessing the evidence for the food-disease relationships.

As indicated earlier, FSANZ outlined its rationale for giving pre-approval in the Draft Assessment Report for the food-disease relationships relating to calcium, sodium, folic acid, and saturated and *trans* fatty acids (see Attachment 10 of the Draft Assessment Report[1]) and in the Preliminary Final Assessment Report for claims relating to fruit and vegetables, and for determining that the evidence available to date did not reach the level needed to approve the food-disease relationships related to wholegrains and bran, and long chain omega-3 fatty acids (see Attachment 5 of the Preliminary Final Assessment Report[2]).

The rationale behind mandating the inclusion of the context of a 'healthy diet' is that it is specified in the Policy Guideline (and further rationale is provided in Attachment 6 – General Level Health Claims).

The rationale for requiring a food carrying a high level health claim to meet the nutrient profiling scoring criteria is the same as that for general level health claims and is provided in section 11.6.1 of the Final Assessment Report. Refer also to section 2.1.2 of this Attachment.

The nutrient profiling scoring criteria have replaced the previous disqualifying criteria for health claims proposed in the Draft Assessment Report. In response to a submitter comment, it should be noted that the purpose of food vehicle eligibility criteria is completely separate from the purpose of substantiation. Substantiation refers to determining whether the relationship between a factor (food component or food) and a health outcome is sufficiently certain that this can be stated on the package. The Policy Guideline also notes that such statements should not *promote irresponsible food consumption patterns* and *support … initiatives that promote healthy food choices*. FSANZ has interpreted this as meaning that some products might have characteristics that mean they should not carry the substantiated claim, even if they contain the food component that is the subject of the claim.

With regard to the process undertaken to select the food-disease relationships for review by FSANZ, an explanation is given under Chapter 1 of Attachment 10 of the Draft Assessment Report[1]).

In brief, an iterative consultation process was undertaken to develop an agreed short-list of food-disease relationships that would be given priority for review. The list was developed taking account of stakeholder interest in potential high level health claims, the relevance of food-disease relationships to public health nutrition priorities in both Australia and New Zealand, and the potential for resulting high level health claims to apply broadly to a range of foods rather than to favour specific food products. The iterative process included a stakeholder workshop followed by an electronic mail out, public consultation via the Initial Assessment Report, liaison with the Standards Development Advisory Committee and finally the FSANZ Board.

After short-listing the relationships for review, FSANZ called for interest from the scientific community to identify experts who might undertake the reviews. Experts with expertise relevant to the subject matter of each food-disease relationship were contracted.

[1] http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/p293draftassessmentr3501
[2] http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm

The SAG considered the Contractors' reviews, on occasion requested further work be done on the review, and then advised FSANZ on the strength of evidence that was available for each of the food-disease relationships. The SAG sometimes agreed with, but other times disagreed with, the authors' conclusions. The membership and terms of reference of the SAG is on the FSANZ website[3]. SAG members are from academic institutions and government organisations; there are no industry members.

For food-disease relationships substantiated by the SAG, FSANZ set conditions around the high level health claims in the Table to clause 7 of the draft Standard. A range of issues have been considered in setting those conditions, including the issue of bioavailability, which had been a matter recommended for thorough consideration by stakeholders in response to the Draft Assessment Report. More detail about bioavailability and when and how it is necessary to take the issue into consideration with regard to high level health claims, will be included in the *Application Handbook*.

FSANZ has completed all seven reviews that were commissioned for Proposal P293 and due to resource constraints does not have plans to conduct further reviews at this time. Additional food-disease relationships may be pre-approved through assessment of applications to FSANZ after Standard 1.2.7 is gazetted. FSANZ would review existing food-disease relationships if sufficient evidence emerged to question the relationship and/or an application was received to trigger this process.

It was noted in the Preliminary Final Assessment Report (Section 9) that the intent in the Draft Assessment Report was not to refer to the 'general population' as part of the wording of the claim if the specific health effect can be attributed to the general population. This was not clearly reflected in the draft Standard, hence the drafting was amended to reflect this intent. This aligns with the approach with general level health claims and addresses the submitter concern expressed above. There were no comments received from submitters in relation to the wording conditions in terms of claims about specific population sub groups at this stage of consultation.

1.3.4 Protection of commercial confidentiality

During the course of the ongoing assessment of Proposal P293, parliamentary processes to amend the FSANZ Act have been finalised and the amended Act came into effect on 1 October 2007. Division 1, subdivision G of the Act contains procedures for variations of the Nutrition, Health and Related Claims Standard that apply to an application if the variation sought is a high level health claims variation. An Applicant seeking pre-approval of a new food-disease relationship or a variation to an existing high level health claim may elect to have FSANZ give public notice calling for submissions. This election will have to be advised in writing with the application and at the time of lodging the application. If the Applicant does not elect at the time of lodging the application, public submissions will not be invited and details of the application will not be made publicly available.

[3] http://www.foodstandards.gov.au/foodmatters/healthnutritionandrelatedclaims/scientificadvisorygroup/index.cfm

In situations where FSANZ has accepted the application and follows the procedure for high level health claims applications that will not be made public, FSANZ will only give notification to the Applicant, the High Level Health Claims Committee[4] and the Food Regulation Standing Committee (FRSC) that the application has been accepted. FSANZ will consider any recommendations from the High Level Health Claims Committee or comments from FRSC. If, after completion of the assessment, FSANZ recommends variations to the Standard that include pre-approval of a new food-disease relationship, that decision will be treated in confidence until the amended Standard is gazetted. The Applicant in such circumstances would be notified by FSANZ prior to gazettal of the Standard and from that notification would be able to prepare to launch their product carrying the high level health claim immediately after gazettal of the amended Nutrition, Health and Related Claims Standard. The Applicant would have an advantage of being first to market with a product carrying the claim.

2. APPROVED FOOD-DISEASE RELATIONSHIPS

2.1 Introduction

The following sections outline the recommended approach and the rationale for this, as well as applicable submitter comments for each approved food-disease relationship. Detail about the following conditions has been included where appropriate for each claim. Attachment 6 provides detail about the rationale for the wording conditions and compositional criteria that apply to general level health claims. This rationale also applies to the general conditions for high level health claims.

