

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

**Summary of submissions received in response
to the Consultation Paper**

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1. CLAIMABLE FOOD CRITERIA OR NUTRIENT PROFILING SCORING CRITERIA FOR CLAIMS ABOUT VITAMINS AND MINERALS

Submitter	Group	Comments
ADECRON Food Tech Consulting Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> Absolutely in favour of Option 3. Consistent approach. This should also include special purpose foods standardized under standard 2.9 as applicable. Nutrient Content Claims per serving now consistent and the change will get rid of Clause 8 with its blend calculations for permitted claims. General level health claims should indeed be subject to the NPSC. This change is better for generating healthy innovative foods than the prescriptive Claimable food categories. Makes it very clear that permission to claim is NOT permission to add!
Australian Food and Grocery Council (AFGC)	Industry (Australia)	<ul style="list-style-type: none"> Supports FSANZ's recommendation that nutrition content claims not be subject to any food vehicle eligibility criteria. Supports the FSANZ recommendation as an interim measure until such times as a review of Standard 1.3.2 and the adoption of new Nutrient Reference Values is undertaken, and notes that FSANZ has stated that it is not intended to review which foods, i.e. 'claimable foods', may be fortified. Notes this will then perpetuate the confusion as to the rationale as to why certain foods may be fortified. It is 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 the NPSC. Concerned that general structure-function statements about a nutrient would be prohibited on claimable foods which do not meet NPSC requirements. Rejects the premise that certain foods, such as cheese, edible oils and spreads, are 'bad' and should be prevented from making claims. Many of such foods are consumed in only small quantities and provide a source of nutrients as part of a total balanced diet. Food intended to be eaten in conjunction with other foods and in small quantities, such as Vegemite or malt extracts, can provide good source of vitamins or minerals. As FSANZ has identified this provides a consistent approach with other nutrients and biologically active substances which the AFGC commends. Is also consistent with the principles proposed by FSANZ for using general level health claims not included in the list of pre-approved claims. Opposes the application of NPSC as a basis for permitting health claims. The use of nutrient profiling systems which impose nutrient qualifying and disqualifying criteria derived from population dietary advice onto individual food products is scientifically flawed.
Australian Nut Industry Council (ANIC) and Nuts for Life	Industry (Australia)	<ul style="list-style-type: none"> Supports option 3.

Submitter	Group	Comments
Australia Self Medication Industry (ASMI)	Therapeutic (Australia)	<ul style="list-style-type: none"> • Supports option 3. • Agrees with FSANZ’s rationale on nutrient profiling. However, adds that a food should already be inherently healthy before it can make a health claim / claim on vitamin and mineral content.
Bayer Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports option 2. • This option appears to give consistent risk management for health claims by ensuring that food are of appropriate nutritional content in line with national public health priorities. • Suggests further measures to strengthen Option 2. • A mandatory statement relating to consumption as part of a balanced diet whenever nutrient and health claims are made; • Cautionary statements when over-consumption of a particular nutrient may cause harm; and • Applying nutrient content claim criteria to macronutrients and biologically active substances. There are no permissions for such substances. • Option 3 will allow claims to be made on foods that are not consistent with national health priorities e.g. potato chips if they contain more than 10% of a nutrient.
Cadbury Schweppes Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 3. • Also supports that in order to make a content claim for vitamins and mineral there needs to be a minimum of 10% of the RDI per serve. • Clarification is ought that under this proposal all foods listed in the Table to Clause 3 of Standard 1.3.2 would continue to be able to be fortified with Vitamins and Minerals as set out in the Table and that a corresponding nutrition content claims could be made. However, a general level health claim could only be made if the food then complied with the Nutrient Profiling Scoring Criteria.
Campbell Arnott’s Asia Pacific	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports option 3. • Also supports FSANZ on general level health claims where all general level health claims would be subject to the same scientifically-based substantiation process, and the claimable food requirements is removed fro claims about vitamins and minerals. • Does not support Option 2 hybrid approach. This option will confuse consumers by inconsistently applying nutrition related claims criteria and potentially deny consumers additional information bout the nutritional status of the foods they consume.
The Cancer Council Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Does not support any of the proposed options. • Suggests an alternative option of applying the NPSC to all claims (nutrient content, general level, and high level). • Explicitly opposes option 3. • Understands the need for as much simplicity as possible in the standard. For this reason, the NPSC should apply to all types of claims. A single system would ensure there is consistency and clarity. • Not aware of any evidence that general level health claims have a different influence on consumer behaviour than nutrition content claims.

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		<ul style="list-style-type: none"> Concerned that many consumers would reasonably assume that all food making nutrition or health claims are meeting general health criteria.
Cereal Partners Worldwide (CPW)	Industry (Australia)	<ul style="list-style-type: none"> Supports Option 3 for content claims but do not support the application of the NPSC for general level health claims. The impact would be significant. Questions if industry would support vitamin and mineral addition to foods when potentially no nutrient function claim could be supported. This could lead to a reduction of vitamin and minerals intake of the population. Believes the NPSC limits industry ability to be innovative. Thinks consumers will be confused should these claim and supporting information just disappear.
Cerebos Foods	Industry (Trans Tasman)	<ul style="list-style-type: none"> Supports Option 3 (rationale included in submission) Supports removal of claimable foods for general level health claims but does not support the replacement with the NPSC. Believes the NPSC is flawed when applied to individual products and created boundaries between products, making good and bad foods when overall diet is more important.
Chamber of Commerce & Industry WA	Government (Australia)	<ul style="list-style-type: none"> Supports the removal of claimable foods criteria for foods carrying nutrition content claims. Believes nutrition and general level health claims should be exempt from the NPSC providing that the nutrient, substance or property of the claim can be scientifically substantiated.
CHOICE	Consumer (Australia)	<ul style="list-style-type: none"> Preferred approach is to replace the claimable food approach with the NPSC and extend its application to all nutrition content claims as well as general level health claims. Believes that the rationale for the development of the current claimable food concept – that claims made in relation to vitamins and minerals are used only on foods that are consistent with healthy eating guidelines – justifies this approach. It is vital that a situation where consumers are led to believe that otherwise unhealthy foods are healthy because they contain some vitamins and minerals is not created. Failing that, second preference is to apply the NPSC to nutrition content and general level health claims about vitamins and minerals. This maintains the existing rationale that claims made in relation to vitamins and minerals are used only on foods that are consistent with healthy eating guidelines, but prevents any confusion and inconsistencies that may arise if the claimable food criteria and NPSC exist concurrently. Does not support proposed Option 3. This approach ignores the existing rationale that claims made in relation to vitamins and minerals should only be used on foods that are consistent with healthy eating guidelines. Believes that this principle should underpin the entire nutrition, health and related claims Standard and justifies the application of the NPSC to foods carrying nutrition content claims. CHOICE would not support any regulatory option that eliminates the need for products making such claims to satisfy either claimable food criteria or NPSC. Believes it is more important to retain the current claimable food approach than to remove it for the sake of consistency.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • A number of public health and nutrition organizations and experts have also supported the application of the NPSC to products carrying nutrition content claims. Despite this, FSANZ continues to dismiss these calls on the basis that there is no evidence that consumers are misled by nutrition content claims on unhealthy foods. • CHOICE is aware that FSANZ recently conducted consumer research into the use and interpretation of some nutrition content claims on foods, and participants' intent to purchase products carrying nutrition content claims. A summary of this research and its findings was presented at the SDAC meeting on 31st October 2007. A number of SDAC members raised concerns about the validity of the research particularly as the findings appear to suggest that consumers would be less likely to purchase a product carrying a nutrition content claim over a product that did not carry a claim. • This is at odds with the currently industry practice, not to mention logic and commonsense. Based on this research, the use of nutrition content claims are used widely on food labels and in marketing. • At the time, FSANZ reported that the research was undergoing peer review by behavioural scientists from the US Food and Drug Administration and CSIRO-Human Nutrition, as well as a statistician. • To the best of CHOICE's knowledge, this research has not been released to the public. Until such time as this research is released to the public, following peer review, we question the extent to which FSANZ can rely on this research to inform its decision not to apply the NPSC to foods carrying nutrition content claims.
Commonwealth Scientific and Industrial Research Organisation (CSIRO)	Research and Academia (Australia)	<ul style="list-style-type: none"> • Supports Option 3. • This Option allows consistency with non vitamin/mineral content claims, and allows legitimate claims regarding nutritional composition to be made on food products which currently are unable to do so.
Comvita	Industry (New Zealand)	<ul style="list-style-type: none"> • Supports Option 3.
Confectionery Manufacturers of Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports Option 3.
Consumers NZ	Consumer (New Zealand)	<ul style="list-style-type: none"> • Supports Option 2. • This will ensure that claims made in relation to vitamins and minerals are used only on foods that are consistent with healthy eating guidelines, and that there is consistency in the food vehicle eligibility criteria approach for health and nutrition claims about all nutrients. • Does not support proposed Option 3. Under this option, any product can make claims about vitamins or minerals, regardless of whether it is healthy or unhealthy. This practice is already common in the breakfast cereal market where high energy, high sugar cereals make vitamin and mineral claims and mislead consumers into thinking they are healthy.
Dairy Australia	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 3. • Holds the view that most cheeses, regular fat milk with added functional ingredients and standard yoghurts should be eligible to make nutrition content claims and general level health claims about vitamins and minerals.

Submitter	Group	Comments
Dairy Farmers	Industry (Australia)	<ul style="list-style-type: none"> Does not indicate a preferred option. Does not support Option 3.
Department of Agriculture, Fisheries and Forestry (DAFF)	Government (Australia)	<ul style="list-style-type: none"> Does not indicate a preferred option. Considers that the overlap with Standard 1.3.2. – Vitamins and Minerals should be further examined. FSANZ proposes to remove the requirement for content and general level health claims made about vitamins and minerals to be subject to the ‘claimable food’ eligibility criteria. This suggested change goes some way to reducing inconsistencies within the proposed Health Claims Standard. However, in the absence of a review of Standard 1.3.2, this proposed change will create a discrepancy between the permissions to fortify foods with vitamins and minerals and the permissions to make general level health claims on these foods. Standard 1.3.2 will allow ‘claimable foods’ to be fortified but many ‘claimable foods’ will not meet the nutrient profile model and will, therefore, not be allowed to make general level health claims.
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> Rejects the proposed option. Proposes two alternative options for nutrition content claims: <ol style="list-style-type: none"> Retain claimable foods criteria for vitamins and minerals as set out in Standard 1.3.2 and extend food criteria to other biologically active substances. This places some protection around appropriateness of foods to be fortified, whether by vitamins or minerals or other substances. The preferred option is to have all content claims and general level health claims subject to NPSC. FSANZ’s conclusion that there is no consumer influence conveyed by the use of content claims is evidently flawed when considered in light of the wide use of these types of claims by the food industry. Unpublished studies from New Zealand, as well as previous research, have concluded that content claims have a ‘halo’ effect on foods, particularly for consumers who have low incomes and/or English as a second language.
Department of Health & Human Services Tasmania	Government (Australia)	<ul style="list-style-type: none"> Concerned by the potential for inconsistent public health messages where food of otherwise limited nutritional value may promote the presence of ten percent of the Recommended Daily Intake of a vitamin or minerals which being high in saturated fat, salt or sugar; nutrients which are recommended to be reduced. There is no evidence that the removal of claimable foods will have a positive impact on the public’s health. Consumers may misinterpret nutrient content claims (Andrews et al 1998). When favourable nutrition information or health claims are presented, consumers have more favourable attitudes toward the product, nutrition attitudes, and purchase intentions (Kozup et al 2003). Self-reported use of nutrition labels and claims is common in New Zealand and Australia, but actual use and understanding appears limited (Ni Mhurchu and Gorton 2007). Available evidence suggests that consumers who do look at nutrition labels can understand some the terms used but are confused by other types of information (Cowburn and Stockley 2005). Lack of understanding is one of the reasons Maori, Pacific and low income New Zealander’s rarely use nutrition labels (Food Standards Australia New Zealand 2003; Signal et al 2008). Consumer research supported by Food Standards Australia New Zealand indicates that consumers have trouble interpreting nutrition claims (Food Standards Australia New Zealand 2003; Roy Morgan Research 2003).

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Removing the claimable foods criteria would allow a wider range of foods to carry vitamin and mineral content claims. There are indications that promotion of vitamins and minerals content claims may confuse consumers as to the overall nutritional profile of the foods. • Findings from recent FSANZ research on consumer use of content claims around fat, salt and sugar were not consistent with trends in other published research. Concerned that the proposal to remove claimable foods from vitamin and mineral content claims is based on survey data that is not publicly available and has not yet been validated. • Recognises the enforcement concerns associated with different criteria for general level health claims and nutrition content claims and therefore supports the use of NPSC and the removal of claimable foods criteria for food making general level health claims about vitamins and minerals for consistency. • Also supports NPSC for vitamins and minerals, and other content claims on ‘biologically active substances’ such as non-culinary herbs for consistency with the intent of promotion of healthy food choices to consumers. The science underpinning vitamin and mineral claims is well established. The level of substantiation for biologically active substances is less rigorous. Under the current proposal the presence of the substance is sufficient to be able to make content claims that may infer benefits or mislead consumers as to the level present or the potential benefit. • Would prefer to see the retention of claimable foods for vitamins and mineral content claims and extension of claimable foods to other ‘biologically active substances’ rather than no criteria. Given that there are some inconsistencies within claimable foods, this provision could be refined with the review of vitamins and minerals to consider the inclusion of Nutrient Reference Values in the Food Standards Code. • While claimable foods is an imperfect tool, it provided some protection to consumers. It would result in less impact on industry as current vitamin and mineral content claims would continue to be permitted in the current form.
Department of Human Services - Victoria	Government (Australia)	<ul style="list-style-type: none"> • Supports the removal of the claimable food criteria for vitamin and mineral general level health claims, given all foods carrying general level health claims must meet the NPSC. The NPSC are superior to the claimable food criteria and will ensure consistency across all health claims. • Does not believe there is sufficient information available to respond to the issue of changing the conditions around content claims for vitamins and minerals. In order to support the removal of the claimable food criteria from content claims, Victoria needs to be confident that the measures in place will provide an adequate safety net to ensure these do not contradict national nutrition policies. • Understands that foods permitted to be fortified will remain unchanged, and vitamins and minerals will be permitted to be added only to those foods list in Standard 1.3.2. Therefore the changed criteria for content claims would be relevant only for those foods with ingredients high in vitamins and minerals. • Concerned that the removal of the 90% primary food criterion will enable content claims on foods not consistent with dietary guidelines. Envisage that calcium and vitamin C may be of greatest concern through the addition of whey powder or fruit.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Requests dietary modelling be undertaken to determine which foods (specifically confectionery, desserts and high energy snack foods and drinks) will be eligible to make vitamin and mineral content claims if the claimable food criteria is removed, in order to ensure that the requirements for fortification and the 10% RDI requirement provide an adequate safety net. • Acknowledges the consumer research quoted by FSANZ but disagree it shows consumers do not attribute a health benefit to content claims. The research did not assess any content claims involving vitamins and minerals. By contrast there is both Australian and international research that indicate that consumers do attribute a health benefit to vitamin and mineral content claims. • This issue also raises significant inconsistencies with substances other than vitamins and minerals (SOVM). There are currently no provisions in the Food Standards Code for SOVM. Policy guidelines are in the process of being. There needs to be a consistent approach with vitamins and minerals and SOCM in terms of foods permitted to have SOVM added, and the minimum amounts required to enable a content claim. Victoria supports the planned review of Standard 1.3.2 and the development of a standard for SOVM as a priority to address these inconsistencies.
Dietitians Association of Australia (DAA)	Public Health (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. • There are limitations with both Options 2 and 3 as presented in the proposal. • Given the lack of evidence related to consumer understanding of nutrition content claims related to vitamins and minerals, DAA considers that the risks of Option 3 are greater than the risks carried by Option 2.
Fonterra Co-operative Group Ltd	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports Option 3. • Comments that many foods able to make general level health claims under previous P293 renditions (i.e. claimable foods) will no longer be eligible. • States that NPSC is not perfect as does not allow core food groups (e.g. nuts and cheese), would like this addressed but prefers a system that allows for innovation and new food categories without the need to apply for food category recognition in the Food Standards Code and in doing so risk competitive advantage. • Comments that the current legislation is silent in relation to general level health claims and that many manufacturers are making these responsibly and without challenge from enforcement agencies.
Food and Beverage Importers Association (FBIA)	Industry (Australia)	<ul style="list-style-type: none"> • Does not state a preferred option. Comments suggest support for Option 3. • The Association supports removing the claimable food criteria for claims about vitamins and minerals so that there are no food vehicle eligibility criteria for foods carrying nutrition content claims, including claims about vitamins and minerals. • The 'claimable foods' approach is antiquated, unduly complex and prevents accurate, substantiated statements about the actual vitamin or mineral content being made about some categories of food.
Food Technology Association of Australia (FTA)	Industry (Australia)	<ul style="list-style-type: none"> • Favours Option 3. • The NPSC as currently envisioned is still not satisfactory and needs further consideration. A better system needs to be devised.

Submitter	Group	Comments
Frucor Beverages Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> • Supports Option 3. • Clarification is sought from FSANZ as to whether the removal of the 'claimable food' criteria from Standard 1.3.2 will also mean that this condition for nutrition content claims is revoked from the other Standards in the Code.
George Weston Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 3.
Glycemic Index Ltd	Industry (Australia)	<ul style="list-style-type: none"> • As detailed in previous submissions on P293 from GI Ltd, there is a lack of evidence to prove that consumers understand nutrition content claims. While FSANZ has undertaken more detailed consumer research in this area over the past 6 months, this has not been released for independent scrutiny, and as such its validity is undetermined. Therefore, GI Ltd believes that based on the evidence before it, all nutrition content claims, like all other components of the health claims continuum, should be required to meet the NPSC. • While GI Ltd acknowledges the irregularities in the current system of 'claimable foods', it believes the current safeguards are better than having none at all. GI Ltd therefore supports Option 2.
Go Grains Health and Nutrition Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. • Supports the principle that nutrition content claims about vitamins and minerals are not subject to food eligibility criteria. However, does not support the principle that general level health claims about vitamins and minerals are subject to the NPSC. • Propose that general level health claims about vitamins and minerals should remain subject to the 'claimable foods' requirement until such time as this can be reviewed in the context of the Nutrient Reference Values (NRVs) and the overall issue of fortification. • If vitamin and mineral claims become subject to the NPSC, there is the potential for significant adverse outcomes for consumers which could include: <ul style="list-style-type: none"> – A reduction in the number of voluntarily fortified foods available (especially breakfast cereals), as the incentive to fortify is diminished; – Substantially less nutrition information available on pack; and – Consumers are likely to suspicious about why foods that have carried nutrition information for many years suddenly no longer do so.
Goodman Fielder Home Ingredients	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 3. • Does not support the application of the NPSC to general level health claims. • Considers that if a food contains sufficient amounts of a nutrient or nutritive substance, irrespective of whether that food has been fortified or the nutrient is naturally present, a nutrition content claim AND a structure function claim should be permitted. • Concerned that statements such as 'calcium is important for healthy bones and teeth' would be considered a general level health claim and prohibited on claimable foods which do not meet NPSC requirements.