2.1.1 Minimum amount of nutrient (or substance)

Where the claim refers to a nutrient (or substance) that has potentially beneficial health effects, the minimum amount of the nutrient (or substance) that the food must contain has been specified in the draft Standard. This is to ensure that a reasonable amount is added or is available naturally in the food carrying the claim. The Policy Guideline states that there must be *enough of the specified component to achieve the claimed benefit when consumed as directed*. In most instances this will relate to the amount normally consumed in a day.

2.1.2 Nutrient profiling scoring criteria

As a result of the revised approach to the food vehicle eligibility criteria for general level health claims, all foods carrying high level health claims based on any of the pre-approved food-disease relationships *must* meet the generic nutrient profiling scoring criteria (previously referred to as disqualifying criteria).

The requirement to meet the nutrient profiling scoring criteria aligns with the Policy Guideline which states that foods intended to carry the health claim must meet specific eligibility criteria. The rationale for requiring a food carrying a general level health claim to meet the nutrient profiling scoring criteria is explained in section 11.6.1 of the Final Assessment Report and also applies to high level health claims.

[4] As indicated in the 2007 amendments to the FSANZ Act, FSANZ will establish a High Level Health Claims Committee. This Committee will provide advice to FSANZ on Applications for new high level health claims.

It is possible some foods may be permitted to carry high level health claims where they may not meet the nutrient profiling scoring criteria, but where there is sufficient evidence that the food provides appropriate benefit for a target population.

2.1.3 Ineligible foods

For a small number of claims, foods not permitted to carry the claim will be specified. This will include foods that are not recommended to be eaten by the target population to which the health claim might otherwise apply. It may also include foods consumed by the general population, but for which the relationship has not been fully substantiated for a particular form of the food.

2.1.4 Health outcome (serious disease or biomarker)

The wording conditions specify the health outcome that *must* be included in the claim. In some instances, there is a choice of more than one health outcome that can be used. Specifying the health outcome that can be used in the wording ensures that the claim is confined to the substantiated relationship/s. This avoids misleading consumers with respect to health outcomes that have not been substantiated or biomarkers that are not validated for the health outcome in question. Where possible and appropriate, health outcomes are described using commonly understood terms.

2.1.5 Target population

The wording conditions *may* specify a target population that must be included in the claim. The target population is based on the substantiated relationship, although in some cases it may be slightly broader than this. Broadening the target population provides wider appeal to industry, while also ensuring that the risk of harm is unlikely. In cases where a population group has not been specified the total population is taken to be the target population.

2.1.6 Context of a healthy diet

The wording conditions specify that the context of a 'healthy diet' *must* be included in the claim. This condition aligns with the requirement in the Policy Guideline that high level health claims may only be made in the context of the appropriate total diet. For some claims additional criteria about overall diet are specified. These conditions are based on the evidence that the likelihood of the health outcome is enhanced by adhering to additional dietary recommendations.

2.2 Calcium, Vitamin D and Osteoporosis

2.2.1 Decision

FSANZ recommends that a high level health claim is based on the pre-approved relationship between calcium, vitamin D status and osteoporosis. The conditions for using this claim are:

- the food must contain at least 290 mg of calcium per serving;
- the food must meet the nutrient profiling scoring criteria except for foods standardised in Standards 2.9.2, 2.9.3 or 2.9.4;

- the wording of the claim must:
    - include calcium as the property of the food, with or without vitamin D;
    - include reference to reduced risk of osteoporosis, enhanced bone mineral density or reduced risk of osteoporotic fracture;
    - include that the claim is only applicable to people of at least 65 years of age;
    - be in the context of a healthy diet with a high intake of calcium from a variety of foods; and
    - include reference to the need for adequate vitamin D status; and
- the claim may also refer to the vitamin D content of the food, as long as the food contains enough vitamin D to qualify for a nutrition content claim.

These conditions are outlined in the Table to clause 7 of the draft Standard.

2.2.2 Draft Assessment Report – approach taken and submitter comments

Conditions for this claim were proposed in the Draft Assessment Report. These included that the food carrying this claim must contain at least 300 mg of calcium per serve, and must be a 'claimable food'. The wording conditions were the same as those outlined above.

Several submissions addressed issues related to the calcium, vitamin D and osteoporosis health claim.

Some submitters, particularly those from industry, contended that the minimum claimable amount of calcium was too high and that whole milk would be excluded as a claimable food. They noted that whole milk is a suitable food for the frail elderly, a group most at risk of compromised bone health. By contrast, other submitters were of the opinion that whole milk should not be eligible because a health claim might encourage a greater consumption of milk containing saturated fat.

Several submissions were received indicating that dairy foods such as cheese, flavoured milk, standard yogurt and custard might not be eligible to make osteoporosis claims because of small serving sizes. The submitters argued that these foods are important sources of calcium for elderly people with small appetites, the very group to whom the osteoporosis claim is being targeted.

It was queried as to why two calcium claims were being proposed when they were covering the same topic.

A number of submitters suggested that the target age should be lowered because the indicator of osteoporosis used was fracture risk, a risk that is higher in the elderly than in younger age groups but other biomarkers of fracture risk, such as bone mineral density, are affected by calcium intakes at younger ages.

One submitter highlighted that other lifestyle factors have an important role in the risk of osteoporosis including exercise, smoking, caffeine and phosphorus consumption. Of particular note, was that vitamin D status must always be considered when making claims about calcium and osteoporosis.

There was also the suggestion that the bone health benefits of calcium intake continue after cessation of intake and that this should be considered in the context of the claim.

2.2.3 Preliminary Final Assessment Report – approach taken and submitter comments

Having regard to the submissions provided in response to the Draft Assessment Report, FSANZ lowered the minimum claimable amount of calcium per serve from 300 to 290 mg, an amount of calcium that would allow most whole milks to meet the calcium requirements of a health claim. In addition, the requirement that foods carrying this claim are 'claimable foods' was removed and replaced with the requirement that the foods meet the nutrient profiling scoring criteria. The other conditions remained the same.

Some submitters noted their support for the change in criteria for the high level health claim about calcium, vitamin D status and osteoporosis. However, one submitter noted that the criteria of 290 mg of calcium per serving will not allow claims on some small packs e.g. 150 g or 170 g yoghurt when these are in fact a suitable size for the elderly for whom this claim is intended.

2.2.4 Rationale for final decision

FSANZ is of the opinion that 290 mg calcium is the appropriate amount in a serving size of food in order for that food to carry an osteoporosis health claim. FSANZ does not consider it appropriate for foods containing smaller amounts of calcium to carry a claim because a small serving containing less than 290 mg calcium would require multiple servings of that food to be consumed in order to attain a clinically relevant calcium intake. Thus, a claim based on smaller amounts of calcium could be misleading.

For the calcium, vitamin D and osteoporosis claim, the draft Standard specifies the target population group as *persons* 65 years and over. Although the evidence for an effect on fracture risk has been substantiated in *women* over 65 years of age, few studies have included older men. Thus, the beneficial effect may apply to older men but this has yet to be confirmed and there is unlikely to be any added risk to older men from increasing their calcium intake through foods. In addition, FSANZ is aware that a claim targeted only at older women is restrictive to food manufacturers and a broader target population is preferable.

The food-disease relationship that has been substantiated is between the intake of calcium, vitamin D and osteoporosis. FSANZ has not substantiated a relationship between other lifestyle factors and osteoporosis; hence they are not included in the claim. FSANZ notes however, that the context for the claim is a healthy diet with a high intake of calcium from a variety of foods and adequate vitamin D status.

The recommendation that vitamin D status *must* always be considered when making the calcium and osteoporosis claim has not been adopted. FSANZ referred this recommendation to Professor Reid, Auckland University, (who undertook the review of calcium intake alone or in combination with vitamin D and risk of developing osteoporosis for FSANZ in 2005), for an update on evidence regarding the role of vitamin D. He notes widespread agreement that additional vitamin D is only of value when circulating levels of 25-hydroxyvitamin D are below a certain value whereas calcium alone is effective in reducing bone loss in older women.

The review of the food-disease relationship found only possible evidence for a high calcium intake at younger ages and reduced risk of fracture at an older age, and then only if the high intake is sustained. Thus, FSANZ does not agree with the proposition that the benefits of calcium intake to bone health have been substantiated at the level necessary to make a high level health claim about the continued benefits after cessation of intake.

It was queried as to why two calcium claims were being proposed when they were covering the same nutrient. The WHO defines osteoporosis on the basis of a low bone density and low bone density is a risk factor for fracture. Therefore, if a change in bone density with calcium intake has been substantiated this should also be sufficient to substantiate a claim around fracture risk and osteoporosis. FSANZ therefore considers that there is a sound basis for having two claims for calcium at different compositional levels and targeted at different population groups.

2.3 Calcium and enhanced bone mineral density

2.3.1 Decision

FSANZ recommends that a high level health claim is based on the pre-approved relationship between calcium and enhanced bone mineral density. The conditions for using this claim are:

- the food must contain at least 200 mg of calcium per serving;
- the food must meet the nutrient profiling scoring criteria except for foods standardised in Standards 2.9.2, 2.9.3 or 2.9.4; and
- the wording of the claim must:

    - include calcium (as the property of the food);
    - include reference to enhanced bone mineral density; and
    - be in the context of a healthy diet with a high intake of calcium from a variety of foods.

These conditions are outlined in the Table to clause 7 of the draft Standard.

2.3.2 Draft Assessment Report – approach taken and submitter comments

Conditions for this claim were proposed in the Draft Assessment Report. These included the requirement to state the 'general population' as the target population and the food carrying this claim must be a 'claimable food'. The wording conditions were the same as those outlined above.

There was support for the amount per serve required to make this health claim (200 mg of calcium). Submitters noted that this means that all types of milk and yoghurt and most hard and semi-hard cheeses will be eligible.

All other comments on this health claim received in response to the Draft Assessment Report have been presented in section 2.2.2 and responded to in section 2.2.4.

2.3.3 Preliminary Final Assessment Report

There were two minor changes to the drafting in the Preliminary Final Assessment Report – that the food must meet the new nutrient profiling scoring criteria (instead of being a 'claimable food') and the target population of the 'general population' was removed. There were no submitter comments about this claim.

2.3.4 Rationale for final decision

The specifications for this claim are less rigorous than those for the calcium, vitamin D and osteoporosis claim. A requirement for an adequate vitamin D status has not been specified nor has a target population. Professor Reid's review concluded that calcium alone has a beneficial effect on bone mineral density irrespective of vitamin D status and that this effect applies to a broad age range, particularly for women. He also noted that vitamin D is not an important dietary constituent in Australia and New Zealand with nearly all requirements being met by sunlight exposure.

The minimal compositional requirement of 200 mg calcium per serve qualifies for a good source claim. Professor Reid's review noted that as much as 1,500 mg per day were required to obtain beneficial responses in bone density. Thus, several serves of calcium rich foods per day are required to obtain this amount.

2.4 Folic acid and neural tube defects

2.4.1 Decision

FSANZ recommends that a high level health claim is based on the pre-approved relationship between folic acid and neural tube defects. The conditions for using this claim are:

- the food must contain at least 40 µg folic acid per serving;
- the food must meet the nutrient profiling scoring criteria except for foods standardised in Standard 2.9.3;
- the claim is not permitted on certain foods that are not recommended for consumption by pregnant women, for example soft cheeses; and
- the wording of the claim must:

    - include folic acid (as the property of the food);
    - include reference to reduced risk of foetal neural tube defects;
    - include that the claim is only applicable to women of child bearing age;
    - include 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
    - be in the context of a varied diet including food sources of folate.

These conditions are outlined in the Table to clause 7 of the draft Standard.