Submitter	Group	Comments
Heinz Wattie's Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports Option 3. • Believes that this is a positive step in removing excessive criteria and enabling a level playing field for making nutrition content claims on products that contain a sufficient amount of a nutrient or nutritive substance. • With the removal of claimable food criteria, Heinz Wattie's supports the use of the NPSC to determine eligibility.
Horticulture Australia Ltd (HAL)	Industry (Australia)	<ul style="list-style-type: none"> • Supports FSANZ's preferred approach (Option 3).
Innovations & Solutions – Wendy Morgan	Industry (Australia)	<ul style="list-style-type: none"> • Supports the FSANZ preferred Option 3 (a): no food eligibility criteria for foods carrying nutrition content claims (NCC) on vitamins and minerals. • This is consistent for requirements for other nutrients and bioactive substances. Also, the restrictions on the addition of vitamins and minerals remain limited to specific foods. • Does not support either of the options (1) or (2). Limiting general level health claims to 'claimable' foods when all foods are permitted to claim vitamins and minerals (if Recommendation 1 above is implemented) unfairly discriminates against foods with a significant vitamin/mineral content which are not in the 'claimable' foods category. The Table which lists 'claimable' foods in Standard 1.3.2 is an arbitrary listing of foods which has expanded in an <i>ad hoc</i> manner as applications are received from FSANZ. Limiting general level health claims to foods which meet the NPSC provides an artificial distinction between foods which does not take account of the net nutritional value of each food. Additionally, guidance for diets as a whole has been applied to individual foods. This is inappropriate as some foods may be rich in a positive nutrient (e.g. calcium) and a nutrient in excess (e.g. sodium) which can be counterbalance by other foods in the diet which are low in both sodium and calcium and potentially higher in another nutrient. • Option 1 (a) and (b) is satisfactory only in the short term if there is to be a review of Standard 1.3.2 in the near future as it unfairly limits true and useful information on vitamins and minerals. The 'claimable foods' criteria should be extended to include all foods which contain a significant amount of vitamins and/or minerals. • Currently many 'claimable foods' are only permitted to claim maximum amounts of vitamins and minerals based on a 'reference quantity'. The proposed new Standard 1.2.7 refers to 'serves'. Foods with smaller serving sizes than their 'reference quantity' will need to add more vitamins or minerals to be eligible for a NCC. However, maximum claims are based on 'reference quantities'. Also, in general, foods with serving sizes smaller than the reference quantity currently in the marketplace will need to increase the content of vitamins and or minerals to meet a requirement for both reference quantity and serving size to meet at least 10% RDI. This seems an unnecessary imposition.

Submitter	Group	Comments
International Chewing Gum Association	Industry (International)	<ul style="list-style-type: none"> • Supports Option 3 in that chewing gum could carry nutrition content claims. • Support removing claimable foods for general level health claims but concerned over the possibility that the NPSC may be applied to chewing gum bearing such claims. NPSC are based on the amounts of ‘undesirable’ nutrients per 100 g of product, this is inappropriate for foods consumed in small quantities, such as chewing gum, that if can not supply an ‘unhealthy’ amount of energy, saturated fat, sugar, or sodium. • Suggest exempting chewing gum from the NPSC – concerned that tooth whitening chewing gum will not pass and not be able to carry a general level health claim pertaining to the products’ verified dental benefits. • If FSANZ does not agree with the request for a categorical exemption for chewing gum, suggest a specific exemption allowing products otherwise disqualified under NPSC to still bear a general level health claim if one serving contains less than 1 % of the DI per serving of the ‘disqualifying’ ingredient. Request a mechanism for requesting case-by-case exemptions from the NPSC requirements.
Kraft Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> • As indicated in previous submissions, in favour of the removal of all requirements against food eligibility criteria for nutrition content claims and thus on the point relating specifically to nutrition content claims supports FSANZ’s Option 3. • Believes that it is in the consumers’ interest that all foods are able to make nutrition content claims. Where Kraft differs on Option 3 is that this principle should also be extended to general structure function claims related to nutrients highlighted in nutrition content claims. • Continues to oppose the concept of the NPSC determining eligibility for general level health claims. The NPSC which FSANZ are proposing are fundamentally flawed as it is not based in science and does not consider dietary intake. The system is subjective rather than objective. The evaluation is based on 100 g of the food regardless of normal serve size, i.e. a bread spread or salad dressing which are normally consumed in small quantities are treated exactly the same way as, for example, an entire pasta meal. Further, it does not consider the role of the food in the diet, so chocolate (an indulgent treat) is considered same way as bread (a daily staple). The shortcoming arises from treating individual foods as if they are sole contributors to a diet. • The proposed system thus results in the unequal treatment of certain foods. This has been clearly demonstrated in the impact assessment performed by FSANZ and we question why FSANZ continues to move down the path of proposing the NPSC as a disqualifying factor. • Under the proposed NPSC, Vegemite, an Australian national icon, would not be permitted to make claims about the benefits of the vitamins it contains. Kraft Foods cannot see any benefit to the consumer on this. Vegemite historically had a major role in providing needed vitamin B during World War II and continued beyond this when good nutrition was scarce. To this day it continues to play a role in the diet of Australians, including contributing folate to assist Government programmes to minimize Neural tube Defects. The reason for disqualification of Vegemite under the NPSC is the sodium level, driven by the fact that the assessment is against 100 g, where the recommended and typical serving size of Vegemite is 5 g.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Kraft Foods currently fortifies a range of processed cheese with vitamin D to assist with calcium absorption. It has recently been noted that doctors are becoming concerned about the vitamin D status of many Australians, so Kraft Foods is assisting in addressing these concerns. Under the NPSC disqualification model, a number of these cheese products would not be able to make general level health claims in the form of nutrient function information thereby denying the consumer valuable information on the benefits of the micronutrients.
Murray Goulburn Co-operative Co. Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports FSANZ's preferred Option 3(a). • Do not support the use of the NPSC in the form presented in the draft Standard which indicates that only a minority of cheese types and modified regular milk products would be eligible to carry general level health claims. • Supports Dairy Australia in that most cheeses, and regular fat milk with added functional ingredients should be eligible to make nutrition content claims and general level health claims in relation to vitamins and minerals (as milk and cheese are specifically included in the Australian Dietary Guidelines).
National Centre of Excellence in Functional Foods (NCEFF)	Research and Academia (Australia)	<ul style="list-style-type: none"> • Presents the following positions: • There is value in the existing claimable foods criteria because it privileges primary foods. • There are considerable limitations in relying entirely on a NPSC because it only privileges current knowledge on nutrients at the expense of the food and diet matrix, however : • The current knowledge on nutrients can be categorized as translating to health effects that may be positive (e.g. prevents deficiency, so single foods can contribute in the total diet), or negative (e.g. excess linked to disease, so the amount of these nutrients needs to be limited in the total diet) • Based on a history of safe use, primary foods could be privileged over reconstructed foods as the source of delivery of nutrients of both categories and therefore should not be subjected to the NPSC values in the same way as reconstructed foods. For example, the NPSC values could be used to differentiate categories within primary food groups, but not to disqualify them. • Given that primary foods are also imperfect, and have been reformulated in ways that appear to support health (e.g. low fat milk), there could be inclusions and exclusions of foods within the categories of primary foods. • The whole system relies on continuous uptake of new knowledge from nutrition science, so should remain dynamic as such. • There could be some direction for the development of reconstructed foods based on health principles relating to the provision of positive nutrients and the limitation on those where excess in the total diet is problematic. <p>Recommended approach:</p> <ul style="list-style-type: none"> • Retain claimable food criteria as proposed in the Draft Assessment report and Preliminary Final Assessment report <i>plus</i> foods carrying nutrient content and general level health claims must meet the NPSC unless they are claimable foods.

Submitter	Group	Comments
National Foods Limited	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports the principles behind Option 3, but rejects the Option in its current form. • Supports the removal of the ‘claimable food criteria’ but oppose the need for foods wanting to carry a general level health claim to comply with the NPSC. • Considered cheese may not qualify. • In supporting the removal of the ‘claimable foods’ criteria, National Foods requests the opportunity to comment on the drafting of any proposed revisions to this Standard and/or the Vitamins and minerals Standard 1.3.2.
The National Heart Foundation of Australia	Public health (Australia)	<ul style="list-style-type: none"> • Supports Option 3 • This option has the benefit of promoting consistency in that it aligns the risk management approach for claims about nutrition content and general level health claims about all nutrients thereby lessening confusion for industry, consumers and enforcement regarding conditions for making claims. • It has the intent of addressing the current inequity for nutrition content claims about vitamins and minerals compared with macronutrients and biologically active substances. • It allows a food which contains a claimable amount of vitamin and mineral to declare it. • However, this option has the potential to allow claims about vitamins and mineral on suboptimal nutritious foods which may mislead vulnerable, consumers who have limited nutrition awareness or ability to interpret NIPs. • This option has the potential for content claims to continue to be used as a marketing tool, especially with respect to vitamins and minerals implying benefits for consumers.
The National Heart Foundation of New Zealand	Public health (New Zealand)	<ul style="list-style-type: none"> • Supports Option 2 (Hybrid), to help prevent vitamin or mineral and general level health claims appearing on some foods that are inconsistent with food and nutrition guidelines. • This option has the potential to exclude some foods of poor nutritional quality from making vitamin and mineral claims, thus helping to protect some of the more ‘vulnerable’ members of society who have limited nutrition awareness or ability to interpret NIPs. • While the Heart Foundation sees the benefit of promoting consistency for claims about nutrition content and general level health claims about all nutrients it believes neither options 1 or 3 provide sufficient ‘screening’. This screening should prevent nutrition or vitamin or mineral claims appearing on some foods that are inconsistent with food and nutrition guidelines. • Acknowledges while option 2 had it’s limitations (an inconsistent approach, potentially less incentive for industry to reformulate some foods in a direction consistent with food and nutrition guidelines and the ‘claimable’ foods list is not ideal and is out of date), this option potentially holds the most benefit for public health.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Considered recommending an amendment to option 2 so it would read (a) <i>foods carrying nutrition content claims must meet the NPSC</i>; (b) <i>foods carrying general level health claims must meet the NPSC</i>. However, it was felt this option would potentially hinder innovation and product redevelopment (e.g. the manufacturer of a cereal bar with more fibre or a potato chip with reduced levels of saturated fat and salt may not be able to communicate these attributes to the consumer and therefore possibly not make those positive changes to the product's nutritional profile as there would be no marketing advantage in doing so). • Also considered recommending a further option that would read (a) <i>foods carrying nutritional content claims must be 'claimable foods'</i>; (b) <i>foods carrying general level health claims must meet the NPSC</i>. However, it was felt this was not an appropriate option as it would exclude some products, e.g. edible oils and margarines, from making any form of nutrition claim, yet allow a product such as Coco Pops to make a source of fibre claim.
Nestle Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. • Supports the removal of eligibility criteria for vitamin and mineral nutrient content claims. • If a food contains a sufficient amount of a nutrient or nutritive substance, irrespective of whether the food has been fortified or the nutrient is naturally present, a nutrition content claim should be permitted. • Does not support the application of the NPSC to general level claims on vitamin and minerals. • The food industry may not support vitamin and mineral additions to food where potentially no nutrient function claims could be made. This could lead to a significant reduction in the contribution of these foods to the vitamin and mineral intake of the population. • There is potential for consumer confusion where vitamin and mineral information had been present on foods and associated material, and then silently disappears. • The NPSC also limits the ability for the food industry to innovate and differentiate their foods on the market.
New South Wales Centre for Public Health Nutrition	Public health (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. • Believes a stricter set of criteria than the claimable food criteria, such as the NPSC, should be applied across the board (i.e. for all claims). • Cites previous peer reviewed publications that have demonstrated that nutrition content claims and health claims do indeed affect consumer behaviour. The effect of nutrition content claims in relation to vitamins and minerals on consumers' choice, however, remain unknown. • While there is acknowledgement of the need for consistency in regulation of the health claim, they believe disqualifying criteria provides a better safeguard from potentially misleading claims, and consider that the current suggestions by FSANZ, i.e. no disqualifying criteria at all for nutrition content claims, is a retrograde movement. • Prefers the NPSC over the claimable food criteria as it would lead to consistency.
New Zealand Dietetic Association (NZDA)	Public Health (New Zealand)	<ul style="list-style-type: none"> • Supports Option 2. • Support is conditional on applying the claimable food criteria to all nutrition content claims (suggests modifying (a) of the Option to read 'foods carrying nutrition content claims must be 'claimable foods').

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Considers that Option 3 carries greater risk for the proliferation of foods inconsistent with the NZ Food and Nutrition Guidelines and healthy dietary patterns carrying nutrition claims, and thus increases potential for a negative impact on health. • NZDA is concerned that, without a vehicle eligibility framework applying to nutrition content claims, there is substantial potential for industry to exploit the frivolous addition of nutrients and/or biologically active substances as a marketing tool. This would increase the potential for added public confusion over nutrient claims and counter claims. • FSANZ states that consumer research indicates that additional risk management for nutrition content claims is not needed. However, the survey referenced was limited to questions about fat, fibre, and sugar content. Only 320 survey respondents were from New Zealand inevitably resulting in a low number of Maori and Pacific respondents. Sixty-one respondents in the total sample identified as indigenous thus research should not be considered to reflect the point of view of Maori and Pacific people, both high need New Zealand population groups.
New Zealand Food and Grocery Council	Industry (New Zealand)	<ul style="list-style-type: none"> • Does not indicate a preferred Option. • Supports the recommendation that nutrition content claims not be subject to food vehicle eligibility criteria. This would mean the removal of the ‘claimable food’ requirement in respect of vitamins and minerals. • Does not support the recommendations that all general level health claims, whether about vitamins, minerals, micronutrients or biologically active substances, be subject to NPSC. Supports the removal of the claimable food requirements from general level health claims concerning vitamins and minerals. • The application of the NPSC perpetuates the categorization of foods as ‘good’ and ‘bad’ which conflicts with the principle that it is the consumption of a balanced diet that is all important. • The requirement of applying NPSC will fetter many manufacturers from making general level health claims.
New Zealand Food Safety Authority (NZFSA)	Government (New Zealand)	<ul style="list-style-type: none"> • NZFSA supports an amended Option 3: <i>Amend claimable food approach (remove claimable food criteria):</i> <ul style="list-style-type: none"> (a) <i>foods carrying nutrition content claims must meet the NPSC;</i> (b) <i>foods carrying general level health claims must meet the NPSC.</i> • Support the removal of ‘claimable food’ criteria for nutrition content claims (as per option 3) and therefore having the same criteria applied to vitamins and minerals as to other properties of the food. ‘Claimable food’ is an outdated classification method and is empirical, not science based. However, they agree with the Ministry of Health’s view that option 3 as proposed by FSANZ will allow content claims to be made on energy dense-nutrient-poor foods without any disqualifying criteria. This approach alone is inconsistent with national guidelines for healthy eating and is not in the best interests of public health. Therefore in addition to removing the claimable food criteria, NZFSA support the addition of a requirement that foods carrying any nutrient content claims (including vitamins and minerals) meet the NPSC.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Reviews of published and unpublished research clearly show that consumers associate content claims with health benefits, which indicates that consumers do not understand the distinction between nutrition content and health claims (Ni Mhurchu and Gorton 2007, Williams 2005). Of greater concerns is the recent, soon to be published, research by Auckland University that suggests the majority of New Zealanders misinterpret nutrition content claims, with low income groups more likely to inappropriately believe that content claims imply the food is healthy.
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> • Does not support Option 3. • States that this approach would allow vitamin and mineral content claims to be made on energy dense-nutrient-poor foods without any disqualifying criteria. As such, this approach is inconsistent with national guidelines for healthy eating. • Strongly supports an option that amends the claimable food approach for vitamins and minerals provided some eligibility criteria are retained for content claims. • The preferred approach is to replace the claimable foods criteria for vitamins and minerals with NPSC for nutrition content and general level health claims. • Also recommends that the NPSC apply to all content claims, particularly where specific conditions are not outlined in the Table to clause 11. • If the option above is not possible NZ Ministry of Health prefers Option 1, as it is preferable to have some nutritional criteria on vitamin and mineral nutrition content claims than none at all. • Reviews of published and unpublished research clearly show that consumers associate content claims with health benefits, which indicates that consumers do not understand the distinction between nutrition content claims and health claims.
NSW Food Authority	Government (Australia)	<ul style="list-style-type: none"> • Does not support the removal of ‘claimable foods’ criteria from nutrition content claims. Is concerned that applying the NPSC to general level health claims for vitamins and minerals may place an unjustifiable burden on small business. • Requests FSANZ consider the progress and drivers of the review of the UK nutrient profiling system that is currently taking place. Concerned that key criticisms of the UK system are in the NPSC, i.e. the use of standard serving size for claims eligibility and the potential for foods to be ‘engineered’ into eligibility based on protein content (e.g. chicken nuggets). Concerned that the NPSC may encourage excess addition of artificial sweeteners and fat substitutes to food, with the unintended consequence of promoting the ‘engineering’ of special purpose foods above the consumption of regular food as part of a balanced diet. • Does not consider vitamin and mineral claims to be equivalent to claims relating to macronutrients (e.g. protein). Notes that the policy guideline for the voluntary fortification of foods with vitamins and minerals requires that permissions do not promote increased consumption of foods high in salt, sugar or fat. Considers that a vitamin C content claim on a packet of crisps to be inconsistent with this requirement due to its large serving size (approx. 50 g).

Submitter	Group	Comments
		<ul style="list-style-type: none"> Notes that the current claimable foods criteria allows margarine to make nutrition content claims with respect to fat soluble vitamins, however is less concerned as the serving size of these foods is much smaller (approx. 5 g) and the market is rapidly moving towards fat reduced spreads. Concerned with the application of the NPSC to general level health claims relating to vitamin and mineral content. Supports the intent of the NPSC but concerned small business may not be able to determine if their food complies and will label it anyway to avoid losing market share. Suggests an on-line tool similar to that used for nutrition information panels.
New Zealand Beef and Lamb Marketing Bureau	Industry (New Zealand)	<ul style="list-style-type: none"> Agrees with Option 3 for the inclusion of all foods being eligible to carry nutrition content claims. Reservations still exist about only foods meeting the NPSC being able to carry general level health claims. This will disadvantage certain consumers for whom a generic 'healthy' diet is inappropriate. Those who have special or increased dietary needs may not be able to recognize valuable sources of nutrients because foods are excluded. It is not clear from Table 1, which cuts of meat are affected. 'Leaner' and 'fattier' descriptors are not adequate and further clarification is necessary. The proposed criteria also have the potential to exclude foods widely acknowledged as being part of a healthy, balanced diet, thus confusing consumers by giving mixed messages.
New Zealand Commerce Commission	Government (New Zealand)	<ul style="list-style-type: none"> Does not specify a preferred option. Supports the option that best prevents consumer confusion and enables consumers to make informed decisions based on accurate and meaningful information. Queries why all nutrition content claims are not subject to profiling criteria. Consumers are likely to perceive a food as being healthy where it claims to have a particular substance of attribute.
Nu-Mega Ingredients Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> Supports Option 3 – no food eligibility criteria for foods carrying nutrition content claims. All foods which contain a significant amount of a nutrient or biologically active substance should be able to provide this information. Does not support foods carrying general level health claims to have met the arbitrary NPSC. Supports a system which encourages the use of scientifically substantiated general level health claims which do not mislead consumers. A scoring system which takes account of only a few nutrients and foods required for a healthy, balanced diet has the potential to mislead consumers. The selection of nutrients is also questionable. Not all protein is beneficial as some are rich in amino acids and their breakdown products have been shown to cause DNA damage. Fats in the NPSC are only referenced by saturated fatty acids, yet there are many types of fatty acids which offer negative (e.g. <i>trans</i> fatty acids) or positive physiological effects (e.g. long chain omega-3 fatty acids such as DHA). Supports the application of current conditions for use of omega-3 fatty acid nutrition content claims (Standard 1.2.8 Clause 13) to the new Standard and these should be used as the minimum conditions of use for general level health claims making a scoring criteria system redundant for these claims.