2.4.2 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 specified above except that the food had to contain no less than 65 μg folate and/or folic acid per serve and the wording of the claim had to include a recommendation that women consume at least 680 μg of dietary folate equivalents (DFEs) per day or 400 μg of folic acid per day, at least the month before and three months after conception.

One submitter highlighted that the health claim referred to folic acid but 'folate' and 'folic acid' were being used interchangeably in the draft Standard. The use of the term 'dietary folate equivalent' in the draft Standard was also adding to the confusion.

The prescriptive language of this health claim, its focus on a negative rather than a positive message, and the fact that it has not been widely adopted by industry to date, suggests that the wording of the claim should also be revised.

It was recommended that the claim be made within the context of a 'healthy diet' or a 'variety of foods' as required for all other high level health claims and as specified in the Policy Guideline.

Submitters suggested that the prohibition of products regulated under Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods from making this claim should be deleted as some products regulated under this Standard are marketed to pregnant women.

2.4.3 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report, the following changes were made:

- a food must comply with the new nutrient profile scoring criteria; previously the food must have met the disqualifying criteria; and
- the recommended amount of DFEs was amended from 680 DFEs per day to 670 DFEs per day. This amendment was a correction. The amount of folic acid recommended by the NHMRC and NZ Ministry of Health (2006) is 400 μg per day which equates to 670 μg of DFEs per day[5].

One industry submitter reiterated their recommendation of deleting the exclusion of products regulated under Standard 2.9.3 from making the folic acid neural tube defect claim.

It was noted that foods containing phytosterol esters or tall oil phytosterols should be excluded from making the claim; thus removing the need to update the Table to clause 7 if further permissions are granted in the future.

It was recommended that the claim be permitted to refer to either 670 μg of dietary folate or 400 μg of folic acid daily and that both these amounts not be required in a single label claim.

[5] 1 μg of folic acid with meals or as fortified foods = 1.67 DFEs, therefore 1.67 x 400 μg = 668 DFEs.

One industry submitter made comments regarding the general conditions for the folic acid high 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.

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

Changes since the release of the Preliminary Final Assessment Report include:

- the food must contain no less than 40 µg folic acid per serve; previously it referred to 65 µg folate and/or folic acid per serve;
- all foods containing phytosterol esters or tall oil phytosterols have been prohibited from making the claim rather than just those regulated under Standard 2.4.2; and
- the wording condition for a recommendation of 400 µg folic acid per day in the context of a varied diet was included; previously it had referred to DFEs without reference to overall diet.

2.4.5 Rationale for final decision

The reasons for the recommendation that the food must contain no less than 40 µg folic acid per serve are:

- The NHMRC and NZ Ministry of Health (NHMRC and NZ Ministry of Health, 2006) recommendation in relation to prevention of neural tube defects refers only to folic acid, not to natural folates or total folates expressed as DFEs.

- The FSANZ high level health claim review of this relationship only indicated a convincing' relationship with folic acid. In regard to natural folates, the evidence was not 'convincing' largely due to issues associated with quantifying the amount of natural folate consumed, bioavailability and stability, and lack of consistency in the results of the few studies that had examined the relationship.

- The NHMRC and NZ Ministry of Health (NHMRC and NZ Ministry of Health, 2006) recommendation, released after FSANZ's high level health claim review was completed, is for 400 µg folic acid per day. The condition that a food must contribute at least 10% of this (i.e. 40 µg per serve) is consistent with other aspects of the health claims standard. This amount is also seen as complementary to the recommendation that women consume a 400 µg folic acid supplement rather than relying totally on food fortified either voluntarily or mandatorily with folic acid; noting however, that 40 µg folic acid per serve is a larger amount (due to its greater bioavailability) than the current 40 µg folate per serve in Standard 1.1A.2.

- 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 qualifying criteria and using serving sizes recommended on product packaging, these breads, including heavy grain breads, meet the qualifying criteria to carry this claim.

The context of the claim to include 'a varied diet' has been amended to accord with the NHMRC and NZ Ministry of Health (2006) folic acid recommendation to prevent neural tube defects and is in keeping with the context of other high level health claims.

The claim is not permitted on foods that pregnant women are advised not to consume due to the risk to the unborn baby, such as soft cheeses and with unproven safety in the case of foods containing phytosterols. Thus, foods containing added phytosterols, such as margarines, have been prohibited from carrying the claim.

The rationale for each element of a high level health claim that must be included are described in Section 2.1. The wording requirements for this claim are less prescriptive than those under the Transitional Health Claims Standard which allows for more flexibility for industry. FSANZ notes that manufacturers may also prefer to use a less wordy general level health claim.

2.5 Saturated fatty acids and LDL cholesterol

2.5.1 Decision

FSANZ recommends that a high level health claim is based on the pre-approved relationship between saturated fatty acids and LDL cholesterol. The conditions for using this claim are:

- the food must meet the conditions for a *low saturated fatty acid* nutrition content claim;
- the food must meet the nutrient profiling scoring criteria except for foods standardised in Standards 2.9.2, 2.9.3 or 2.9.4; and
- the wording of the claim must:

    - include saturated fatty acids (the property of the food);
    - include reference to reducing blood cholesterol, or total blood cholesterol, or blood LDL cholesterol, or serum LDL cholesterol, or total serum cholesterol, or serum cholesterol levels; and
    - be in the context of a healthy diet with a variety of foods low in saturated fatty acids.

These conditions are outlined in the Table to clause 7 of the draft Standard. The conditions for a nutrition content claim in relation to *low saturated fatty acids* are outlined in the Table to clause 11 of the draft Standard.

2.5.2 Draft Assessment Report – approach taken and submitter comments

The conditions for this claim as proposed in the Draft Assessment Report have been retained, with the exception that the 'general population' as the target population has been removed. In addition, foods carrying this claim now need to meet the nutrient profiling scoring criteria rather than the disqualifying criteria.

Most submitters were supportive of the claim however, two submitters questioned the validity of the relationship and another suggested that LDL cholesterol was not the best predictor of cardiovascular risk but that consideration should be given to apolipoprotein B (Apo B).