Submitter	Group	Comments
Obesity Policy Coalition	Public Health (Australia)	<ul style="list-style-type: none"> • Supports Option 1. • All types of nutrition content and health claims should only be permitted in relation to foods consistent with healthy eating guidelines. • Concerned about FSANZ’s proposal for removal of the ‘claimable food’ requirements from nutrition content claims for vitamins and minerals so that such claims would not be subject to any kind of food vehicle eligibility criteria. • Query FSANZ’s comment that risk management is not needed for nutrition content claims. Note that this comment is based on consumer research which FSANZ has not published and which stakeholders cannot access. • This research must be considered in light of published consumer research, which has shown that nutrition content claims may induce positive biases towards products, including ‘halo effects’ and ‘magic bullet effects’. • Concerned that some foods that are able to carry nutrition content claims under the existing claimable food requirements (e.g. high sugar breakfast cereals) and agrees that consistency in risk management of claims is desirable. Therefore, nutrition content claims as well as health claims should be subject to NPSC. • FSANZ has not provided sound rationale for separate risk management strategies for nutrition content claims and general level health claims. Cites research showing that nutrition content claims and general level health claims produce similar consumer behaviour, and that consumers do not distinguish between nutrition content, nutrition function and general level health claims.
Parmalat Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 3 but considers it unjust that some general level health claims will no longer be allowed under the NPSC. • Believes the NPSC should be modified to enable products such as milk with omega-3 and other whole milk products to pass. • Suggests a transition period of 2 years plus stock-in-trade provision apply to accommodate products currently complying with claimable foods.
The Public Health Association of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Does not agree with any of the options put forward by FSANZ. • Proposes an alternative option that requires all food carrying nutrition content claims to meet the NPSC. This is justified by: <ul style="list-style-type: none"> – concern regarding the limited evidence provided that consumers are not confused between nutrition content and general level health claims; – nutrition content claims have an implied health claim via limited consumer nutrition knowledge; – concerning lack of knowledge around safe levels of intake of other substances (e.g. such as ginkgo biloba) which are also classed as nutrients in the proposed standard; – providing consistency with all other claims; – providing better consistency with dietary guidelines and nutrition policies.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • The food industry can already make nutrition content claims in the nutrition information panel on any food, thus can inform the consumer without the unnecessary persuasion of front-of-pack marketing which can be used to heavily promote poor dietary choices. • 10% of the RDI is a very easily attainable standard for making a nutrition content claim. • Should FSANZ not accept this alternative option, as a minimum suggest the retention of the concept of ‘claimable foods’ within decision-making processes. This concept is one of the few remaining provisions within the food regulatory system that helps to protect the nutrient integrity of the food supply and hence it is a proactive risk management approach for guiding decisions associated with food composition and/or labelling. Also recommend the claimable foods system is reviewed and expanded to include substances other than vitamins and minerals (e.g. ginkgo biloba).
Queensland Health	Government (Australia)	<ul style="list-style-type: none"> • Does not support any of the 3 options given by FSANZ. Their position is that the best interests of public health nutrition would be served if NPSC applied to all foods carrying claims (nutrient content and health claims). This would be consistent with the Policy guidelines- Specific order policy principles- For voluntary fortification. • However, they recognise that this raises a number of practical issues and therefore suggest the following option: <ul style="list-style-type: none"> – Retain claimable food criteria for content claims for vitamins and minerals and extend to cover content claims for substances other than vitamins and minerals that are added for a health benefit. – Remove claimable food criteria from general health claims and require all foods making general health claims to comply with the NPSC. • Such an approach will still provide a level of protection to consumers reducing the potential for them to be misled about the nutrient profile of the food, and allow the use of ‘low’, ‘reduced’ claims with respect to fat, sugar, salt, etc without claim criteria (unless these foods also have claims in relation to added substances). This will maintain the incentives for industry to innovate and improve the nutritional profile of foods and not result in additional costs to manufacturers who are currently adding vitamins and minerals to foods. • Currently the nutritional profile of some of the claimable foods is not ideal. However some of the high fat foods such as margarines are consumed in small servings. Many of the high sugar claimable foods such as breakfast cereals currently carry nutrient function claims. Under the proposed nutrition and health claims standard these will need to be reformulated in order to continue to carry these claims. • Strongly believes that Option 3 as recommended by FSANZ is not consistent with the intent of Standard 1.3.2 or with the intent or policy guidelines for nutrition, health and related claims. • The intent of Standard 1.3.2 is to allow vitamin and mineral content claims only on foods made from 90% primary foods or foods on the specified list. This prevents foods with ingredients naturally high in vitamins and minerals from making claims unless they are essentially primary foods.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Removing the claimable food criteria for addition of vitamins and minerals will allow the use of content claims on energy dense-nutrient poor foods such as potato crisps, cakes etc if their ingredients contain sufficient vitamins and minerals. This could make these products more attractive to consumers promoting consumption patterns inconsistent with health eating guidelines. This is not consistent with the policy guideline on nutrition, health and related claims. • For these reasons, believe that claimable food criteria should be applied to substances other than vitamins and minerals which are added for health benefits. Currently there are no standards to regulate the addition of substances other than vitamins and minerals to foods. Acknowledge that a policy guideline with respect to the addition of substances other than vitamins and minerals to foods is in the process of development. However there is no guarantee that this will result in the development of a standard or standards to regular such additions. Currently there is nothing to stop manufacturers adding biologically active substances to energy dense-nutrient poor foods and making a content claim to advertise their presence. • FSANZ has justified Option 3 on the basis that their research on consumers indicates that consumers do not attribute health benefits to content claims and therefore additional risk management for nutrition content claims is not needed. However this research did not consider foods with content claims about vitamins and minerals. Vitamins, minerals and other biologically active components are positive additions of nutrients to foods and their presence is likely to be interpreted differently to the removal of macronutrients such as fat and sugar. It is clear from the type of marketing about the vitamin and mineral content of food that industry regards content claims as a major marketing advantage.
Sanitarium Health Foods	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports that nutrition content claims not be subject to any food vehicle eligibility criteria • Recognises that some strategic changes to 1.3.2 are needed not to prevent it clashing with the health claims standard. • It seems logical that food products containing sufficient amounts of nutrients or nutritive substances should be able to highlight their presence. • Supports a consistent approach with other nutrients and biologically active substances. • Care should be taken to ensure that foods currently outside of Standard 1.3.2 are not advantaged in terms of the range and quantity of vitamins and minerals about which they could make a claim. What can be added, the maximum claim conditions and claim provisions of standard 1.3.2 should continue to apply until the standard is formally reviews. • It should be made clear that claims for naturally occurring vitamins and minerals should be able to be made irrespective of whether the product category is listed in Standard 1.3.2 or not.
Simplot Australia Pty. Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports option 3, this is consistent with the approach for other nutrients and biologically active substances

Submitter	Group	Comments
Dr. Rosemary Stanton	Public Health (Australia)	<ul style="list-style-type: none"> • Does not agree with FSANZ’s preferred Option 3. • Considers the NPSC should be used for all health claims, including content claims. This should replace the current system of claimable foods. If FSANZ decides against this approach, next preference is to extend the claimable foods criteria for all nutrients, using the claimable food criteria as listed as footnote 1 on page 5 of the Consultation Paper. This would prevent products containing more than 10% added sugar or fat from making vitamin/mineral content claims. However, the definition for claimable food would also need to include a cut-off point for sodium content as occurs with the NPSC. • A number of previous submissions from consumer and public health groups have noted the problems of omitting disqualifying criteria from nutrition content claims. No explanation has come from FSANZ as to why these submissions have been rejected. • There is little evidence that the public understands differences between general and high levels claims or how nutrition content claims differ from other healthy claims about food. • The consumer research conducted for FSANZ and presented to the Standard Development Advisory Committee in October 2007 had illogical and quite unbelievable findings, including claims that consumers would be less likely to purchase a food that had a nutrition content claims. The public is entitled to believe that any health claims, including nutrient content claims would only be made on foods that are generally compatible with definitions of a ‘healthy’ food. This requires a regulatory framework that does not permit claims for added minerals and vitamins or other nutrients to appear on foods that do not fit with the principles contained in the Dietary Guidelines for Australians. • The idea the disqualifying criteria should only apply to foods that make a ‘high level’ claim is not logical to the public and could also be inconvenient for industry. The definition of a ‘high level’ claim is a categorisation that has been defined by FSANZ but is neither known or logical to the general shopper. The shoppers however, would assume that claims on food packaging and in advertisements are controlled by some authority which would be acting in the consumers’ interests. • Allowing claims for mineral or vitamin content only on claimable foods has not prevented such claims on foods high in components incompatible with the Dietary Guidelines.
Tomox Pty Ltd (Susan Thompson, Consultant Dietitian)	Industry (Australia)	<ul style="list-style-type: none"> • Notes there is merit in simplifying the Code but not at the risk of confusing consumers. • Questions whether FSANZ has evidence on how consumers view vitamin and mineral claims. Notes America research has shown that parents have a high regard for vitamins and minerals when choosing food for children. E Sloan ‘The top 10 Functional Food Trends: the next Generation’. Food Technology 2005 56 (4) 32-57. • It is important for general health to be sure that promotion of vitamin and mineral content in a less healthy food choice does not inappropriately enhance the food or beverage’s appeal. • Concerned that option 3 (NPSC) limits the ability of some basic foods to make health claims, e.g. nutrient dense foods such as regular cheese and flavoured milks.

Submitter	Group	Comments
Unilever Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports option 3. • Does not support the inclusion of the NPSC for general level health claims on vitamins and minerals as part of this option. • The proposed NPSC system is an arbitrary system and this will have the effect of preventing truthful statements about food content and the function of the relevant components in the body, as part of a healthy diet. • In transitioning across to a different basis for vitamin and mineral nutrition content claims, there are liable to be certain complexities and it is essential to understand the planned drafting and implementation for this change, in order to be able to adequately assess its impact. Therefore, they support this proposal, pending viewing of the proposed drafting. • If the proposed change and also the flow-on effect to nutrient function claims were to proceed, there needs to be an adequate transition.

2. CRITERIA FOR NUTRITION CONTENT CLAIMS ABOUT SATURATED FATTY ACIDS AS A LOW PROPORTION OF THE TOTAL FATTY ACIDS CONTENT

Submitter	Group	Comments
Australian Self Medication Industry (ASMI)	Therapeutic (Australia)	<ul style="list-style-type: none"> • Supports option 2. • This option provides an appropriate level of information for consumers to make informed decisions.
Bakers Delight	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 2. • This modification will allow wholegrain/nut/seed breads that are high in unsaturated fats to also highlight the proportionally low saturated fat content. • This is not currently possible with the <1.5g saturated fat per 100g criteria. • Expresses concern that the wording of the claim ('low proportion of saturated fatty acids of total fatty acid content') will be confusing for consumers. Bakers Delight recommends that different wordings be trialled to see which one is the most understood by consumers.
Bayer Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports option 2

Submitter	Group	Comments
Campbell Arnott's Asia Pacific	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports option 2. • This will allow meaningful information on products with healthier fatty acid profiles and encourage more informed consumer choice. • Does not support Option 3. Foods with a fat content below the 30g threshold would be unable to make claims regarding the nutritional benefits of the oils present while a similar food with over 30g would be able to make such claims. It may also encourage an increase in the fat content of foods to above 30g per 100g to ensure eligibility of such a claim. • Campbell Arnott's does not support Option 4. Such restrictions are inconsistent with other content claims and will limit communication of important and useful nutrition information for consumers.
New Zealand Commerce Commission	Government (New Zealand)	<ul style="list-style-type: none"> • Does not specify a preferred option. • Supports the provision of information to consumers to allow informed choice of foods, however is concerned that consumers may interpret the claim 'low proportion of saturated fatty acids' as meaning 'low in saturated fatty acids' when a product may not, in fact, be low in overall saturated fat content.
Confectionery Manufacturers of Australasia Ltd.	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports option 2
Consumers NZ	Consumer (New Zealand)	<ul style="list-style-type: none"> • Supports option 1. • Appreciates the intention of creating the proportional fatty acid claim criteria, however is concerned that proportional fatty acid claims may be too complex and may mislead consumers about the overall nutritional content of a food. • Does not support options 3 and 4. These options would allow foods such as potato crisps any creamy mayonnaise to carry proportional fatty acid claims.
Commonwealth Scientific and Industrial Research Organisation (CSIRO)	Research and Academia (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. Considers all the proposed options to be unsatisfactory. • Suggests that claims about foods low in saturated fatty acids should be allowable if they meet either an absolute level of saturated fat (i.e. < 0.75 g per 100 mL of liquid food and 1.5 g per 100 g of solid food), or no more than 28% saturated fatty acids as a proportion of the total fatty acid content. In this way, neither low fat nor high unsaturated fat foods are discriminated against. • Does not agree that the food must make an associated mono or polyunsaturated fatty acid claim. Some research suggests that consumers do not understand these terms, that lengthy text for manufacturers to place on labels is prohibitive and that the presence of these fatty acids is there by default, hence not adding anything informative. • All foods labelled with a low or proportionally low in saturated fat claim should also comply with a trans fat free claim. If this is not the case, the criteria as it stands will allow some high trans fat foods up to 28% trans. • A standard for the claim of low saturated fat that also necessitated that the food met a criterion for trans fats as this would discourage the use of partially hydrogenated fats in the food supply.

Submitter	Group	Comments
Dairy Australia	Industry (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. • Does not support option 2. • The FSANZ consultation paper does not contain the simplest option for a nutrient content claim about saturated fatty acids as a low proportion of total fatty acid content. This would be to define in the standard what a low proportion of fatty acid content is for saturated fat (for example, it could be defined at 28% of total fatty acids). • If the fatty acid content of a food is not more than 28% saturated fatty acids, it seems difficult to realistically propose a composition where less than 40% of the fatty acids are poly- or mono-unsaturated. • There appears to be a high likelihood of increasing consumer confusion if foods are permitted to appear with different claims relating to saturated fatty acids – this potential appears to be increased if one claim is required to carry additional information (but inverse) about the content of another fatty acid. • The health objective of reducing total dietary intake of saturated fats appears to be much better served by a nutrient content claim relating to the absolute amount.
Dairy Farmers	Industry (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. • Concerned that the proposal contains no specified maximum level for manufactured trans fats as a disqualifier. • Are concerned that this could support an increase in levels of trans fatty acids (TFA) in the food supply and therefore increased consumption by allowing some products with high manufactured trans fat levels to make this nutrition content claim. • It acknowledges that the concerns about the potential health effects of TFA relate to ‘particularly those that are manufactured’.
Department of Health and Human Services TAS	Government (Australia)	<ul style="list-style-type: none"> • Supports amended option 2 if the claim is permitted (so that the conditions are the same as for the mono and polyunsaturated fatty acid claim). • Does not dispute the intent of the proportion of saturated fatty acid but is concerned that the proposed claim for proportion of saturated fatty acids is overly complex and will not provide additional benefit for consumers. • Research indicates that many consumers do not understand proportions or percentages and therefore consumers may be confused or misled by low saturated fat and low proportion of saturated fatty acids.

Submitter	Group	Comments
Dietitians Association of Australia (DAA)	Public Health (Australia)	<ul style="list-style-type: none"> • Supports option 2. • Remains concerned about the overall usefulness of any of the Options presented by FSANZ in helping consumers to choose foods with an optimal proportion of unsaturated fats. • Support for option 2 is conditional on changes being made to the criteria such that the food contains no more than 28% saturated fat and trans fat and no less than 40% monounsaturated or polyunsaturated fat, as a proportion of total fat. • Suggests other ways of describing the benefits of having greater amounts of unsaturated fat than saturated fat in a food, independent of the total amount of fat. For example, ‘favourable fatty acid ratio’, ‘healthier fatty acid ratio’, ‘higher proportion of healthier fats’. Examples of acceptable alternative wordings should be placed in an editorial comment in the standard and/or in the user guide. • Does not support option 3. A number of foods would be excluded as they fall below this level such as avocados, some salad dressings, oil-based dips, breads with a high seeds content, some fish and seafood (fresh and processed), and some baked products such as biscuits and cakes (based on healthier oils and baking fats).
Food and Beverage Importers Association (FBIA)	Industry (Australia)	<ul style="list-style-type: none"> • Does not support any of the options presented. • Do not see the need for requirements additional to that ‘the food must contain, as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids’. • The Association therefore supports the introduction of a new category of claim to provide for ‘low proportion’ claims.
Frucor Beverages Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> • Supports option 2.
George Weston Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports option 2. • Option 2 will provide incentive to industry to re-formulate products to include a healthier fatty acid profile and allow for increased consumer choice for healthier products, especially in categories typically associated with high saturated fatty acid content such as cakes. • Does not support option 1. Some foods which fail to meet the stricter criteria for low in saturated/trans fats still have a beneficial fatty acid profile compared to similar food types and therefore should be able to communicate this difference to consumers. • Does not support option 3. This will unnecessarily restrict communication on foods containing lower amounts of fat which still have a higher proportion of unsaturated fats to saturated fats. • Does not support option 4. This option has the potential to create confusion. • Recommends flexibility in the wording used for the claim, so that it can be communicated in a consumer friendly way.