A notable focus of submitter comments was on eligible foods. In particular there was concern that the claim was restricted to all low fat foods rather than allowing foods higher in unsaturated fats. This recommendation was made on the basis that LDL cholesterol reduction is greater when saturated fatty acids are replaced with unsaturated fatty acids. Similarly, some core foods, such as dairy foods, may not be eligible to make the claim because of their fat content.

In keeping with the concern about eligible foods, two submitters suggested a similar addition to the conditions for a nutrition content claim for low saturated fats. The recommendation states that the food contain as 'a proportion of the total fatty acids content, no more than 28% saturated fatty acids and *trans* fatty acids' as an additional alternative to the permitted upper amounts of saturated and *trans* fatty acids in liquid and solid foods (0.75 g per 100 mL and 1.5 g per 100 g, respectively).

There was also the suggestion that the target group, 'the general population', was not required.

2.5.3 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report it was proposed that the generic nutrient profiling scoring criteria would apply to this claim (replacing the 'disqualifying criteria'). The proposed condition that the wording of the claim applies to the general population was also removed.

One submitter highlighted that other lifestyle factors that influence LDL cholesterol, such as body weight and physical activity would add to the overall message and provide context. They also considered that lowering LDL cholesterol may not be appropriate for all age groups.

Another submitter reiterated the concern that fatty acid balance is more critical than the amount of fat in the diet, particularly in populations such as the elderly who are at greater risk of insufficient energy intake.

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

The claim statement (b) in column 3 of the Table to clause 7 (for saturated fatty acids and LDL cholesterol) has been changed from *the specific health effect is may help reduce blood cholesterol….*to *the specific health effect is reduction of blood cholesterol…* This change was made so that this claim statement is consistent with comparable statements for other high level health claims.

2.5.5 Rationale for final decision

The conditions for this claim as proposed in the Preliminary Final Assessment Report have been retained.

FSANZ is not intending to use the criterion of 'no more than 28% saturated fatty acids and *trans* fatty acids as a proportion of the total fatty acids content' for this claim, although it was considered as a criterion for nutrition content claims in the Consultation Paper released in December 2007. FSANZ would however, consider additional compositional criteria for this health claim if an Application was made to amend Standard 1.2.7 (refer to chapter 25 in Attachment 5).

The food-disease relationship that has been substantiated is between the intake of saturated fatty acids and plasma concentrations of LDL-cholesterol. FSANZ has not validated plasma Apo B concentration as a biomarker for coronary heart disease or substantiated a relationship between food intake and plasma Apo B concentrations. FSANZ has also not substantiated the impact of other lifestyle factors.

No target population has been specified for this claim. The review of this food-disease relationship included a large number of studies across the age spectrum including several studies involving children and adolescents. There was a consistent dose-response relationship across all age groups.

2.6 Saturated and *trans* fatty acids and LDL cholesterol

2.6.1 Decision at final assessment

FSANZ recommends that a high level health claim is based on the pre-approved relationship between saturated and *trans* fatty acids and LDL cholesterol. The conditions for using this claim are:

- the food must meet the conditions for a *low saturated and trans fatty acid* nutrition content claim;
- the food must meet the nutrient profiling scoring criteria except for foods standardised in Standards 2.9.2, 2.9.3 or 2.9.4; and
- the wording of the claim must:

    - include saturated and *trans* fatty acids (the property of the food);
    - include reference to reducing blood cholesterol, or total blood cholesterol, or blood LDL cholesterol, or serum LDL cholesterol, or total serum cholesterol, or serum cholesterol levels; and
    - be in the context of a healthy diet with a variety of foods low in saturated and *trans* fatty acids.

These conditions are outlined in the Table to clause 7 of the draft Standard. The conditions for a nutrition content claim in relation to *low saturated and trans fatty acids* are outlined in the Table to clause 11 of the draft Standard.

2.6.2 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report, the majority of submitter comments related to both the saturated and *trans* fatty acid claims. Hence comments have been presented in section 2.5.2 on the saturated fatty acids and serum LDL cholesterol claim.

It was suggested that the relationship between *trans* fatty acids and LDL-cholesterol should be limited to manufactured sources rather than to total *trans* fatty acids comprising manufactured and naturally-occurring trans fatty acids.

There was also the concern that FSANZ had assumed that intakes of *trans* fatty acids in Australia and New Zealand were low despite little evidence for this.

2.6.3 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report it was proposed that the generic nutrient profiling scoring criteria would apply to this claim. The proposed condition that the wording of the claim applies to the general population was also removed.

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

The claim statement (b) in column 3 of the Table to clause 7 (for saturated and *trans* fatty acids and LDL cholesterol) has been changed from *the specific health effect is may help reduce blood cholesterol….*to *the specific health effect is reduction of blood cholesterol…* This change was made so that this claim statement is consistent with comparable statements for other high level health claims.

2.6.5 Rationale for final decision

The conditions for this claim as proposed in the Preliminary Final Assessment Report have been retained.

In relation to the recommendation to consider only manufactured sources of *trans* fatty acids, the authors of the review commissioned by FSANZ identified a limitation in the evidence base noting that some of the studies did not distinguish clearly between vegetable and animal sources of *trans* fatty acids, however, 'consistency of the findings suggests that the association is a genuine one'. Thus, the evidence on which the relationship was substantiated included some studies in which naturally-occurring *trans* fatty acids were present. A differential effect on blood lipids of consuming 'manufactured' or 'natural' *trans* fatty acids was not established.

FSANZ conducted a formal scientific review of *trans* fatty acids in the food supply and reported back to the Australia and New Zealand Food Regulation Ministerial Council in May 2007. FSANZ estimated that Australians obtain only 0.6 per cent of their daily energy intake from *trans* fatty acids and New Zealanders only 0.7 per cent. Because mean intakes in Australia and New Zealand are similar to those in the referent group in cohort studies or the control group in experimental studies examining the effects of *trans* fatty acids, it is not clear whether there would be changes in health outcomes if intakes decrease.

Hence the applicability of the relationship examined to the Australian and New Zealand population is uncertain and so a claim that mentions *trans* fatty acids without mention of saturated fats was not approved.