Submitter	Group	Comments
Go Grains Health and Nutrition Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports option 2. • This option will enable cereal products – especially breads and breakfast cereals that contain wholegrains, nuts and seeds – to highlight their proportionately low saturated fat content. • Questions whether consumers understand the concept of ‘low proportion of saturated fatty acids of total fatty acid content’ and recommends that some investigation be undertaken to ensure that the wording of the final claim is meaningful to consumers.
Heinz Wattie’s Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Does not state a preferred option. • Including a ‘proportion’ claim for saturated fat will allow some products (e.g. foods rich in monounsaturated and/or polyunsaturated fats) that would otherwise not be permitted to communicate about saturated fat, to be able to do so. • Making a claim about saturated fat requires a declaration of total, saturated, trans, polyunsaturated and monounsaturated fats in the nutrition information panel. As the fatty acid profile will be available to the consumer in the nutrition information panel, Heinz does not believe that a mono or polyunsaturated fat claim need be made in association with the low proportion saturated claim.
Nestlé Australia Ltd.	Industry (Australia)	<ul style="list-style-type: none"> • Supports option 2.
New South Wales Centre for Public Health Nutrition	Public Health (Australia)	<ul style="list-style-type: none"> • Supports option 1. • Concerned that the new claim could be carried on foods high in total fat and SFA, prompting consumers to choose these ‘proportionately low SFA’ foods in preference to foods low in total fat and SFA. • Believes that information regarding fatty acid profile should be conveyed through consumer education campaigns rather than nutrition content claims on food.
New Zealand Dietetic Association (NZDA)	Public Health (New Zealand)	<ul style="list-style-type: none"> • Supports option 2. • Support is conditional on the removal of the requirement for foods to make an associated mono or polyunsaturated fatty acid claim.
New Zealand Food and Grocery Council	Industry (New Zealand)	<ul style="list-style-type: none"> • Does not explicitly indicate support for a preferred option. Comments suggest support for either option 3 or 4. • The recommendation that the claim is permitted if no more than 28% of saturated fatty acids and trans-fatty acids is present is supported by the FGC. • The requirement in respect of mono and polyunsaturated fatty acid is not however supported. If a claim concerning saturated fat is made, mono and polyunsaturated fatty acids must be included in the nutrition information panel.
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> • Does not support option 2. • Disagrees that consumer understanding will be facilitated under option 2 because the wording of the claim will include information about the fatty acid profile of the food. Consumers will be confused with the nutrition jargon and lengthy wording of proportional claims.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Would support an option that did not allow claims about saturated fatty acids as a proportion of the total fatty acids. This is consistent with the national guidelines for healthy eating, which recommend New Zealanders reduce their total saturated fat intake. • If FSANZ determines that proportional claims can be made, the Ministry would like to see some criteria around the fat content of foods. Prefer these criteria to be the same as the conditions for making a ‘low saturated fatty acid’ claim. • Of the four options presented in this consultation paper, the Ministry believes that option 4 is closest to their preferred position as the food must be eligible according to the NPSC.
Obesity Policy Coalition	Public Health (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. • Concerned that the ‘low proportion of saturated fatty acid’ claims proposed under Options 3 and 4 would mislead consumers to believe foods making these claims were low in total fat, or that consumers would be confused about whether saturated fat was low as a proportion of total fat or the total food. • Also concerned that some foods high in total fat could make these claims whereas other foods <i>lower</i> in saturated fat but also lower in total fat could not. This may lead to greater consumption of foods higher in saturated and total fat. • Further consumer research in this area appears to be needed. • Information about saturated fatty acids in foods as a proportion of total fatty acids may be best dealt with through development of appropriate dietary education guidelines.
Unilever Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Does not support any of the proposed options. • Option 1 does not permit information to be provided about the fat profile of a product if the product has a significant fat content. • Option 2 is out of step with any other nutrition content claim criteria and imposes an additional burden on the claim that is not warranted. • Option 3 will mean that many products containing a significant fat content (but not over 30g fat per 100g) would be precluded from making a claim. • Option 4 is contrary to the current framework for nutrient content claims where the NPSC is imposed at a general level health claim level, not at a nutrient content level. • Proposes system with criteria of maximum of 28% saturated and trans fatty acids of total fat and 1% trans fatty acids of total fat, for claims about saturated, saturated and trans fatty acids and low cholesterol claims.
Fonterra Co-operative Group Ltd	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Does not support FSANZ preferred option (Option 2) as fails to see how this can be communicated in a clear and non-confusing way to the consumer. • Points out that the rationale for Option 2 appears to be the relatively large amounts of saturated fat are less harmful in the presence of larger amounts of MUFA or PUFA, suggests the same reasoning should be considered for saturated fat on cheeses.

Submitter	Group	Comments
Cadbury Schweppes Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 2
Parmalat Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 2
Chamber of Commerce & Industry WA	Government (Australia)	<ul style="list-style-type: none"> • Supports Option 2 as believes this provides consistency in regulatory approaches that fosters product innovation.
Cereal Partners Worldwide (CPW)	Industry (Australia)	<ul style="list-style-type: none"> • Recommends that foods with less than 28% saturated fatty acids be able to carry a ‘low proportion of saturated fatty acid’ claim.
Campbell Arnott’s Asia Pacific	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports Option 2 and thinks this will allow meaningful information on products with healthier fatty acid profiles. • Does not support Option 3 as it may encourage an increase in the fat content of food to above 30g per 100g to ensure eligibility for a claim. • Does not support Option 4
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> • Supports Option 2 with the provision that the full claims be placed together on the label.
CHOICE	Consumer (Australia)	<ul style="list-style-type: none"> • Supports regulatory option 1 to maintain the status quo, but encourages the use of healthy eating messages to highlight the benefits of healthy oils and nuts. • Believe that proportional fatty acid claims may be too complex and mislead consumers about the overall nutritional content. They may not be used widely by food manufacturers because the claims will be too wordy. • Fair trading laws could be used to regulate misleading claims about fatty acid content. • Should FSANZ deem it necessary to develop specific regulation for proportional fatty acid claims CHOICE prefers proposed option 2. Manufacturers should not make a proportional fatty acid claim unless a monounsaturated or polyunsaturated fatty acid claim is made. The regulation should prohibit the splitting of fatty acid claims. • Does not support option 3 and 4 as the criteria would allow unhealthy foods, such as chocolate hazelnut spread, potato crisps, jam cookies to carry proportional fatty acid claims.
National Centre of Excellence in Functional Foods (NCEFF)	Research and Academia (Australia)	<ul style="list-style-type: none"> • In the end, consumers need to chose <i>foods</i> and know the limits of consumption on portion sizes and food groups. Would consider this issue in the light of their earlier propositions – differentiating between primary and reconstructed/manufactured foods, and providing guidance for the development of new foods.
Murray Goulburn Co-operative Co. Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports FSANZ proposal to allow a claim for ‘low proportion of saturated fatty acids’ but does not support the additional requirement for a mono or polyunsaturated fat claim.

Submitter	Group	Comments
Horticulture Australia Ltd (HAL)	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 2: However, believes foods should be able to make this claim with and without reference to monounsaturated and polyunsaturated fats. In addition they should be able to make a ‘high proportion of unsaturated fats’ claim. • Would prefer to see the new ‘low proportion of’ nutrition content claims criteria for saturated and trans fats being consistent with the requirements for making high level health claims. Nuts will not be able to access the pre-approved saturated fat and cholesterol lowering high level health claim as nuts (other than chestnuts) do not meet the low saturated fat level of 1.5g per 100g. Yet research has shown that eating nuts regularly can lower blood cholesterol.
Nu-Mega Ingredients Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports the additional nutrition content claim, as the ‘Low saturated fat’ nutrition content claims as proposed will only be relevant to lower fat foods. • The public would benefit more if such claims could also be used on higher fat foods when the overall fatty acid profile is conducive to health benefits. • This would encourage greater use of healthier fats in foods.
New Zealand Beef and Lamb Marketing Bureau	Industry (New Zealand)	<ul style="list-style-type: none"> • The proposed criteria for saturated and trans fatty acids are not suitable for a number of lean red meat cuts. These cuts are low in saturated fat in terms of g/100g, so the Bureau proposes criteria set in terms of percentage fatty acids OR g/100g. • This retains the original proposed criteria, but allows for the inclusion of fats with a high proportion of monounsaturated/polyunsaturated, whilst not excluding lean products, low in all fat types, which represent an important part of a healthy, balanced diet.
ADECRON Food Tech Consulting Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> • Agrees with going to option 2. • Cannot see the reason to limit it to high fat foods only (options 3) and with an arbitrary 30% fat cut off point. This may tempt people to increase the absolute fat level of foods. • Has checked some database info of some of the foods outlined in table 2 (see submission): Some issues identified: <ul style="list-style-type: none"> a) Salmon: one variant failed (King Salmon) on % sat fat, another one passed (NZ Food Files) b) Eggs fail (37% sat) c) Rice Bran Oil only just passes with 41 mono, 34 poly and 22 sat (current product label info). Of all the oils it seems to be one with a much closer ratio of mono to poly and a relatively high saturated fat level. • Blends of dairy and vegetable oils would permit the use of no more than 30% of milk fat if canola oil was used (see modelling table). Less with other oils, down to 12% of milk fat for rice bran oil/butter blends. Obviously fails with palm oil. In all cases either mono or poly would be high enough (>40%) to make a claim. See bolded figures. • Suggestion: try find other more common term or descriptor for ‘proportionately’ to reduce consumer confusion?

Submitter	Group	Comments
Australian Nut Industry Council (ANIC) and Nuts for Life	Industry (Australia)	<ul style="list-style-type: none"> • Supports option 2. • All nuts except chestnuts, meet the criteria of no more than 28% of total fats as saturated fats (see table 1 in submission for data on the percentage of fats as a proportion of total fats). • Feels that foods should be able to make this claim with and without reference to mono and polyunsaturated fats and be able to make a high proportion of unsaturated fats claim. There may be space difficulties on small product labels. • Suggests that foods with less than 28% of total fat as saturated and trans fat but 72% or more total fats as mono and polyunsaturated fats be able to say <i>contains a high proportion of unsaturated fats</i> or <i>contains a high proportion of polyunsaturated and monounsaturated fats</i>. • Would prefer to see the criteria for this claim flow on to the criteria for making high level health claims. Nuts will not be able to make use of the pre-approved SFA/cholesterol lowering high level health claim as nuts (other than chestnuts) do not meet the low saturated fat level of 1.5g/100 g. • A polyunsaturated fat to saturated fat ratio of greater than 1 is required to reduce heart disease risk and replacing saturated fat with poly and monounsaturated fat will lower heart disease risk and blood cholesterol (1). Lowering the saturated fat content by itself will not achieve the desired ratio – eating foods rich polyunsaturated and monounsaturated fats are also required. <p>(1) Lipid Management Guidelines--2001. National Heart Foundation of Australia, The Cardiac Society of Australia and New Zealand. <i>Med J Aust</i> 175 Suppl, S57-85 (2001).</p>
Sanitarium Health Foods	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Does not support any of the proposed options. • Does not believe it necessary for foods that make this claim to also be required to carry an associated claim about mono or polyunsaturated fats as this information will be required on the NIP anyway. • Recommends that claims be allowed for foods with a ‘low proportion of saturated fats’ with the following criteria: the food contains no more than 28% saturated plus trans fatty acids relative to the total fatty acid content, and the level of saturated, mono and polyunsaturated fatty acids be declared in the NIP.
The National Heart Foundation of New Zealand	Public Health (New Zealand)	<ul style="list-style-type: none"> • Does not support any of the proposed options. • Has concerns regarding how helpful the proposed options are to help consumers understand the concept of the different types of dietary fats. • Comments that option 1 limit these claims to low fat foods meaning oils, nuts, seeds etc would not be able to make nutrition content claim or general or high level claims relating type of fat to blood cholesterol levels. • Under Option 3, they argue that it is more important to be able to communicate about the fat profile of all fat-containing foods, regardless of total fat content. By limiting foods to those that are 30% fat or more, a number of foods would miss out, e.g. avocados, some salad dressings, high seed content cereals, seafood, some baked products.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Under option 4, argues that this introduces differing eligibility criteria for foods carry a low proportion of saturated fat and may create confusion and introduce the anomaly that no other nutrition content claim conditions must meet the NPSC. This is inconsistent, inequitable and undermines the approach for nutrition content claims about other substances based on FSANZ consumer research that additional risk management for nutrition content claims is not needed. • Under option 2, argues that to mandate inclusion of a MUFA or PUFA content claim is not necessary and has the potential to confuse consumers. Points out that the Code requires declaration of trans, PUFA and MUFA when a claim about cholesterol or fatty acids is made. • Pleas that saturated and trans fatty acids are considered together for these claims and recommends this across all potential claims in relation to saturated and/or trans fatty acids. • The permitting of low/lower saturated and trans unsaturated fats claims is a positive way that the food industry can assist consumers in identifying foods low in unhealthy fats. • Recent research commissioned by the Heart Foundation of Australia, examined key messages around healthy eating including specific references to fats that indicated the simpler the messages, the more likely the target audience is to read and to have some understanding of the healthy fats issue. Furthermore, the more involved the description of fat, the more confused people become about fat.(Elliot and Shanahan Research for Heart Foundation. Reactions to Modified Resource Material for Parents and Guardians on Children and Weight Information (phase 2). Dec 2002). • For these reasons, believes that in making claims around saturated fat that it be limited to those types of fat that are considered ‘unhealthy’ and not be confused with other healthy types of fats such as MUFA and PUFA on a label. • In other forms of extended communication such as websites, consumer info-lines, pamphlets etc, more detailed messages around fats are appropriate and possible. • The new proposed trans fat limit recognises the potentially more adverse effect of trans fats on health than saturated fats and the Heart Foundation Tick Programme’s approach to encouraging limits to trans from hydrogenated fats in the food supply. • Proposes a new option: New category of claim to the effect that a food has a low proportion of saturated fat of total fats, i.e. the food contains as a proportion of the total fatty acid content no more than 28% saturated fat and trans and the food contains no more than 1% trans fat of total fat. • The proposed principle of a ‘low proportion’ of saturated fat and maximum trans fat level claim, should flow through and apply to other nutrition content claims in table to clause 11 in which the property relates to low saturated fat (cholesterol, trans fat, saturated fat, saturated and trans fat (see submission for table of proposed conditions)). In addition, that this principle flow through to general level and high level health claims. • This claim will be able to be used in association with foods with a healthier fat profile and which are probably the most useful food sources for achieving the desired shift in diet from a low fat diet to a diet with an optimised proportion of healthy unsaturated fats.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Believes it is very important that it be possible to make the combined claim with a max of 28% saturated and trans fats. At the same time, limit the amount of trans fat to encourage food manufacturers to avoid using partially hydrogenated fats. • This is an important claim as it allows food industry to communicate key messages about saturated and trans fat together. This is especially important as many products will not meet the trans free requirements. • Argues that this application will reinforce the idea, complement the conditions for ‘low proportion’ of saturated fat and provide consistency across nutrition content claims.
The National Heart Foundation of New Zealand (continued)	Public Health (New Zealand)	<ul style="list-style-type: none"> • Recommends their proposed conditions for the ‘low proportion’ of saturated and trans fatty acid claim be included in the conditions for the high level health claim about the relationship between saturated and trans fat and LDL cholesterol. • The review undertaken for FSANZ to consider this high level health claim resulted in the following conclusions: <ul style="list-style-type: none"> – Direct convincing association for saturated fatty acids and total and LDL cholesterol. – Clear dose response effect apparent with increasing amounts of saturated fatty acids . – The extent of the LDL cholesterol reduction achieved by lowering intake of saturated fatty acids is dependent upon the source of replacement energy. – Replacing saturated fatty acids with polyunsaturated fatty acids would result in appreciably greater reductions in LDL replacement than with either carbohydrate or monounsaturated fatty acids. – The current evidence for the direct association between saturated fatty acids and coronary heart disease is more appropriately described as ‘probable’. – Although there are significant limitations for the trans fats data, these do not preclude the conclusion that the association between trans fatty acids and LDL cholesterol is a ‘convincing’ one. – The association between trans fatty acids and coronary heart disease is described as ‘probable’. • The evidence from this review supports the importance of being able to communicate to consumers changes in dietary fats – including to influence the choices in foods that have a significant fat content.
Simplot Australia Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Considers that the criteria that the food contains as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids is adequate for a claim about saturated fatty acids as a low proportion of the total fatty acids content. • By default, the unsaturated fatty acid content is high. • Foods such as fish (a valuable source of omega-3 fatty acids) and vegetable oils which are higher in total fat but contain favourable unsaturated fatty acid profiles do not meet the proposed criteria for a low saturated fatty acid but would meet the proposed criteria. • Note Heart Foundation recommends choosing both plant and marine omega-3 food sources and fish should be eaten at least twice a week.
Tomox Pty Ltd (Susan Thompson, Consultant)	Industry (Australia)	<ul style="list-style-type: none"> • Pleased that FSANZ has considered nutrient balance and the food matrix in this proposal. • Concerned that this proposal could encourage an increase in levels of manufactured trans fatty acids in the food

Submitter	Group	Comments
Dietitian		<p>supply by allowing some manufactured products with high trans fatty acids to make the claim.</p> <ul style="list-style-type: none"> • A maximum level of manufactured trans fat needs to be specified if this claim is to proceed. • This claim is unlikely to be used on any dairy products given that natural saturated fat level is much greater than 28% despite some being listed in the table 2 on page 14.
Food Technology Association of Australia (FTA)	Industry (Australia)	<ul style="list-style-type: none"> • Agree with option 2.
The National Heart Foundation of Australia (supported by Unilever)	Public Health (Australia)	<ul style="list-style-type: none"> • Does not support any of the proposed options. • Have concerns regarding how helpful the proposed options are to help consumers understand the concept of the different types of dietary fats. • Comments that option 1 limit these claims to low fat foods meaning oils, nuts, seeds etc would not be able to make nutrition content claim or general or high level claims relating type of fat to blood cholesterol levels. • Recent research (1) in the area of achieving the Dietary Guidelines for Australians of 6- 8% polyunsaturated fats and the Heart Foundation’s recommendation of higher intakes of 8-10%(2), indicates the P/S (polyunsaturated fat/saturated fat) ratio is a better reflection of the fatty acid targets than an absolute value of saturated fat intake. (1) Shrapnel, B and Nestel, P. Linoleic acid and coronary heart disease. Research 2007. (in press). (2) National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand. Position statement on lipid management. 2005. • Under Option 3, they argue that it is more important to be able to communicate about the fat profile of all fat-containing foods, regardless of total fat content. By limiting foods to those that are 30% fat or more, a number of foods would miss out, e.g. avocados, some salad dressings, high seed content cereals, seafood, some baked products. • Under option 4, they argue that this introduces differing eligibility criteria for foods carry a low proportion of saturated fat and may create confusion and introduce the anomaly that no other nutrition content claim conditions must meet the NPSC. This is inconsistent, inequitable and undermines the approach for nutrition content claims about other substances based on FSANZ consumer research that additional risk management for nutrition content claims is not needed. • Under option 2 they argue that to mandate inclusion of a MUFA or PUFA content claim is not necessary and has the potential to confuse consumers. Points out that the Code requires declaration trans, PUFA and MUFA when a claim about cholesterol or fatty acids is made. • Pleas that saturated and trans fatty acids are considered together for these claims and recommends this across all potential claims in relation to saturated and/or trans fatty acids. • The permitting of low/lower saturated and trans unsaturated fats claims is a positive way that the food industry can assist consumers in identifying foods low in unhealthy fats. • Recent research commissioned by the Heart Foundation of Australia, examined key messages around healthy eating including specific references to fats that indicated the simpler the messages, the more likely the target

Submitter	Group	Comments
		<p>audience is to read and to have some understanding of the healthy fats issue. Furthermore, the more involved the description of fat, the more confused people become about fat.(Elliot and Shanahan Research for Heart Foundation. Reactions to Modified Resource Material for Parents and Guardians on Children and Weight Information (phase 2). Dec 2002).</p> <ul style="list-style-type: none"> • For these reasons, believe that in making claims around saturated fat that it be limited to those types of fat that are considered ‘unhealthy’ and not be confused with other healthy types of fats such as MUFA and PUFA on a label. • In other forms of extended communication such as websites, consumer info-lines, pamphlets etc, more detailed messages around fats are appropriate and possible. • The new proposed trans fat limit recognises the potentially more adverse effect of trans fats on health than saturated fats and the Heart Foundation Tick Programme’s approach to encouraging limits to trans from hydrogenated fats in the food supply. • Proposes a new option: New category of claim to the effect that a food has a low proportion of saturated fat of total fats, i.e. the food contains as a proportion of the total fatty acid content no more than 28% saturated fat and trans and the food contains no more than 1% trans fat of total fat. • The proposed principle of a ‘low proportion’ of saturated fat and maximum trans fat level claim, should flow through and apply to other nutrition content claims in table to clause 11 in which the property relates to low saturated fat (cholesterol, trans fat, saturated fat, saturated and trans fat (see submission for table of proposed conditions)). In addition, that this principle flow through to general level and high level health claims. • Believe it is very important that it be possible to make the combined claim with a max of 28% saturated and trans fats. At the same time, limit the amount of trans fat to encourage food manufacturers to avoid using partially hydrogenated fats. • This is an important claim as it allows food industry to communicate key messages about saturated and trans fat together. This is especially important as many products will not meet the trans free requirements. • Argues that this application will reinforce the idea, complement the conditions for ‘low proportion’ of saturated fat and provide consistency across nutrition content claims.
The National Heart Foundation of Australia (continued)	Public Health (New Zealand)	<ul style="list-style-type: none"> • Recommends their proposed conditions for the ‘low proportion’ of saturated and trans fatty acid claim be included in the conditions for the high level health claim about the relationship between saturated and trans fat and LDL cholesterol and coronary heart disease. • The review undertaken for FSANZ to consider this high level health claim resulted in the following conclusions: <ul style="list-style-type: none"> – Direct convincing association for saturated fatty acids and total and LDL cholesterol. – Clear dose response effect apparent with increasing amounts of saturated fatty acids . – The extent of the LDL cholesterol reduction achieved by lowering intake of saturated fatty acids is dependent upon the source of replacement energy. – Replacing saturated fatty acids with polyunsaturated fatty acids would result in appreciably greater reductions in LDL replacement than with either carbohydrate or monounsaturated fatty acids.