2.7 Sodium and blood pressure

2.7.1 Decision

FSANZ recommends that a high level health claim is based on the pre-approved relationship between sodium and blood pressure. The conditions for using this claim are:

- the food must meet the conditions for a 'low salt' nutrition content claim;
- the food must meet the nutrient profiling scoring criteria except for foods standardised in Standards 2.9.2, 2.9.3 or 2.9.4;
- the wording of the claim must:

    - include sodium or salt (the property of the food);
    - include reference to maintenance of normal blood pressure or reduced blood pressure;
    - include reference to the general adult population; and
    - be in the context of a healthy diet with a variety of foods low in salt or sodium.

These conditions are outlined in the Table to clause 7 of the draft Standard. The conditions for a nutrition content claim in relation to *low salt* are outlined in the Table to clause 11 of the draft Standard.

2.7.2 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 specified above except that the property of the food included just *sodium* and the context is a healthy diet with a variety of foods low in *salt*.

One submitter contended that there is insufficient evidence to support this claim and that experts remain divided on the potential public health benefit of decreasing sodium intake. Other submitters disagreed, stating that there is sufficient evidence to support this food-disease relationship, although the relationship may not apply to those with normal blood pressure.

Some submitters questioned the criteria and conditions stipulated for the proposed claim. In particular, comments were submitted about the disqualifying criteria (now referred to as nutrient profiling scoring criteria) proposed in the Draft Assessment Report. Submitters provided examples of certain foods that would not be able to make the claim because of the proposed disqualifying criteria, such as whole milk. It was also suggested that consideration should be given to the effect of the whole food.

One submitter suggested that the target audience for the claim be extended to the general population, not just the general adult population, and that other factors that are associated with blood pressure other than sodium are included in the context (e.g. intakes of fruit and vegetables, potassium, and alcohol, as well as body weight and physical activity).

2.7.3 Preliminary Final Assessment Report – approach taken and submitter comments

In the Preliminary Final Assessment Report it was proposed that the generic nutrient profiling scoring criteria would apply to this claim rather than the disqualifying criteria. The proposed conditions for the wording of the claim were also amended to permit the property of the food and the dietary context to contain reference to either salt or sodium. In the Draft Assessment Report the proposed wording had required reference to sodium as the property of the food but the wording of the claim had to be in the context of a healthy diet containing a variety of foods low in salt.

One submitter expressed their continuing concern that other dietary and lifestyle factors also influence blood pressure and adding these would add context to the claim.

2.7.4 Rationale for final decision

The conditions for this claim as proposed in the Preliminary Final Assessment Report have been retained.

Concerns were raised that claims could not be made on whole milk because its saturated fat content would exceed the disqualifying criteria for health claims. Using the nutrient profiling scoring criteria system, it would be expected that most regular full fat milk would be eligible to carry this health claim.

The review commissioned by FSANZ noted that other lifestyle factors also contribute to blood pressure control but the conclusion was restricted to an assessment of the strength of the evidence for lowering sodium intake on blood pressure response. As a result, FSANZ has retained the focus of this claim to sodium and blood pressure. All the studies included in the review were undertaken on adults; hence the 'general adult population' has been retained as the target group.

Although the review examined sodium exposure and was not restricted to salt; 'salt' or 'sodium' can be used interchangeably within the wording of the claim. The nutrition content claim conditions, which this claim must meet however, align with the food-disease relationship and refer to total sodium from all sources (sodium naturally present, salt and sodium containing additives).

2.8 Increased intake of fruit and vegetables and coronary heart disease

2.8.1 Decision

FSANZ recommends that a high level health claim is based on the pre-approved relationship between *increased* intake of fruit and vegetables and coronary heart disease. The conditions for using this claim are:

- the food must meet the nutrient profiling scoring criteria except for foods standardised in Standards 2.9.2, 2.9.3 or 2.9.4;
- the claim is not permitted on fruit juice or vegetable juice standardised under Standard 2.6.1 or beverages standardised under Standard 2.6.2;
- the food must contain a minimum of 90% fruit or vegetable by weight;
- the claim is permitted on dried fruit and dried vegetables; and
- the wording of the claim must:

    - include reference to reduced risk of coronary heart disease; and
    - be in the context of a healthy diet with an *increased* intake of both fruit and vegetables and consisting of a variety of foods.

These conditions are outlined in the Table to clause 7 of the draft Standard.

2.8.2 Preliminary Final Assessment Report – approach taken and submitter comments

This claim was first proposed in the Preliminary Final Assessment Report. In the Preliminary Final Assessment Report, the compositional and wording conditions for the dietary context for this claim were the same as those specified above except for the following:

- the claim was not permitted on fruit juice; vegetable juice was permitted; and
- the claim statement must state vegetables before fruit.

There were numerous submissions about the fruit, vegetable and coronary heart disease health claim. Generally submitters were supportive of the claim, particularly as it accords with existing public health messages, although one submitter questioned the conclusions in the FSANZ commissioned review. The majority of concerns related to foods that would be excluded from using this claim.

There were concerns that the minimum of 90% by weight of fruit and/or vegetables excludes many mixed foods that would be good sources of fruit and/or vegetables (e.g. soups). To overcome this, one submitter suggested that an additional alternative to the specification by weight be 'two serves or more of fruit and/or vegetables per serve of food'. Two submitters also questioned why fruit juice was excluded, particularly as technologies exist to ensure the juice is nutritionally comparable with the whole fruit.

Other submitters were concerned that there needed to be tighter restrictions around the foods that would qualify (e.g. powdered foods derived from fruit and vegetables; vegetable juice; dried fruit).

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

Changes since the Preliminary Final Assessment Report was released include:

- vegetable juice (as well as fruit juice) and other fruit-based beverages are not permitted to make the claim; and

- the condition to refer to ‘vegetables’ before ‘fruit’ in the claim statement has been removed.

2.8.4 Rationale for final decision

The Scientific Advisory Group who assessed the report concluded that there was a ‘convincing’ level evidence of a relationship between dietary fruit and vegetable intake and risk of coronary heart disease. This conclusion was based on evidence of a consistent relationship between coronary heart disease morbidity and mortality and fruit and/or vegetable intake from 12 good quality prospective cohort and retrospective case-control studies. It was noted that the dose-response effect varied, although this was most probably due to inconsistent measures of fruit and vegetable intake between studies. These findings are supported by several randomised controlled studies using blood pressure and lipid levels, which are validated biomarkers for heart disease, as the outcome.

Although there is a consistently reduced risk for those in the highest consumption group compared with the lowest consumption group, there is some variation in the results for those with moderate intakes. In some studies, those with moderate intakes have the same degree of risk reduction as those in the highest intake groups, while in other studies those with moderate intakes have a smaller degree of risk reduction than those with the highest intakes. This variation may be partly related to different levels of consumption in the various groups studied. Therefore, FSANZ considers there is no basis for specifying a minimum number of serves in the claim statement. However, to ensure the claim is not misleading to consumers the food must consist predominantly of fruit and/or vegetables (i.e. a minimum of 90% by weight).

In the FSANZ commissioned review, intake of specific fruits and/or vegetables was not distinguished sufficiently to identify a relationship between specific fruits and/or vegetables, such as nuts, and coronary heart disease outcomes.

FSANZ has not assessed a food-disease relationship for fruit and/or vegetables and cancer, hence the claim statement relates only to reduced risk of coronary heart disease.

Fruit and vegetable juices (and drinks containing fruit and vegetable juices) are not permitted to make the claim because the evidence from the cohort and case control studies was largely based on serves of fruit and vegetables; only a small number of studies considered additional juice intake. Dried fruit and vegetables are permitted to make the claim because these are considered nutritionally comparable to fresh fruit and vegetables.

2.9 High intakes of fruits and vegetables and coronary heart disease

2.9.1 Decision

FSANZ recommends that a high level health claim is based on the pre-approved relationship between a *high* intake of fruit and vegetables and coronary heart disease. The conditions for using this claim are:

- the food must meet the nutrient profiling scoring criteria except for foods standardised in Standards 2.9.2, 2.9.3 or 2.9.4;

- the claim is not permitted on fruit juice or vegetable juice standardised under Standard 2.6.2 or non-alcoholic beverages and brewed soft drinks standardised under Standard 2.6.2;
- the food must contain a minimum of 90% fruit or vegetable by weight;
- the claim is permitted on dried fruit and dried vegetables; and
- the wording of the claim must:

    - include reference to reduced risk of coronary heart disease; and
    - be in the context of a healthy diet *high* in both fruit and vegetables and consisting of a variety of foods.

These conditions are outlined in the Table to clause 7 of the draft Standard.

2.9.2 Preliminary Final Assessment Report – approach taken and submitter comments

This claim was first proposed in the Preliminary Final Assessment Report. In the Preliminary Final Assessment Report, the compositional and wording conditions for the dietary context for this claim were the same as those specified above except for the following:

- the claim was not permitted on fruit juice; vegetable juice was permitted; and
- the claim statement must state vegetables before fruit.

Submitter comments to this claim have been summarised in section 2.8.2 about the claim for fruit, vegetables and coronary heart disease.

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

In the Preliminary Final Assessment Report the substantiated food-disease relationship was stated as *A diet rich in vegetables and fruit and coronary heart disease.* Since *diet* is not included in the definition of health claim it should not be mentioned as the subject of a high level health claim. Consequently, the wording has been changed to *A high intake of fruit and vegetables and coronary heart disease*.

2.9.4 Rationale for final decision

The rationale for the changes to this claim is described in section 2.8.4.

While subtly different, two fruit, vegetable and coronary disease heart claims have been made because the evidence supports both. As the evidence has established an inverse relationship between fruit and/or vegetable intake and coronary heart disease, increasing consumption of fruit and/or vegetables reduces the risk and the higher the intake the greater the risk reduction. The review did note however, that there is some indication of a threshold effect beyond which additional intake does not reduce risk. In Australia for example, very few people are estimated to consume high intakes of fruit and vegetables and few consume the recommended two serves of fruit and five serves of vegetables per day; hence claims for both ‘increased’ intakes and a ‘high’ intake of fruit and vegetables to reduce the risk of coronary heart disease are applicable.

3. NON-APPROVED FOOD-DISEASE RELATIONSHIPS

FSANZ's rationale for non-approval of two food-disease relationships as proposed in the Preliminary Final Assessment Report is summarised in this section. Full details of FSANZ's consideration of the two relationships are provided at Attachment 5 of the Preliminary Final Assessment Report[6].

3.1 Wholegrains, bran and coronary heart disease

3.1.1 Preliminary Final Assessment Report – summary of FSANZ's conclusion and submitter comments

In the Preliminary Final Assessment Report, FSANZ advised that the evidence was 'not convincing' to support a high level health claim for wholegrains, bran and coronary heart disease. This differed from the conclusions drawn by the author of the FSANZ commissioned review who considered that the evidence supported a protective effect of wholegrains and bran against coronary heart disease. A summary of FSANZ's rationale is as follows:

- the definition of wholegrain was ill-defined in many of the studies assessed and in some cases dietary fibre intake, which included sources other than wholegrains, was the exposure variable assessed;
- there was inadequate control of confounding variables in many of the studies leading to the conclusion that a 'healthy' diet rather than wholegrains and bran are associated with reduced risk of coronary heart disease; and
- results from studies considering consumption of oats and barley, which are high in soluble fibre, could not be generalised to wheat, which is low in soluble fibre and the primary type of wholegrain eaten in Australia and New Zealand.

There were numerous submitter comments to FSANZ's conclusion of this food-disease relationship.

Several submitters disagreed with FSANZ's recommendation not to pre-approve this relationship and requested that this conclusion be reconsidered. They felt that the FSANZ commissioned review provided a 'convincing' level of evidence for a relationship between wholegrains, bran and coronary heart disease. In particular, that the prospective studies included in the review showed convincingly that whole grain consumption protects against coronary heart disease in a dose-response manner with overall reductions of 20-30%. Several submitters urged FSANZ to consider the findings in a meta-analysis published since the review was completed (Mellen *et al*., 2007) which reported that consumption of at least 2.5 servings of wholegrains per day was associated with a 21% reduction in the risk of cardiovascular events compared to the consumption of just 0.2 servings per day.