Submitter	Group	Comments
		<ul style="list-style-type: none"> - The current evidence for the direct association between saturated fatty acids and coronary heart disease is more appropriately described as ‘probable’. - Although there are significant limitations for the trans fats data, these do not preclude the conclusion that the association between trans fatty acids and LDL cholesterol is a ‘convincing’ one. - The association between trans fatty acids and coronary heart disease is described as ‘probable’. • The evidence from this review supports the importance of being able to communicate to consumers changes in dietary fats – including to influence the choices in foods that have a significant fat content.
The Cancer Council Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Supports option 1. • The options proposed in the Consultation Paper in relation to nutrition content claims about saturated fatty acids as a low proportion of total fatty acid seem extremely complex, and the Cancer Council has concerns that consumers may assume foods making this type of claim were low in total fat, and may be influenced to over consume these foods. • Options 3 and 4 will mean that some foods high in total fat are able to make low proportion of saturated fat claims while other foods <i>lower</i> in saturated fat but also lower in total fat will be prevented from making these claims. This may lead to greater consumption of higher saturated fat, total fat and energy. • Are concerned that FSANZ is bowing to pressure from certain sectors of the food industry in making this claim fit different food products.
Australian Food and Grocery Council (AFGC)	Industry (Australia)	<ul style="list-style-type: none"> • Recommends that foods with less than 28% saturated fatty acid be able to carry a ‘low proportion of saturated fatty acids’ claims. • Recommends the inclusion of a claim for foods to be able to carry a statement ‘low proportion of saturated fat and trans fat’ claims. • FSANZ has raised concerns that consumers may confuse the ‘proportionate’ claim with a simple low saturated fat claim to the extent that they would be misled. • Considers this to be unlikely for many higher fat products because for many food types the high fat content is well known to consumers. In addition, the fatty acid content of foods will be shown on the Nutrition Information Panel, along with the total energy. • Does not consider it is necessary to require that additional claims for mono and poly unsaturated fatty acids are required to support this claim and rejects Option 2 on this basis. Since one of the concerns that FSANZ previously raised is the need to keep the message simple in order that consumer confusion is avoided, the compound claim relying on providing both saturated and unsaturated fatty acid information fails this first criteria. • Furthermore, there is no extra information provided by requiring an unsaturated claim, as by default a product for which the saturated fat is known and the total fat is known then the unsaturated fats may be deduced from the NIP. The requirement for additional information on mono and poly unsaturated fats should only be required where the inverse claim is made, that the food has a high proportion of mono / ploy unsaturated fatty acids, and that such a claim should also impose a limit of 28 per cent saturated fatty acid.
Kraft Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Believes that all the options suggested are flawed and proposes that:

Submitter	Group	Comments
		<p>Any Food with less than 28% saturated fatty acids be permitted to carry a 'Low proportion of saturated fatty acids' claim.</p> <ul style="list-style-type: none"> • Believes that wherever possible, simple messaging to consumers is always preferable to complex, as long as there are no negative implications. A simple requirement against saturated fatty acid proportion communicates the information and offers no confusing elements. • Option 1 – Rejected – is not in the interests of providing relevant information to consumers. • Option 2 – Rejected – brings an unnecessary level of complexity to the claim, providing no real benefit to consumers but potentially confusing them. • Option 3 – Rejected – Restricting the claim to foods with greater than 30% fat level is arbitrary and not based on dietary principles. It poses an unnecessary level of restriction not in the consumer's interest. • Option 4 – Rejected – as mentioned previously Kraft foods strongly opposes the NPSC approach as being subjective, resulting in unequal treatment of different foods.
Innovations & Solutions – Wendy Morgan	Industry (Australia)	<ul style="list-style-type: none"> • Supports the FSANZ proposal (Option 2) that a NCC relating to the proportion of saturated fatty acids should be permitted as detailed in previous submissions. • Supports the FSANZ criteria for the proportions of different fatty acids. If less than 28% of the fatty acids are saturated and trans, there is no need to stipulate the quantity of mono and polyunsaturated fatty acids as the remaining 72% of fatty acids will be comprised of mono and polyunsaturated fatty acids. • Does not support the criterion whereby an associated mono or polyunsaturated claim must also be made. This information may not be relevant for some products or may be confusing, or labels may not have space for additional wording. • Does not support FSANZ Option 1 as this limits 'healthy oils' and foods containing them from highlighting the low saturated fat advantage. The Code should make it easy for useful claims to be made. • Does not support FSANZ Option 3 as the quantity of fat does not affect the positive impact of a desirable fatty acid profile. • Does not support FSANZ Option 4 as NPSC do not apply to any other NCC and this would be discriminatory and restrict communication of useful information to the public.
Glycemic Index Ltd	Industry (Australia)	<ul style="list-style-type: none"> • In theory, the use of this new nutrition content claim relating to a lower proportion of saturated fat, and trans fats, will be able to be used on higher fat foods, with a healthier fat profile, to help people choose foods with an optimal proportion of saturated and unsaturated fats, to improve the overall fatty acid profile of their diets. GI Ltd therefore supports Option 2.
NSW Food Authority	Government (Australia)	<ul style="list-style-type: none"> • Does not support the introduction of proportionate fatty acid claims. Believes it will not be easily understood and does not address the issue of the overall consumption of fatty acids in the diet, and may have the unintended consequence of promoting the over-consumption of foods with 'healthier' fatty acid profiles. Consumers wanting this information would be better served consulting a dietitian. Does not understand the rationale behind permitting such claims as this information is already available in the NIP. • Concerned that current criteria for proportionate fatty acid claims places no finite limit on the total fat content of a food, it merely places limits on the structure of the fatty acid profile.

Submitter	Group	Comments
Department of Human Services - Victoria	Government (Australia)	<ul style="list-style-type: none"> • Supports Option 2 with the proviso that the full claim be placed together and not split (e.g. with ‘low in saturated fat’ on the front of the packet with ‘relative to the total fatty acid content’ on the back).
New Zealand Food Safety Authority (NZFSA)	Government (New Zealand)	<ul style="list-style-type: none"> • Supports an amended Option 4: <i>New category of claim to the effect that the food has a low proportion of saturated fatty acids of total fatty acid content, limited to foods that meet the NPSC.</i> • Foods can make a claim to the effect of a ‘low proportion of saturated fatty acids’ if: <ul style="list-style-type: none"> – the food contains, as a proportion of the total fatty acid content no more than 28% saturated fatty acids and trans fatty acids; and – the food contains no more than 1% trans fatty of total fat; and – the food meets the NPSC. • Believes that in this proposed proportional claim the 28% saturated fatty acids and trans fatty acids potentially allows provision for manufacturers to include higher levels of trans fatty acids into food products. The suggested amendment is an attempt to ensure manufacturing practice continues to maintain a very low level of trans fatty acid in food products. However the more fundamental issue is whether consumers will understand the resulting claim. There is a concern that consumers could interpret the claim as a low saturated fatty acid claim. • If the Code was to remain silent in this area (as per option 1), the low proportion of saturated fatty acid claims currently available could continue to be made with no parameters around them regarding saturated fat content. This would create an inconsistency in the treatment of claims.
Queensland Health	Government (Australia)	<ul style="list-style-type: none"> • Does not support Option 2. Supports Option 1 –Status Quo. • Believes that while there are advantages in allowing foods with a beneficial fatty acid profile e.g. oils, nuts, seeds, margarines, avocados, fish, etc to make this claim there are a number of issues with this option. On balance, they believe the negative issues outweigh any positive ones. • Some difficulties with this option: <ul style="list-style-type: none"> – the claim could also be made by quite an extensive range of less healthy foods; – there is potential for consumers to be confused over the proportionality issue or over the difference between these claims and ‘low’, ‘reduced’ fat/ saturated fat claims or about the total saturated fatty acid content; – the claim may reduce the impact of messages to the consumer with regard to cutting total saturated fat in the diet. • Overall the claim is not consistent with one of the major public health messages about reducing saturated fat in the diet. • Foods with beneficial fatty acids profiles can still make monounsaturated and polyunsaturated fatty acids claims subject to the conditions around these claims. The exact wording of the claim is not clear nor whether FSANZ intends to specify it. Some possibilities are: <ul style="list-style-type: none"> – this food has a low proportion of saturated fatty acids relative to the total fatty acid content; – this food is low in saturated fat (or fatty acids) relative to the total fat (or fatty acid) content.

Submitter	Group	Comments
		<ul style="list-style-type: none"> If such claims were approved, it would be essential for all parts of the claim to remain together in the one place and not split up on different parts of the pack. Otherwise there is the potential for the consumer to be misled about the saturated fatty acid content.
Goodman Fielder Home Ingredients	Industry (Australia)	<ul style="list-style-type: none"> Does not support any of the proposed options. Supports a new option as proposed by the National Heart Foundation – A food with a low proportion of total fat as saturated fat, i.e. the food contains as a proportion of the total fatty acid content no more than 28% of saturated fat and trans fat AND the food contains no more than 1% of total fat as trans fat. Option 1 effectively limits these claims to low fat foods, which means that those with higher proportions of unsaturated fats cannot display content, general level or high level health claims. Option 2 – it is not necessary to mandate the inclusion of a monounsaturated or polyunsaturated fatty acid content claim in addition to the proportion saturated fatty acid claim. This is also a new precedent and inconsistent with requirements elsewhere in the Code. Option 3 – it is important to be able to communicate about the fat profile of all fat containing foods, regardless of total fat content. Option 4 introduces differing eligibility criteria for foods with a low proportion of saturated fat, may create confusion, and introduce the anomaly that no other nutrition content claim conditions must meet the NPSC. Also proposes that the low proportion of saturated fat criteria be applied to nutrient content claims for cholesterol, trans fat, saturated fat, and saturated and trans fat.
The Public Health Association of Australia	Public Health (Australia)	<ul style="list-style-type: none"> Recommends that this sort of claim not be allowed for the present. This is because in their experience consumers are still totally confused about fat and the different types of fatty acids, and are rarely able to distinguish the difference between them. This sort of claim could be added to the Standard once we have had a chance to assess how consumers will cope with basic, non-comparative/proportional claims. PHAA is also concerned about the type of food categories that would be allowed to make fatty acid proportional claims under FSANZ’s proposed system, e.g. confectionery, ice cream, cakes and biscuits. This again does not support dietary guidelines or the efforts of nutrition educators in promoting healthy eating. Should FSANZ insist on allowing proportional fatty acid claims, PHAA would support a modified Option 4, i.e. these claims are limited to foods that meet the NPSC. PHAA believes that foods containing proportionately 28% saturated and trans fat is very high in comparison to usual dietary recommendations that total diets consist of 10%

Submitter	Group	Comments
Dr. Rosemary Stanton	Public Health (Australia)	<ul style="list-style-type: none"> • Supports option 1 – retain the <i>status quo</i>. • This does not preclude a food label stating that the product contains mono or polyunsaturated fats. • Healthy eating campaigns can emphasise the value of products such as nuts and seeds and point out the nature of their healthier unsaturated fats and other nutritional attributes. • Options 3 and 4 would be misleading and Option 2 seems to be an option to suit manufacturers of margarines and spreads. • The fact that the Dietary Guidelines suggest that Australians moderate their total fat intake remains relevant.

3. CRITERIA FOR NUTRITION CONTENT CLAIMS ABOUT *TRANS FAT FREE*

Submitter	Group	Comments
ADECRON Food Tech Consulting Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> • Agrees with option 2 to permit ‘trans fatty acid’ free claim if sat fat no more than 28%. • Please quantify detection limit in the regulation to clarify the grey area between ‘not contain any detectable’ and ‘free’. The 2 are not the same. • Understands that the level of detection in NZ is typically 0.1% as part of the fatty acid profile using GLC (higher even for IR?). This could mean that what is free today may in future, with a change in analytical accuracy, fail to be free. Even now all a lab result will give is ‘not detected’, not an absolute assurance that it is ‘free’. • Suggestion to add under definitions: ‘Free of xxxx fatty acids means not detectable in the finished food product as consumed at a detection limit of 0.1% of all fatty acids’ or similar wording. In time detection levels can be adjusted if necessary.
Australian Nut Industry Council (ANIC) and Nuts for Life	Industry (Australia)	<ul style="list-style-type: none"> • Supports option 2. • All raw nuts are free of trans fat and contain less than 28% of total fats as saturated fat. • A definition of ‘free’ would be useful, i.e. absolute zero or beyond the level of reporting as well as information on how ‘trans fat free’ should be referred to in the NIP.
Sanitarium Health Foods	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports option 2. • Believes this will allow manufacturers to provide more meaningful information to help consumers avoid trans fats in their diets, as many processed foods that traditionally contain trans fats are also high in total fat. • The practical use of trans (and other) fat free claims will be limited, unless the definition of ‘free’ with respect to food is defined at being ‘at a level irrelevant to the normal diet’. CoPoNC have set suitable criteria for these claims.

Submitter	Group	Comments
The National Heart Foundation of New Zealand	Public Health (New Zealand)	<ul style="list-style-type: none"> • Supports option 2. • Recommends the definition of ‘free of’ with regard to trans fat be given further consideration. Would ‘free of trans fat’ mean ‘no trans fat at all’ or ‘no detectable trans fat’? • Notes that from their experience in NZ< different labs have different level of sensitivity for trans fat testing, some can report trans fat levels down to <0.1 g/100 g, another cannot detect trans fat below 0.5g/100g and yet another claim they can detect the trans fat level of ‘zero’ and can report the level of trans fat to two decimal places.
Tomox Pty Ltd (Susan Thompson, Consultant Dietitian)	Industry (Australia)	<ul style="list-style-type: none"> • The requirement for trans fat that ‘free’ means ‘undetectable’ is of concern for content claims in dairy products containing natural trans fat. • The North American Institute of Medicine and Dietitians Association of Australia have cautioned about trying to eliminate trans fatty acids from diets by avoiding meat and dairy foods because this would have undesirable effects on other dietary components.
Food Technology Association of Australia (FTA)	Industry (Australia)	<ul style="list-style-type: none"> • Prefers option 2.
Fonterra	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Remains silent on health claims with specific reference to TFA. • Reminds FSANZ of their previous statements indicating that TFA consumption patterns are non-problematic in the context of the Australian and New Zealand populations. • Would like to see a review of the definition of TFA for the context of food labelling and the adoption of a definition in line with other countries that exclude TFA from ruminant sources. • Are concerned that permitting marketing around the absence of TFA will create confusion or unnecessary angst amongst consumers in relation to the differentiation between TFA from hydrogenated compared to natural sources and the link to adverse health outcomes.
National Health and Medical Research Council (NHMRC)	Government (Australia)	<ul style="list-style-type: none"> • Draws attention to p.262 of the NRVs 2006, in the Chapter on Macronutrient Balance (p.257) which addresses Trans Fatty Acids.
Cadbury Schweppes Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 2
Parmalat Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 2
Chamber of Commerce & Industry WA	Government (Australia)	<ul style="list-style-type: none"> • Supports Option 2 believes this provides incentive for manufacturers to develop healthier option.
Cereal Partners Worldwide (CPW)	Industry (Australia)	<ul style="list-style-type: none"> • Believes claims about trans fatty acids should be permitted on foods with no trans fatty acids, or with very low levels. • Thinks FSANZ needs to state a level below which a ‘free’ claim can be made and requests FSANZ seek agreement from the ACCC.

Submitter	Group	Comments
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> Supports FSANZ recommended option
CHOICE	Consumer (Australia)	<ul style="list-style-type: none"> Supports proposed Option 2 which will establish maximum saturated fatty acid content for products carrying a trans fat claim.
National Centre of Excellence in Functional Foods (NCEFF)	Research and Academia (Australia)	<ul style="list-style-type: none"> In the end, consumers need to choose <i>foods</i> and know the limits of consumption on portion sizes and food groups. Considers this issue in the light of earlier propositions – differentiating between primary and reconstructed/manufactured foods, and providing guidance for the development of new foods.
Murray Goulburn Co- operative Co. Ltd	Industry (Australia)	<ul style="list-style-type: none"> Recommends that the term ‘low in trans fat’ is more useful than ‘trans free’ in identifying those foods which do not contain partially hydrogenated fats in nutritionally significant quantities. A ‘low in trans fat’ claim would then permit dairy ingredients and traces of TFA from refined fats where it is not possible to remove every trace of TFA, this would encourage the use of healthier oils. Recommends the ‘low in trans fat’ claims be permitted with the following conditions: <ul style="list-style-type: none"> a) the food contains no more TFA than 1 per cent of the total fatty acid content of the food; and b) the food contains no more saturated and TFA than – <ul style="list-style-type: none"> (i) 0.75 g per 100 mL for liquid food; or (ii) 1.5 g per 100 g for solid food; or (iii) 28 per cent of the total fatty acid content of the food. Strongly recommends that the definition in Standard 1.2.8, Division 1, Clause 1 for TFA is inappropriate and should be reconsidered as soon as possible in the context of current scientific knowledge and international regulations in this area to exclude all sources of ruminant TFA.
Australian Self Medication Industry (ASMI)	Therapeutic (Australia)	<ul style="list-style-type: none"> Supports option 2. This option provides an appropriate level of information for consumers to make informed decisions.
Bayer Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> Supports option 2.
Campbell Arnott’s Asia Pacific	Industry (Trans Tasman)	<ul style="list-style-type: none"> Supports option 2. Also recommends FSANZ include a low trans fatty acid claim to allow those foods which contain nutritionally insignificant but detectable levels of trans fat, and a low proportion of saturated fat, to accurately inform consumers of the nutrient content of the products. This will encourage greater use of ‘healthy’ oils, and allow foods containing small amount of trans fat (such as dairy fat) to make a low proportion of saturated fat and low trans fat claim. Also recommends that FSANZ applies the WHO target of no more than 1% of total energy from trans fatty acids to individual foods as a condition of making a low trans claim in conjunction with the low proportion of saturated fat claim.
New Zealand Commerce Commission	Government (New Zealand)	<ul style="list-style-type: none"> Does not state a preferred option. The claim ‘free of trans fatty acids’ is inherently misleading when it is used to describe a product containing trans fatty acids, even where there is a very small amount or trace level of trans fatty acid. A ‘free’ claim is an absolute claim, which indicates that a product does not contain a particular substance or attribute.

Submitter	Group	Comments
Confectionery Manufacturers of Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports option 2.
Commonwealth Scientific and Industrial Research Organisation (CSIRO)	Research and Academia (Australia)	<ul style="list-style-type: none"> • Supports option 2. • Notes that according to the ACCC, trans fat free would necessitate a zero trans fatty acid content. Would therefore propose a term ‘very low trans fats’ which would be defined as less than 0.5 g trans fatty acids per 100 g product to accompany any claim for low or proportionally low in saturated fat. • CSIRO’s proposed option does not excessively discriminate against naturally occurring trans fatty acids in lean beef and some low fat dairy foods.
Dairy Australia	Industry (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. • Does not support option 2. • A ‘free of trans fatty acids’ claim only appears to be useful to consumers if it refers to ‘industrially produced trans fatty acids’. The fat of ruminant animals (including dairy fat) contains small amounts of naturally occurring trans fats. • Allowing a ‘free’ of trans fat claim appears to have little potential to address foods with a high industrially produced trans fat content, and considerable potential for a range of foods to carry the claim with little benefit to consumers. • For foods such as avocados and nuts to be allowed to carry a claim such as ‘free of trans fatty acids’ does not contribute to consumer education since these foods were never at risk of containing significant amounts of trans fatty acids. • A trans fat claim should distinguish between the small amount of natural trans fatty acids in ruminant fats and industrially produced trans fat.
Dairy Farmers	Industry (Australia)	<ul style="list-style-type: none"> • Does not indicate a preferred option. • Continues to be concerned that there is no distinction made between manufactured and naturally occurring trans fats. • Reiterates the proposals made in response to P293 in May 2007 for an urgent review of the definition of trans fatty acids to bring it in line with international definitions. Concern has already been expressed that consumers will restrict dairy to the detriment of nutrient intake in an attempt to limit trans fat.

Submitter	Group	Comments
Department of Health & Human Services Tasmania	Government (Australia)	<ul style="list-style-type: none"> Does not indicate a preferred option. Agrees that trans fat free should contain no detectable trans fatty acid. Aware that there is not general scientific agreement regarding the role of naturally occurring trans fatty acids from ruminants and supports the current definition of trans fatty acids including manufactured and ruminant trans fats. Remains concerned about the potential for consumer confusion between ‘trans fat free’ claims on foods that are low in saturated fat and foods that have no more than 28% saturated fatty acid as a proportion of total fatty acid content, but supports the promotion of a beneficial fatty acid profile. An additional statement that helps consumers to differentiate between high fat foods with a beneficial fatty acid ratio such as trans fat free and healthy fatty acid profile and low saturated fat trans fat free foods may be of benefit to consumers.
Dietitians Association of Australia (DAA)	Public Health (Australia)	<ul style="list-style-type: none"> Supports option 2.
Food & Beverage Importers Association (FBIA)	Industry (Australia)	<ul style="list-style-type: none"> Supports option 2.
Frucor Beverages Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> Supports option 2.
George Weston Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> Supports option 2. It is understood that ‘free’ means the ‘lowest detectable level’. Support the AFGC recommendation for FSANZ to seek clarification with ACCC on the meaning of ‘free’.
Go Grains Health and Nutrition Ltd	Industry (Australia)	<ul style="list-style-type: none"> Does not indicate a preferred option. Expresses concern about the use of the word 'free' in relation to the content of any substance in food. It is unrealistic to expect baked foods made with fats and oils to have absolutely no trans fat, but they may have so little as to be nutritionally irrelevant.
Heinz Wattie’s Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> Supports option 2. A definition of ‘free’ of trans fat should be provided; e.g. free means not detectable, or below a certain level. Agreement must be reached with the Australian Competition and Consumer Commission (ACCC) and the New Zealand Commerce Commission prior to release of the new standard 1.2.7 to ensure the interpretation of ‘free’ does not contravene trade practices/fair trading legislation.
Nestlé Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> Supports option 2. Requests that FSANZ seeks agreement from the ACCC for the conditions of making ‘free’ claims.
New South Wales Centre for Public Health Nutrition	Public Health (Australia)	<ul style="list-style-type: none"> Supports option 2. There are some concerns that manufacturers could simply replace trans fat with saturated fats, however, this issue may partly be addressed by the ‘less than 28% SFA of total fatty acid’ criteria.

Submitter	Group	Comments
New Zealand Dietetic Association (NZDA)	Public Health (New Zealand)	<ul style="list-style-type: none"> • Supports option 2. • The criteria for the term; ‘free of’, requires further clarification. Three New Zealand laboratories report varying sensitivities for the lowest levels of trans fatty acids that can be tested.
New Zealand Food and Grocery Council	Industry (New Zealand)	<ul style="list-style-type: none"> • Supports option 2. • The ability to make such a ‘free’ claim in New Zealand is negated however by the fact the New Zealand Commerce Commission will not permit the use of ‘absolute’ claims unless there is complete absence of the ingredient present. • If such a ‘free’ claim is permitted the matter must be discussed with the New Zealand Commerce Commission, to obtain a recommendation on the level of trans-fatty acids below which the claim can be made.
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> • Supports option 1. • Trans fatty acid intakes are relatively low in New Zealand and saturated fatty acid intake remains the most important modifiable determinant of blood cholesterol levels and cardiovascular disease. • Therefore, option 1 is consistent with the national guidelines for healthy eating, which recommend New Zealanders reduce their total saturated fat intake.
The National Heart Foundation of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Supports option 2.
The Cancer Council Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Supports option 2.
Australian Food and Grocery Council (AFGC)	Industry (Australia)	<ul style="list-style-type: none"> • Recommends that: <ul style="list-style-type: none"> – a ‘free of trans fatty acid’ claim be permitted on foods with no trans fatty acids, or foods with very low levels; – FSANZ prescribe a level of trans fatty acids, below which the ‘free’ claim can be made; and – FSANZ resolve with the ACCC the criteria for the use of the claim, other than the total absence or undetectability of the substance in a food. • Foods may have no/very little trans-fatty acids – free of trans fatty acid claims should be permitted in both cases. FSANZ has argued that foods with higher levels of fat should be able to carry a ‘low proportion of saturated fatty acids’ claim. • Has supported this argument and considers a similar approach should be adopted for trans fatty acid claims. Foods higher in fat should be able to make free of trans fatty acid claims (when this is the case) to inform consumers. • Agrees that the claim should also be restricted based on saturated fatty acid levels.
Kraft Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 2. • Requests that, in light of the ACCC defining ‘free’ claims as absolute claims, FSANZ also defines a level at which ‘free’ claims can be made, as absolute free levels are very difficult to assure – even through analysis.

Submitter	Group	Comments
Innovations & Solutions – Wendy Morgan	Industry (Australia)	<ul style="list-style-type: none"> • Supports the proposal for the criteria for ‘free of <i>trans</i> fatty acids’. However, this claim will have limited use as most foods which the public would assume contained <i>trans</i> fatty acids, may still contain traces of <i>trans</i> fatty acids. Hence those foods which would most usefully highlight the much lower levels of <i>trans</i> fatty acids would not be able to do so. • Therefore recommends that FSANZ consider the inclusion of a ‘low in <i>trans</i> fatty acids’ claim whereby the <i>trans</i> fatty acid content is nutritionally insignificant and either the ‘low unsaturated fatty acids’ or the ‘low proportion of saturated fatty acids’ criteria are also met. The advantages of allowing a ‘low in <i>trans</i> fatty acids’ NCC are: <ul style="list-style-type: none"> i) Offers a solution to the dilemma of the definition of ‘free’ which is dependent on analytical techniques; ii) Small amounts of <i>trans</i> fatty acids are nutritionally insignificant but it may be unfeasible to completely remove them, e.g., where small amounts of dairy products are used as ingredients in foods. • This will require FSANZ to set a limit on the level of <i>trans</i> fatty acids to be eligible for a ‘low’ NCC. Suggests using the World Health Organisation target of no more than 1% energy from <i>trans</i> fatty acids in the diet and apply this to individual foods as a conservative figure. • If a ‘low in <i>trans</i> fatty acids’ claim is implemented, there is an opportunity to add the following claim or words with similar meaning which would also assist the public in highlighting better food choices: <ul style="list-style-type: none"> – Low proportion of saturated fatty acids and low in <i>trans</i> fatty acids.
Glycemic Index Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports Option 2.
NSW Food Authority	Government (Australia)	<ul style="list-style-type: none"> • Supports FSANZ’s proposed position, noting that such a claim will most likely be used on high fat foods.
Department of Human Services - Victoria	Government (Australia)	<ul style="list-style-type: none"> • Supports Option 2. • Continues to have concerns with ‘free of’ claims. The Trade Practices Act defines ‘free of’ as having no detectable amount. • Requests that FSANZ discusses this issue with the ACCC and agree on an approach to ‘free of’ claims, or alternatively define in the Code what constitutes ‘free of’. Industry needs to be confident when making ‘free of’ claims.
New Zealand Food Safety Authority (NZFSA)	Government (New Zealand)	<ul style="list-style-type: none"> • Supports an amended Option 2 whereby the food must also meet the NPSC, for consistency. • Inclusion of the provision ‘no more than 28% saturated fatty acids as a proportion of the total fatty acid content’ is in line with National Heart Foundation guidance.
Queensland Health	Government (Australia)	<ul style="list-style-type: none"> • Supports Option 2
Goodman Fielder Home Ingredients	Industry (Australia)	<ul style="list-style-type: none"> • Supports option 2. • This option allows the claim to be used in association with foods that have a healthier profile, and is consistent with other fatty acid claims.

Submitter	Group	Comments
The Public Health Association of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Believes that any free from trans fat claims will further increase consumer confusion about fat and should not be allowed. • Such claims are likely to be similar to cholesterol free claims that have a history of appearing on foods that don't naturally contain cholesterol, thereby leading consumers to believe misnomers such as one brand of olive oil being better than another because of a large print, front of pack nutrition content claim.
Dr Rosemary Stanton	Public Health (Australia)	<ul style="list-style-type: none"> • Supports Option 2 as trans fat free claims should only be made on products that limit saturated fat. • The aim should be to eliminate industrially-manufactured trans fat. • The Institute of Medicine in the United States has declared there is no safe level of trans fat and this opinion would be shared by most nutritionists. • However, she understands FSANZ and others' concerns that it would be undesirable if companies replaced trans fat in products with higher levels of saturated fat. The solution is to provide consumers with better information and make it mandatory for the nutrition information panel to list the industrially- manufactured trans fat content, as occurs in the USA, Canada, Scandinavian countries and the Netherlands.

4. SUBSTANTIATION OF FOOD-HEALTH RELATIONSHIPS FOR USE AS A BASIS FOR GENERAL LEVEL HEALTH CLAIMS

4.1 Comments on method 1 – list of nutrient function statements

Submitter	Group	Comments
ADECRON Food Tech Consulting Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> • Agrees with inserting method 1 into the standard to clarify requirements.
Australian Food and Grocery Council (AFGC)	Industry (Australia)	<ul style="list-style-type: none"> • Recommends inclusion of a pre-approved nutrient function claim on long chain omega-3 fatty acids, quoting the FSANZ conclusions from the review by Howe et al, quoting ‘...sufficient evidence to support a general level health claim...’. • An omega-3 statement should be included, consistent with the requirements of Standard 1.2.8, clause 13, and also acknowledging the specific requirements of subclauses (3), (4) and (5). • Recommends the claim should be – ‘Omega-3 fatty acids play an important role in heart health.’
Cadbury Schweppes Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • No concerns with this method.
Confectionery Manufacturers of Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports the approach outlined in this method.

Submitter	Group	Comments
Cerebos Foods	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports inclusion of the list of nutrient function statements. • Supports the list being available within the Code, to aid with enforcement. • Supports the list of nutrient function statements being the only part of the proposed Scientific Substantiation Framework that is included in the draft standard. • Strongly supports the inclusion of two iodine nutrient function statements.
CHOICE	Consumers (Australia)	<ul style="list-style-type: none"> • Suggests that a list of pre-approved nutrition function statements be included in or accompany the Standard.
Commonwealth Scientific and Industrial Research Organisation (CSIRO)	Research & Academia (Australia)	<ul style="list-style-type: none"> • The nutrient function statements do not reflect current scientific evidence. • The statements do not necessarily reflect the most important function of that nutrient and in some cases are too restrictive. • For example, in the case of folate one could argue that it is needed for formation of all tissues, not only blood, given its fundamental role in DNA synthesis and repair. • In the case of B12, one could argue that the main consequence of its deficiency is neuro-degeneration rather than reduced blood formation, i.e. maintenance of neural function is a more critical and unique role of vitamin B12.
Consumers NZ	Consumers (New Zealand)	<ul style="list-style-type: none"> • Supports the suggestion that a list of pre-approved nutrition function statements be included into the draft Standards as a Schedule.
Dairy Australia	Industry (Australia)	<ul style="list-style-type: none"> • It would be useful to provide a mechanism with time intervals for pre-defined nutrient function statements to be modified or added to over time.
Dairy Farmers	Industry (Australia)	<ul style="list-style-type: none"> • Recommends a process for regular review of the statements.
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> • Supports this method.
Department of Health & Human Services Tasmania	Government (Australia)	<ul style="list-style-type: none"> • Supports this method, without requirement for further substantiation.
Department of Human Services - Victoria	Government (Australia)	<ul style="list-style-type: none"> • Supports method 1. • This method uses pre-determined nutrition function statements that are unequivocal sources of current substantiated health claims.
Goodman Fielder Home Ingredients	Industry (Australia)	<ul style="list-style-type: none"> • Concerned that FSANZ has not addressed the need for a general level health claim relating to long chain omega-3 fatty acids as part of the pre-approved nutrient function statements. • Standard 1.2.8, clause 13 already includes criteria under which claims for omega-3 fatty acids may be made. • Consistent with these requirements it is appropriate that FSANZ include a pre-approved nutrient function statement for omega-3 fatty acids. • Acknowledges the specific requirements of subclauses (3), (4) and (5) in relation to differentiating the omega-3 fatty acid content based on the presence of ALA, EPA and DHA. • Recommends FSANZ consider pre-approval for a nutrient function statement for both omega-3 fatty acids.

Submitter	Group	Comments
Heinz Wattie's Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Recommends that FSANZ devise a pre-approved general level health claim for omega-3 – such as ‘Omega-3s (DHA/EPA) are important for heart health’. • Quotes FSANZ conclusion from Howe et al (page 13).
Innovations & Solutions – Wendy Morgan	Industry (Australia)	<ul style="list-style-type: none"> • A claim for long chain omega-3 fatty acids should be included based on statements made in the FSANZ Diet-Disease Relationships (Howe et al) (page 13). Quotes ‘...evidence can be rated as ‘probable’ but cannot be rated as ‘convincing’...subsequent opinion by FSANZ is sufficient evidence to support a claim based on the diet-disease relationship between long chain omega-3 fatty acids and cardiovascular health.’ • Recommends the pre-approved nutrition function statement should be – ‘Long chain omega-3s play an important role in heart health.’ • Standard 1.2.8 has criteria for making source and good source claims about long chain omega-3s, and a general level health claim should be permitted based on these requirements. • It is incorrect for FSANZ to remove the previously listed nutrient function statement for DHA on the basis that ‘there are no criteria for claims about DHA in the Code on which to base a general level health claim’, as Standard 1.2.8 clearly states that DHA is an omega-3 fatty acid, and clause 13 of Standard 1.2.8 provides eligibility criteria for source and good source omega-3 claims. • Recommends the following nutrition function statement be reinserted in the list – ‘DHA, an omega-3 fatty acid, supports the normal development of the brain, eyes and nerves.’
National Centre of Excellence in Functional Foods (NCEFF)	Research & Academia (Australia)	<ul style="list-style-type: none"> • Represents the <i>status quo</i> and is therefore least problematic. • The term ‘food-health’ relationship is used but the section appears concerned with ‘nutrient-health’ relationships.
National Foods Limited	Industry (Trans Tasman)	<ul style="list-style-type: none"> • The substantiation requirements for a ‘food-health relationship’ requires two corroborating sources. Is the same true for a nutrient function statement? • FSANZ have removed the claim for omega-3 from the list of pre-approved general level health claims. The wording previously read – Docosahexaenoic acid (DHA): DHA, an omega-3 fatty acid, supports the normal development of the brain, eyes and nerves. • The claim (brain, eyes and nerves) had previously been accepted based on the substantiation undertaken by the Canadian Food Inspection Agency (who remains as a reference on other general level health claims listed in Table 1 of the Consultation Paper). • The Dietary Guidelines for Australian Adults also acknowledge the evidence for omega-3 and quote that ‘...omega-3 fats appear to have a number of beneficial actions, notably in relation to brain development and function, and cardiovascular health’. • The NRVs for Australia and NZ also acknowledge the role of long-chain omega-3 fatty acids and that DHA plays an important role as a structural membrane lipid, particularly in the nerve tissue and the retina, as well as the cardiovascular benefits of long-chain omega-3s. • Quotes the authors’ conclusions from the Technical Report (Howe et al) about that the evidence for CVD risk reduction by omega-3 in foods is convincing. Contends ‘this position is consistent with the NHF of Australia’s draft position paper and the UK’s omega-3 heart health claim..’