Several comparisons were made with the evidence that was found to be convincing for the fruit and vegetables and coronary heart disease claim; in particular that the lack of a link with biomarkers of wholegrain or bran consumption and coronary heart disease is similar to that for fruit and vegetables and coronary heart disease.

[6] http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp293nutritionhealthandrelatedclaims/index.cfm

Some submitters recommended that FSANZ consider the relationship between types of fibre (soluble fibre) and cardiovascular disease, soy protein and heart disease/cholesterol, and soluble fibre and heart disease, as these types of claims have been thoroughly reviewed and are permitted in countries where health claims are allowed to be made on foods.

3.1.2 Rationale for final decision

FSANZ notes the submitter comments in response to the Preliminary Final Assessment Report but has not changed its decision to not permit a high level health claim for wholegrain, bran and coronary heart disease based on the rationale provided in the Preliminary Final Assessment Report.

FSANZ has reviewed the additional paper provided by submitters (Mellen *et al*., 2007) and its findings do not change our decision. Six of the seven studies covered in the additional paper had been reviewed by the SAG which thought that the definition of wholegrain was ill-defined in the studies and may have included fibre derived from non-wholegrain sources. The seventh study, published after the SAG met, had cardiovascular disease as its outcome and so examined a different outcome from the topic of the review.

As noted above, there was some experimental data linking validated biomarkers of heart disease (blood pressure and cholesterol) to fruit and vegetables. By contrast, the biomarker studies examined in the wholegrain review found an association only with soluble fibre, but not for insoluble fibre. High level health claims must be relevant to the population of Australia and New Zealand. As wheat is the predominant wholegrain that would carry a wholegrain claim if it were permitted, and wheat contains insoluble fibre, the biomarker data do not support an association for wheat.

The relationships selected for assessment to underpin high level heath claims were based on the dietary guidelines and intended to be generalisable to the food supply and not favour a single food, such as oats. Although there is considerable overlap, a review of wholegrain and coronary heart disease would not cover exactly the same ground as a review of soluble fibre and coronary heart disease. It was not clear to the SAG that the commissioned review of wholegrains had included all studies (i.e. the totality of evidence) of soluble fibre and so no conclusions around soluble fibre were drawn.

Following gazettal of the Standard, those interested in soluble fibre, (such as oats and barley) could compile a dossier in accordance with the *Application Handbook* and submit an application on this topic.

3.2 Long chain omega-3 fatty acids and cardiovascular disease

3.2.1 Preliminary Final Assessment Report – summary of FSANZ's conclusion and submitter comments

In the Preliminary Final Assessment Report, FSANZ advised that the evidence was 'probable' to support a high level health claim for long chain omega-3 fatty acids and cardiovascular disease. This differed from the conclusions drawn by the authors of the FSANZ commissioned review. A summary of FSANZ's rationale is as follows:

- While the primary evidence for this food-disease relationship is derived from good quality randomised, controlled secondary prevention trials (i.e. involving subjects who already have cardiovascular disease) there is insufficient evidence to link long chain omega-3 fatty acids to the primary prevention of cardiovascular disease.

- The secondary prevention results relied mainly on one large study. Smaller studies disagreed with the large study regarding the timing of the onset of the effect. This was particularly relevant given that the hypothesised mechanism was a reduction in sudden death. It was noted that the large study was being repeated and the results had not yet been reported. As it was theoretically possible that the results of the new study could overturn the previously reported results, the SAG thought that 'probable' was a better description of the degree of certainty of the relationship, rather than 'convincing'.

- The potential physiological mechanisms (such as reduced heart rate variability) associated with increased consumption of long chain omega-3 fatty acids have not been validated as biomarkers of cardiovascular disease and therefore could not be used to substantiate a high level health claim.

- Although there was conclusive evidence for a small effect on lowering blood pressure (validated biomarker for cardiovascular disease), the amount of long chain omega-3 fatty acids consumed from food sources by Australians and New Zealanders would have to increase dramatically to initiate an effect.

There were numerous submitter comments about FSANZ's conclusion of this food-disease relationship. Most notable were several submissions that disagreed with FSANZ's recommendation not to pre-approve this food-disease relationship. They generally felt that the FSANZ commissioned review provided a 'convincing' level of evidence for this food-disease relationship. Some submitters considered that FSANZ's SAG did not have the expertise in this particular field to adequately assess the evidence and FSANZ had not adequately expressed its rationale for its final conclusions in the Preliminary Final Assessment Report.

While the evidence was found not to be 'convincing' for a high level health claim, several submitters expressed their support for the general level health claim. By contrast, some submitters considered that a general level health claim should not be permitted if the high level health claim was not substantiated.

The NHMRC and NZ Ministry of Health (2006) recommendation to increase long chain omega-3 fatty acid intake to reduce the risk of chronic disease was noted by some submitters. It was recommended that FSANZ review this relationship, and one for fish and cardiovascular disease, within two years as the evidence is continuing to emerge.

3.2.2 Rationale for final decision

FSANZ notes the submitter comments in response to the Preliminary Final Assessment Report but has not changed its decision to not permit a high level health claim for long chain omega-3 fatty acids and cardiovascular disease.

FSANZ is aware of general public dietary advice to increase long chain omega-3 fatty acid intake but considers that this advice does not necessarily indicate that a food-disease relationship has been substantiated.

Although there is overlap between the topic area of fish consumption and cardiovascular disease and the area of omega-3 consumption and cardiovascular disease, it was not apparent to FSANZ that the commissioned review included all studies of fish consumption and cardiovascular disease (i.e. the totality of evidence). Therefore no claim around fish has been approved. Following gazettal of the Standard, those interested in this area could compile a dossier in accordance with the *Application Handbook* and submit an application on this topic.

4. REFERENCES

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