Submitter	Group	Comments
		<ul style="list-style-type: none"> • FSANZ claim ‘there are no criteria for claims about DHA in the Code on which to base a general level health claim’. Standard 1.2.8, clause 13 includes criteria...repeated in the Draft and Preliminary Final Assessment Reports for P293. • Consistent with these requirements and based on the scientific evidence for omega-3, it is appropriate that FSANZ include a pre-approved nutrient function statement for omega-3 fatty acids. • Recommends that the pre-approved list for general level health claims includes an omega-3 claim for heart, brain, eyes and nerves.
New Zealand Food and Grocery Council	Industry (New Zealand)	<ul style="list-style-type: none"> • Supports the inclusion of the nutrient function statements in the substantiation framework.
New Zealand Food Safety Authority (NZFSA)	Government (New Zealand)	<ul style="list-style-type: none"> • Supports this method with minor modifications outlined below. • Suggests that the words ‘food-health relationship’ in 1.1 and 1.2 are replaced with ‘nutrient function statements’. • Suggests the words ‘based on’ are changed to ‘consistent with’. • The subclause would then read: 1.1 The nutrient function statements mentioned in Table 1 may be used as the basis of a general level health claim. • The subclause would then read: 1.2 The wording of the statement is not prescribed for the purpose of making a claim, however, the general level health claim must be consistent with the scientific intent of the nutrient function statement. • For consistency with the rest of the Code, the entry in Table 1 for Vitamin B1 should be listed as Thiamin, i.e. spelt without an ‘e’. • If the logic used by FSANZ to remove the DHA claim (supports the normal development of the brain, eyes and nerves) was to be extended to all nutrient function claims, it would limit such claims to vitamins and minerals, protein and dietary fibre. • This could be an unintended consequence of proceeding with the removal of DHA claims. • If the DHA statement was evaluated under method 4 and found to be substantiated could the claim then be made?
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> • Supports method 1 with some modifications. • Believes the wording of nutrient function statements should be prescribed to ensure consistency and assist consumer understanding.

Submitter	Group	Comments
Nu-Mega Ingredients Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> Strongly recommends inclusion of a general level health claim for long chain omega-3 fatty acids in Table 1 as stated in FSANZ Technical Report page 13 (Howe et al). Quotes ‘evidence can be rated as ‘probable’ but cannot be rated as ‘convincing’...the subsequent opinion by FSANZ is sufficient evidence to support a general level health claim based on the diet-disease relationship between long-chain omega-3 fatty acids and cardiovascular health’. This claim should meet the criteria in Standard 1.2.8 clause 13. Recommends the following nutrition function statement – ‘Long chain Omega-3s contribute to the healthy functioning of the heart.’ FSANZ has removed the previously listed nutrient function statement for DHA because there are no criteria for claims about DHA in the Code, which is in fact not the case (refer Standard 1.2.8, clause 13). Recommends the following nutrition function statement be reinserted in the list in Table 1 – ‘DHA, an Omega-3 fatty acid, supports the normal development of the brain, eyes and nerves.’
The Omega-3 Centre	Industry (Australia)	<ul style="list-style-type: none"> Strongly recommends inclusion of a general level health claim for long chain omega-3 fatty acids in Table 1, which should meet the criteria in Standard 1.2.8 clause 13 (min. amount for source and good source claims). Quoting FSANZ Howe et al review (page 13), contends there is sufficient evidence for a general level health claim for long chain omega-3s and cardiovascular health and suggests stating it in the following manner in Table 1 – ‘Long chain omega-3s contribute to the healthy functioning of the heart.’ FSANZ removed the previously listed function statement because ‘there are no criteria for claims about DHA in the Code on which to base a general level health claim’. However this is not the case (refers to Standard 1.2.8, clause 13). Recommends the nutrient function statement be readmitted to the list in Table 1 – ‘DHA, an Omega-3 fatty acid, supports the normal development of the brain, eyes and nerves.’ If DHA is still considered by FSANZ to be an issue, then at the very least a general level health claim on long chain omega-3s should be included as follows – ‘Long chain Omega-3s supports the normal development of the brain, eyes and nerves.’
Parmalat Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> Agree the pre-defined list of nutrient function statements will assist industry, especially those smaller industry players who lack the resources to put together complex substantiation dossiers. What provisions will be made to update nutrition function statements? Given that most statements are linked to the UK JHCI, does this mean updates are linked to changes in the JHCI list? What will be the ongoing review process to have new nutrition function statements added to the list?
Simplot Australia Pty. Ltd	Industry (Australia)	<ul style="list-style-type: none"> Believes there is sufficient evidence to support a pre-approved statement for: ‘Omega-3 fatty acids play an important role in heart health.’ Quotes FSANZ Technical Report (Howe) re sufficient evidence for a general level health claim. Quotes FSANZ media release of 4 April 2007 including comments from Melanie Fisher, that a general level health claim will be able to be made such as ‘omega-3s aid heart health’.

Submitter	Group	Comments
Dr. Rosemary Stanton	Public health (Australia)	<ul style="list-style-type: none"> It would be useful to include these in the Standard for easy reference by companies or members of the public who may wish to check a statement.
Unilever Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> The statement for DHA has been removed 'because there are no criteria for claims about DHA in the Code on which to base a general level health claim'. Unilever contests the basis for the proposed removal of this claim. There are nutrient content claims permitted for omega-3 fatty acids , with specified criteria for EPA and DHA Supports retention of the DHA statement in Table 1.

4.2 Comments on method 2 – prescribed list of pre-approved food-health relationships

Submitter	Group	Comments
ADECRON Food Tech Consulting Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> Agrees with inserting method 2 into the standard to clarify requirements.
Bayer Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> This method could inadvertently lead to high level health claims being made if adequate regulatory measures are not in place within food companies. Adapting wording to have the same meaning, while allowing clarity, requires a high level of skill.
Cadbury Schweppes Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> No concerns with this method.
CHOICE	Consumers (Australia)	<ul style="list-style-type: none"> Supports the provision of a list of pre-approved high level health claims in the Standard.
Confectionary Manufacturers of Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> Supports the approach outlined in this method.
Consumers NZ	Consumers (New Zealand)	<ul style="list-style-type: none"> Supports the provision of a list of pre-approved high level health claims in or accompanying the standard.
Dairy Australia	Industry (Australia)	<ul style="list-style-type: none"> The conversion of pre-approved high level food-health relationships into general level claims is welcomed. Guidelines regarding what is and isn't acceptable would also be useful (e.g. heart health is an acceptable general term for cardiovascular disease, what else is acceptable?)
Dairy Farmers	Industry (Australia)	<ul style="list-style-type: none"> Recommends there is a process for regular review of the pre-approved food-health relationships.
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> Supports this method.
Department of Health & Human Services TAS	Government (Australia)	<ul style="list-style-type: none"> Supports this method.
Department of Human Services - Victoria	Government (Australia)	<ul style="list-style-type: none"> Supports this method. This method uses pre-determined food-health relationships that are unequivocal sources of current substantiated health claims.

Submitter	Group	Comments
Food Technology Association of Australia (FTA)	Industry (Australia)	<ul style="list-style-type: none"> Title should read 'Prescribed list of pre-approved general level food-health relationships' and not high level, otherwise the use of this term makes this description of substantiation of general level health claims incomprehensible with the balance of the whole document.
Heinz Wattie's Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> Requests clarification on the terminology used. The method refers to food-health relationships, yet some of the relationships relate to nutrients rather than food.
National Centre of Excellence in Functional Foods (NCEFF)	Research & Academia (Australia)	<ul style="list-style-type: none"> Refers to pre-approved food-health relationships, but only one of the eight statements relate to food. One relates to the total diet and the other six refer to nutrients. The predominant groups are actually nutrient-health relationships. Reference to acceptable terms such as 'heart health', 'bone health' and 'healthy babies' might be tested with consumers as suitable alternatives for general level health claims and pre-approved as such. Reference only to disease/biomarkers in Table 2 is not helpful when the statement is made that while pre-approved high level health claims relationships may be used in a general level health claim, no reference may be made to disease or biomarkers in general level health claims.
New Zealand Food and Grocery Council	Industry (New Zealand)	<ul style="list-style-type: none"> Supports the inclusion of the food-health relationships in the Scientific Substantiation Framework.
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> Has concerns about method 2. Consumers do not distinguish between a disease (e.g. CHD) and a less specific health claim (e.g. healthy heart). Supports a modified method whereby the general level health claim were pre-approved and the wording prescribed.
Parmalat Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> This will be quite limited in application given it will only benefit in making general level health claim surrounding 5 foods/nutrients. The key to utilising general level health claim is to identify terminology that defines a health effect but does not fall within the definition of a serious disease or biomarker. It would be worthwhile from both an industry and jurisdiction stance that a list of permitted statements that could be substituted for the serious diseases (e.g. heart health in lieu of cardiovascular disease) be developed as guidelines to accompany the substantiation process associated with Method 2.
Dr. Rosemary Stanton	Public Health (Australia)	<ul style="list-style-type: none"> This list could also be included in the Standard. Further consumer research should be done to gauge consumers' understanding of the difference between high level health claims (e.g. prevents heart disease) and general level health claims (e.g. promotes heart health). If consumer research shows a lack of understanding of any difference in these claims, the issue may need to be reassessed.

4.3 Comments on method 3 – prescribed list of scientific source documents

Submitter	Group	Comments
ADECRON Food Tech Consulting Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> Agrees with inserting method 3 into the standard to clarify requirements and tighter clarification on method 3.

Submitter	Group	Comments
Australian Food and Grocery Council (AFGC)	Industry (Australia)	<ul style="list-style-type: none"> • Concerned that the prescribed list is culturally limited. • Fails to provide reference to the scientific opinions by EFSA or other credible scientific sources in Asia. • Australian population is multicultural, yet the only international Authoritative Sources cited, and therefore acceptable to enforcement agencies are the US, UK and WHO. • Concerned that reliance solely on the Cochrane Database is too limited and should only be used as an example of peer-review sources. • There may be other equally useful reviews of scientific publications and the Cochrane Database quickly becomes out-of-date. • ‘Does not support prescribing specific sources of scientific information required for use substantiating additional general or high level claims to those listed in the Food Standards Code’. • Table 3 would be better provided as an example of what is intended in user guides to support the standard. This then allows flexibility in how companies demonstrate the validity of their claims to enforcement agencies. Such an approach is consistent with ‘outcomes based’ regulations and will reduce regulatory burden on industry. • Recommends under clause 3.2 (e), regarding evidence from authoritative texts, that FSANZ amend the term ‘definitive’ to ‘confident’. • The requirements for 2 corroborating sources will help ensure consistency however the word ‘confident’ is a more practical approach to the way health relationships are described.
Bayer Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Prescribed list of source documents gives greater clarity and the use of texts published within the last 10 years is a good reflection of the speed with which new findings are made. • However, scientific reviews are only written many years after new findings are made and could be restrictive to companies who have invested in research. • Suggests reconsidering the list of permitted reputable scientific sources thereby allowing the use of more recent research findings.
Cadbury Schweppes Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • No concerns with this method. Initially thought the list of documents would be very limiting and would question how they would allow for information provided by merging sciences or clinical studies. However, while the sources of approved documents are specific, the type of documents cited does appear to be generic enough to allow for additional information to be included.
Campbell Arnott’s Asia Pacific	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Recommends FSANZ does not preclude other credible substantiation sources by prescribing only those sources listed in Table 3.
The Cancer Council Australia	Public health (Australia)	<ul style="list-style-type: none"> • The recommendation to include a more prescriptive list of pre-approved source documents seems a sensible approach. • However, they suggest that an additional consideration in determining the range of textbooks which can be used to substantiate general level health claims, is that they are appropriately peer reviewed and that the authors and editors of the text books have no commercial conflicts of interest. • It would not be appropriate for someone who is or has been funded extensively by the food industry to be considered a specialist or expert on a particular topic.

Submitter	Group	Comments
		<ul style="list-style-type: none"> The definition of specialist or expert must be made more explicit in the Scientific Substantiation Framework, so that so-called experts in naturopathy and alternative nutrition are excluded. FSANZ needs to be very clear in drafting this section, including guidelines for who would be acceptable authors of the prescribed scientific source documents (i.e. no commercial conflicts).
Cereal partners Worldwide (CPW)	Industry (Australia)	<ul style="list-style-type: none"> Does not support the prescribed list of specific sources. Concerned that the list of sources is geographically limited. The list fails to provide reference to the scientific opinions provided by the EFSA. Australian population is multicultural, yet the list is limited to UK, US and WHO sources. The list should be extended to include published papers in scientific, peer reviewed journals, position papers and scientific reviews conducted by peak medical, nutrition, scientific or public health non government authoritative organisations. To try and produce an exhaustive list of source material will mean that the material will be continually out of date or require amending to keep pace with scientific changes. The approach is extremely restrictive and facilitates enforcement only and does not underpin the aim of fostering an innovative globally competitive food industry.
CHOICE	Consumers (Australia)	<ul style="list-style-type: none"> The findings of the studies or sources selected to support a general level health claim must be consistent with the overall weight of evidence. The balance of evidence should not contradict the two or more selected corroborating sources, nor should evidence be inconclusive. The selected sources should not be published by the same author(s), institution or organisation or be funded from the same sources. The research must be published in reputable peer-reviewed journals or otherwise subject to peer review. Concerned that the use of specialist human nutrition textbooks as supporting sources could allow general level health claims to be based on dubious, insufficient or outdated evidence. Some books available on the topic of nutrition are based on highly dubious research or theories. These would not necessarily stand up to a peer-review process. Scientific textbooks in human nutrition should be removed from the list of authoritative sources.
Confectionery Manufacturers of Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> Supports the approach outlined in this method.
Consumers NZ	Consumers (New Zealand)	<ul style="list-style-type: none"> Supports the provision that two corroborating sources are required in which the food-health relationship is clear, confident and definitive. The selected sources should not be published by the same author(s), institution or organisation or be funded from the same sources. The research must be published in reputable peer-reviewed journals or otherwise subject to peer review.

Submitter	Group	Comments
Commonwealth Scientific and Industrial Research Organisation (CSIRO)	Research & Academia (Australia)	<ul style="list-style-type: none"> • Seems very vague on the quality and type of research results required. • It does not provide any justification why two corroborating sources are sufficient and why no further substantiation is needed.
Department of Agriculture, Fisheries and Forestry (DAFF)	Government (Australia)	<ul style="list-style-type: none"> • Rather than including a prescribed list of source documents, it may be preferable for the standard to be limited to referencing a list which could be more readily updated.
Dietitians Association of Australia (DAA)	Public Health (Australia)	<ul style="list-style-type: none"> • Recommends that the two corroborating sources should be from at least two different authors, preferably from independent laboratories or research institutes. • Supports further guidance on the use of appropriate textbooks to ensure a similar quality and rigour of evidence as with other sources to provide clarity for manufacturers and enforcement agencies.
Dairy Australia	Industry (Australia)	<ul style="list-style-type: none"> • Does not support a prescribed (and therefore restrictive) list of scientific source documents. • The list provides good examples and helpful suggestions of the type of supporting evidence that companies require. • The prescribed listing is restricted for reasons unrelated to whether a proposed claim is truthful and scientifically valid. • As one example, scientific reviews conducted by FSANZ are not included. • The table of authoritative sources would obviously need to be reviewed frequently, e.g. the UK JHCI is not a source of ongoing reviews. • There is potential for conflicting interpretations in the listed sources and methods, and the understanding of even food-health relationships which ‘are clear, confident and definitive’ may change with time. • While the requirement for ‘two corroborating sources’ is clear (assuming these are not required to be from different categories of sources), the possibility of conflicting sources is also apparent and relevant but not well developed in the framework. • The most recent version of documents will result in a spread of publication dates. • Many of the authoritative sources are difficult to locate – this may become more difficult as sources change. • While enforcement is an important issue, the functionality of the standard should not be driven by ease of enforcement. • A table of ‘example authoritative sources’ would be a better and more helpful guide than an arbitrarily abridged prescribed list.
Dairy Farmers	Industry (Australia)	<ul style="list-style-type: none"> • Recommends there is a process for regular review of the authoritative sources.
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> • Does not support this method. • Considers that human nutrition textbooks should not be included without appropriate peer review as they are subject to wide variations depending on author. • Credible information in text books will be derived from valid food health relationship information in other scientific papers which can therefore be used directly for substantiation.

Submitter	Group	Comments
Department of Health and Human Services Tasmania	Government (Australia)	<ul style="list-style-type: none"> • Supports the use of credible source documents less than ten years old. • Believes the description of tertiary level textbooks in human nutrition does not adequately define these sources for enforcement. • Recommends removal of text books from credible source documents. • Comments in text books may be based on emerging theories with varying degrees of scientific rigour. • Supports the removal of textbooks or a more prescriptive definitive description of sources (books listed by FSANZ in a guidelines referred to in the standard) for clarity of enforcement. • The requirement for two corroborating sources is a step in the right direction. • Recommends that these sources should be from separate authors, institution and organisations. • There is still concern over two sources, as it would be possible to find two supporting sources which are not consistent with generally agreed scientific opinion. • The findings of these studies must be consistent with the overall weight of evidence. • The research must be published in reputable peer-reviewed journals or otherwise subject to peer review. • Supports the use of Cochrane reviews, the UK JHCI, prescribed WHO documents, USIM Dietary Reference Intake Series and Australia/NZ National Nutrition Policies.
Department of Human Services - Victoria	Government (Australia)	<ul style="list-style-type: none"> • Concerns about the use of method 3 to justify general level health claims. • Two main concerns with the prescribed list of scientific source documents: 1. The use of ‘scientific textbooks in human nutrition’; and 2. The criterion of using ‘two or more corroborating sources’. • Recommends textbooks from human nutrition and dietetic courses only from local and international universities that are accredited by a body equivalent to the Dietitians Association of Australia. • Recommends that the texts be no older than five years, not ten. • Also recommends a list of suggested textbooks be included in guidelines. • Whilst there is some attempt to control which texts may be used, the ambiguous wording of this source will result in enforcement difficulties. • Potentially this will also allow the use of a range of texts containing nutrition concepts which are not accepted in mainstream, evidence-based science. • The criterion of using two or more corroborating sources does not preclude a manufacturer from using two sources by the same author, or from using two sources that support the contention when there exist others that do not. • Needs to specify that the two sources be from different sections of the list (e.g. two textbooks would not be acceptable).
Fonterra Co-operative Group Ltd	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Inclusion of table 3 in a Standard as proposed means the contents of the table would be exhaustive when in reality there are a variety of other authoritative sources that would be appropriate to include, e.g. EFSA and Canada.

Submitter	Group	Comments
Food & Beverage Importers Association (FBIA)	Industry (Australia)	<ul style="list-style-type: none"> • Does not support the inclusion of a prescribed list of scientific source documents in the Scientific Substantiation Framework in the Standard. • Health benefits is a fast developing area with many credible authorities, including other regulatory bodies, such as the EFSA working in this area. • It seems unnecessarily limiting to include a precise and prescribed list of acceptable sources in the Standard. • Would support the inclusion of an indicative list in a guideline document, which would be much more easily revised to keep the list valid and up-to-date. • Given that the sources are regarded as authoritative, we question the need for two sources to corroborate a relationship. It would seem to us that one source should be sufficient.
Food Technology Association of Australia (FTA)	Industry (Australia)	<ul style="list-style-type: none"> • Suggests that a degree of flexibility be built into the interpretation of what are permitted or recommended or prescribed sources as the sources listed may become redundant, irrelevant or out dated or not the preferred source for publication. For example, an Applicant may have to access a source in another language, a new publication, a publication that has a name change, etc.
George Weston Foods	Industry (Australia)	<ul style="list-style-type: none"> • Recommends the table be used as an example of possible sources rather than an exhaustive list as this is overly prescriptive and excludes other sources of information that are seen as credible. • Could include position papers from credible non-government organisations. • Could include scientific opinions of single or group of experts in a particular field.
Glycemic Index Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports further guidance on the use of appropriate textbooks to ensure the evidence base is at least as good as that from the other methods listed, to ensure equity and clarity for manufacturers and enforcement agencies. • The requirements of method 4 should also apply to the articles printed within textbooks that are allowed to be used as an evidence base. • The two corroborating sources should be from at least two different authors, preferably from independent laboratories or research institutes. • Suggests FSANZ also consider recommending within the Standard the use of other high quality methods of conducting systematic reviews, such as QUOROM for randomized controlled trials or MOOSE for epidemiological studies (references given in submission).
Go Grains Health and Nutrition Limited	Industry (Australia)	<ul style="list-style-type: none"> • Strongly recommends the list be extended to include published papers in scientific, peer reviewed journals which, in most cases, will be far more up to date than the permitted scientific textbooks in human nutrition that may be up to 10 years old. • Proposes that position papers and scientific reviews conducted by peak medical, nutrition, scientific or public health non-government authoritative organisations from Australia, New Zealand and, where relevant, overseas also be included. • Proposes that reports of health claims assessed by overseas governments also be included as acceptable authoritative sources. • The severely restrictive and highly prescriptive approach to the list of authoritative sources facilitates enforcement but inequitably disadvantages industry.

Submitter	Group	Comments
Goodman Fielder Home Ingredients	Industry (Australia)	<ul style="list-style-type: none"> • Concerns that the list of authoritative sources is culturally limited, failing to provide reference to the scientific opinions of EFSA or other credible scientific sources in Asia. • The Australian population is multicultural, with significant ethnic populations from all corners of the globe, yet the only international Authoritative Sources sited, and therefore acceptable to enforcement agencies, are the US, UK and WHO. • Concerned that the reliance solely on the Cochrane database is too limited and should also only be used as an example. • There may be other equally useful reviews of scientific publications and the Cochrane database or reference to the database, quickly becomes out-of-date. • Goodman Fielder does not support prescribing specific sources of scientific information required for use substantiating additional general or high level health claims to those listed in the Code. • The Table to clause 3 would be better provided as an example of what is intended in user guides to support the standard. • This then allows flexibility in how companies demonstrate the validity of their claims to enforcement agencies. • Such an approach is consistent with outcomes based regulations and will reduce regulatory burden on industry. • FSANZ has already moved material from the Scientific Substantiation Framework into supporting documentation and Goodman Fiedler considers the rest should follow. • Such an approach aligns with other regulatory systems, such as those for over the counter medicines, complementary medicines and other listable medicines.
Heinz Wattie's Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Suggests the table is provided as an example of the type of documentation required as this will allow for recently published reviews, new guidelines etc to also be used for substantiation. • This is essential to ensure the most up-to-date information can be used for substantiation. • The current list provides useful guidance as to the type of material that should be used. • However, the science behind nutrition and health is constantly evolving, requiring some flexibility when using this method to substantiate general level health claims.
International Chewing Gum Association	Industry (International)	<ul style="list-style-type: none"> • Seeks clarification where the method requires 'two corroborating sources...in which the food-health relationship is clear, confident and definitive', that no further substantiation is needed. • Would like to clarify that this method can be used not only with current claims, but also as a way of substantiating new claims. • Nowhere does the proposal place any time limit (i.e. only reviews published prior to 2007) on the scientific documentation that may be used, implying that this method of substantiation would be equally applicable to current and future claims. • Appears to indicate that any health claim, whether currently employed or newly developed, can be justified through method 3, so long as it is supported by then current scientific thought. • Suggest inclusion of a statement such as 'this method is applicable to both current and new claims'.

Submitter	Group	Comments
Murray Goulburn Co-Operative Co. Limited	Industry (Australia)	<ul style="list-style-type: none"> • Does not support inclusion of the prescriptive list in the schedule to the standard. • Recommends use of a user guide to provide flexibility and an up-to-date list for authoritative source guidance, rather than a prescriptive regulation.
National Centre of Excellence in Functional Foods (NCEFF)	Research & Academia (Australia)	<ul style="list-style-type: none"> • Has a number of problems. • Authoritative sources need to be considered again. • Inclusion of textbooks remains problematic and should probably be removed or considered as secondary sources to primary references. • Books are used at university level to teach principles rather than be expected to provide the most up to date evidence of fact. • Scientific reviews should have primacy, and should include published systematic reviews in the highest impact nutrition and medical/health journals. • Section 3.2 (a) – the reference to food-health relationships again needs to be considered, noting there is much less evidence for the effect of food than there is for food components. • Section 3.2 (c) – no guidance is provided on how to follow this rule, and it also goes to statements about textbooks made above. • Section 3.2 (d) – again, no guidance on this – should Australian studies exist? • Section 3.2 (e) – the statement needs to be qualified so the meaning is apparent in terms of the balance of evidence from the scientific literature.
National Foods Limited	Industry (Trans Tasman)	<ul style="list-style-type: none"> • National Foods recommends that Table 3 serve as an ‘indicative’ list of possible authoritative sources that stakeholders could use to substantiate a general level health claim. Further examples should be included for the benefit of stakeholders. • Recommends the list of authoritative sources include additional examples and serve as an indicative list only. • The table should be provided in a User-Guide or Guideline document to the Standard, along with other criteria or conditions for substantiation of general level health claims. • In recognising FSANZ intent to simplify the process, certain substantiation requirements have actually become more restrictive. This includes the authoritative sources outlined in Table 3. • The list does not include scientific opinions provided by other international expert bodies (aside from the WHO) and US Institute of Medicine Dietary Reference Intake and FDA, such as the Canadian Food Inspection Agency, Health Canada, the FOSHU system of Japan and EFSA – who have been involved in the recent assessment of health claims for Europe. • The list does not include scientific reviews and position papers from peak medical, nutrition or non-government authoritative organisations (Australian or International) such as the National Heart Foundation, the Dietitians Association of Australia, Osteoporosis Australia, The Australian Society for the Study of Obesity, AMA and the US National Heart, Lung and Blood Institute. • The list does not include scientific reviews beyond the Cochrane library and the UK JHCI.

Submitter	Group	Comments
The National Heart Foundation of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Recommends that the two corroborating sources should be from at least two different authors, preferably from independent laboratories or research institutes. • Supports that textbooks used in substantiation be published within ten years, and would be supportive of the use of more recent publications.
The National Heart Foundation of New Zealand	Public Health (New Zealand)	<ul style="list-style-type: none"> • Recommends with respect to Method 3 (page 27), the two corroborating sources should be from at least two different authors, preferably from independent laboratories or research institutes. • Also supports that textbooks used in substantiation be published within ten years, and would be supportive of the use of more recent publications.
Nestle Australia Limited	Industry (Australia)	<ul style="list-style-type: none"> • Does not support the prescribed list of specific sources of scientific information. • Concerned that the list is geographically limited. • Fails to provide reference to the scientific opinions provided by the EFSA. • Australian population is multicultural, yet the only international sources listed are US, UK and WHO. • The list should be extended to include published papers in scientific, peer reviewed journals, position papers and scientific reviews conducted by pea, medical, nutrition, scientific or public health non government authoritative organisations. • To try to produce an exhaustive list will mean that the material will be continually out of date or require amending to keep pace with scientific changes. • This approach is extremely restrictive and facilitates enforcement only. • The approach does not underpin the aim of fostering an innovative globally competitive food industry.
New Zealand Dietetic Association (NZDA)	Public Health (New Zealand)	<ul style="list-style-type: none"> • Supports the Dietitians Association of Australia in their recommendation that the two corroborating sources should be from at least two different authors, preferably from independent laboratories or research institutes.
New Zealand Food and Grocery Council	Industry (New Zealand)	<ul style="list-style-type: none"> • Opposed to the limited range of authoritative sources referred to in the table. • The prescribed list is too limiting and finite. • There are other authoritative sources in Europe and Asia which could be included in the list. • It would be preferable that clause 3 does not prescribe and limit the sources. • It should instead make reference to the five listed authentic sources as well as EU and Asia sources as examples of authorities. • It should be made clear that it is a non-exclusive list.
New Zealand Food Safety Authority (NZFSA)	Government (New Zealand)	<ul style="list-style-type: none"> • Supports the majority of sources listed in Table 3, but do not support the use of textbooks to substantiate health claims. • Textbooks can vary in quality and the scientific rigour applied to them. • Source documents be on a prescribed list rather than textbooks which are an individual's interpretation of source documents. • A new edition of a textbook could be issued as a result of an update of certain parts of the text, while the relevant chapter remains unchanged.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • The textbook itself could fulfil the 10 year rule, as stated in Table 3 as regards publication, but the information itself may be out of date. • The scientific reviews carried out by the UK JHCI are unlikely to be updated because the JHCI ceased operation on 31 March 07. • Information on the JHCI website is scheduled to remain active until 2010. • Suggests FSANZ needs to further consider how to address the issue of outdated information. • Strongly suggest a requirement be added to this method to ensure the sources of information used as substantiation cannot be solely from one author.
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> • Very concerned about Method 3 and recommends a number of changes be made to improve the quality of the method. • Would support method 3 if these changes were made but does not support the method as it currently stands. • Comfortable that the Australia and NZ Dietary Guidelines are included as appropriate government sources but notes these documents are primarily developed for use by health professionals and not for the purpose of providing evidence for health claims. • Strongly recommends that the two corroborative sources must come from at least two types of authoritative sources listed in the table. • Strongly recommends <i>all</i> authoritative sources are ineligible if they were published more than 10 years previously, an important safeguard. • Recommends criteria be developed to prevent use of information written by the same author writing in two different publications. • Particularly concerned about the use of textbooks. These can vary in quality and may not provide the best and up-to-date evidence available. • Textbooks have the potential to be unreliable and/or biased. • Strongly recommends that textbooks are removed from the list of authoritative sources.
New South Wales Centre for Public Health Nutrition	Public Health (Australia)	<ul style="list-style-type: none"> • There is no requirement regarding authorship (re two corroborating sources). • A single author or the same group of authors could publish in two or more of the sources in the prescribed list, though acknowledges this might be unlikely. • The requirement regarding substantiation from textbooks requires that the books be written and/or edited by specialist academic authors, however the definition of 'specialist academic authors' is not detailed in the Framework, and peer reviewing is not mandatory. • Unless tighter and clearer definition is given, as the current definition is too vague and ambiguous, believes textbooks should not be included as an acceptable source of substantiating evidence.
NSW Food Authority	Government (Australia)	<ul style="list-style-type: none"> • Concerned that there is no mechanism to ensure that two sources from the same author cannot be used to substantiate claims. • Queries the meaning of a 'degree of peer-review' with respect to editorial oversight of human nutrition textbooks.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Would prefer a tighter definition that clearly articulates the degree of scrutiny required to be an acceptable source of evidence for substantiation purposes. • Considers the current drafting of method 3 in the Scientific Substantiation Framework to have serious enforcement implications, due to its ambiguity.
Nu-Mega Ingredients Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • The authoritative sources listed in Table 3 are too restricted and such a table should only be used to indicate the type of authoritative source which is suitable.
Obesity Policy Coalition	Public Health (Australia)	<ul style="list-style-type: none"> • Source documents should be appropriately peer reviewed and not authored or edited by persons with commercial conflicts of interest.
Parmalat Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • It is unclear whether the two or more corroborating sources can be from the same source, e.g. both from WHO sources or both from scientific textbooks in human nutrition, or whether one needs to identify evidence from two different authoritative sources.
The Public Health Association of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Should require more than two corroborating sources, as we would need to do in professional literature to substantiate conclusions regarding a particular issue. • FSANZ should provide a list of suitable textbooks and add to that list on a regular basis, rather than leave it to the industry to determine who is a specialist in a particular topic.
Queensland Health	Government (Australia)	<ul style="list-style-type: none"> • The use of two or more corroborating sources does not preclude the use of two sources from the same author or research group. • The use of two or more corroborating sources does not preclude the use of two sources which support a food-health relationship where there are other sources which do not support the relationship. The evidence needs to be unequivocal. • It is not possible to prescribe completely which text books would be acceptable as a source of evidence. • There are many nutrition textbooks in the market some of which may appear to be written by specialist academic authors but which may deal with unsubstantiated or dubious food-health relationships. • Even specifying textbooks used in a university course does not eliminate this possibility as most textbooks discuss emerging food-health relationships. It is an appropriate role for textbooks to highlight newer developments in nutrition science. Since they are emerging these relationships have varying levels of evidence in their support and this information could be misrepresented by industry. • There are also well documented cases in nutrition science where the evidence for food-health relationships initially appeared to be strong but with further research were not substantiated or significantly modified. Examples are vitamin E and CVD and β-carotene and lung cancer. • Does not support the use of textbooks as acceptable sources for substantiation of general level health claims.

Submitter	Group	Comments
Sanitarium Health Foods	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Concerned that the provision of a fixed list of authoritative sources in Table 3 of the Scientific Substantiation Framework will exclude emerging nutrition science and other credible sources of nutrition information that exist now or in the future. • A prime example of existing credible source absent from the table is recommendations from the EFSA. • The population groups within Australia and NZ are diverse, with significant ethnic groups from around the world, yet the only international Authoritative sources cited are the WHO, UK and US. • If the provision of Table 3 to clause 3.2 is seen as necessary to the Standard, then it should either be provided as a non-exclusive list or significantly expanded to encompass all significant authoritative sources currently existing world wide. • Examples of suitable additions include the EFSA and Health Canada. • Ultimately this provision exist as one option in the Scientific Substantiation Framework, but it would save significant time and expense if as many credible sources are recognised, rather than having to justify them via a systematic review. • Companies should also be free to choose any of the justification options on a ‘best fit for the claim’ basis.
Simplot Australia Pty. Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Considers there are other suitable authoritative sources that could be included in the Scientific Substantiation Framework Table 3 to clause 3, such as the EFSA.
Dr. Rosemary Stanton	Public health (Australia)	<ul style="list-style-type: none"> • This has the potential to cause confusion, especially as to the validity of different source documents. • Difficulties could arise where some alternative theories may be substantiated by complementary medical textbooks, but would be unacceptable from a more conventional scientific perspective. • Some textbooks are written by those who have set up a business marketing products recommended in their texts (specific example of text by Dr Udo Erasmus given). • FSANZ will need to give clear guidelines as to appropriate source documents. • Recommends source documents should be published by different authors. • Recommends source documents should be in different peer-reviewed journals generally accepted as reliable journals. • Recommends source documents should not come from the same organisation. • All funding and other conflicts of interest in any research papers or source documents should be declared. • Where there are potential or actual conflicts of interest, FSANZ may need to give the company access to a FSANZ approved panel of experts who can review the validity of the evidence presented. This represents a pre-approval process but may be necessary for some claims where the evidence does not come from sources used by conventional scientists. • May be easier for FSANZ to remove textbooks from the list and draw up a list of approved journals for published research.

Submitter	Group	Comments
Unilever Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> Does not support the inclusion of a prescriptive list of authoritative sources – in particular a closed list that does not allow for progress in this fast developing area by other regulatory bodies, such as the EFSA, position statements form credible sources and reviews in peer reviewed journals – all very valid sources of reliable and robustly reviewed scientific information. Support the inclusion of an indicative list in a guidelines document as useful, and much more easily revised to help keep the list valid and up-to-date. Do not support point c) as stated in the drafting: c). to ensure that the food-health relationship is valid at the time of reliance on method 3, the relationship should be confirmed by comparison with current scientific literature. As the table refers to the most recent versions of authoritative sources, requiring confirmation with current scientific literature is implying that these documents are not kept up-to-date and cannot be relied upon. This also disagrees with the summary of method 3 in the recommendation as stated under 3.1 stating 'No further substantiation is needed'.

4.4 Comments on method 4 – systematic review

Submitter	Group	Comments
ADECRON Food Tech Consulting Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> Agrees with inserting method 4 into the standard to clarify requirements and tighter clarification on method 4. Welcomes the drafting of documentation to support method 4 for general level health claims to assist industry.
Cadbury Schweppes Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> Concern that if a food-health relationship is still under investigation or it is an emerging food health relationship how can it be appropriately substantiated. Has no concerns with the use of peer reviewed scientific evidence instead of documented evidence but fail to see how a claim can be substantiated when the issue is either still under investigation or is an emerging issue. In both cases the scientific case is unproven. Inclusion of relationships either still under investigation or emerging appears contradictory to the requirements for scientific evidence as per clause 4.3 (page 38) of the Consultation Paper.
The Cancer Council Australia	Public Health (Australia)	<ul style="list-style-type: none"> FSANZ should clearly define who would be appropriate and who would be inappropriate to conduct systematic reviews. Although the process of a systematic review attempts to minimise bias, there have been documented instances in a range of scientific fields that show that different results can be achieved with systematic reviews depending on the background of the person conducting the review.
CHOICE	Consumers (Australia)	<ul style="list-style-type: none"> Agrees that a systematic review of emerging food-health relationships would be sufficient to substantiate a general level health claim, provided that the review is conducted appropriately by a suitably qualified or experienced reviewer (note this comment conflicts with their general comment that 'emerging studies should not be sufficient'). FSANZ must give clear guidelines on how a systematic review should be conducted, including the types of studies that must be included, appropriate sources and acceptable authors.

Submitter	Group	Comments
Confectionery Manufacturers Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> Concerned that the substantiation process may not be sufficiently robust where a food-health relationship is still under investigation or is an emerging food-health relationship, or the relationship has not yet been published in textbooks or undergone a Cochrane systematic review. Questions how appropriate substantiation may be demonstrated.
Consumers NZ	Consumers (New Zealand)	<ul style="list-style-type: none"> Agrees that a systematic review of emerging food-health relationships would be sufficient to substantiate a general level health claim, provided that the review is conducted appropriately by a suitably qualified or experienced reviewer (note this comment conflicts with their overarching comment recorded under general comments that 'emerging studies should not be sufficient...'). FSANZ must give clear guidelines on how a systematic review should be conducted, including the types of studies that must be included, appropriate sources and acceptable authors.
Dietitians Association of Australia (DAA)	Public Health (Australia)	<ul style="list-style-type: none"> Notes that only the Cochrane Database and the UK JHCI are accepted for substantiation. It also states submitters can conduct their own systematic review. Suggests that FSANZ also consider other high quality methods of conducting systematic reviews, such as QUOROM for RCTs or Meta analyses of observational studies in epidemiology (MOOSE) for epidemiological studies. References given in submission.
Dairy Australia	Industry (Australia)	<ul style="list-style-type: none"> Detailed information about acceptable methodology for the conduct of a systematic review, and acceptable study populations, would also be valuable in a user guide.
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> Does not support this method. Does not believe this method of substantiation is justified. Food health relationships should be subject to rigorous peer review and often take many years to substantiate. Allowing unpublished studies to be used involves a risk to public health and places an unacceptable burden on enforcement agencies. The burden of evidence for a health claim, a voluntary action by the food industry, should be placed on industry and should be unequivocal. There is no reason that enforcement agencies (or FSANZ) should justify the use of unproven claims.
Department of Health & Human Services Tasmania	Government (Australia)	<ul style="list-style-type: none"> Has concerns about a method they are being asked to support based on guidelines that are not yet available. In-principle, supports the increasing the evidence base and promoting evidence based decision making and the use of systematic reviews. Systematic reviews sponsored solely by industry groups tend to be less transparent, have few reservations about methodological limitations of the included trials, and had more favourable conclusions than the corresponding Cochrane reviews (Jorgensen et al 2006). The resource and expertise required to assess systematic reviews is significant. Interpretation of results in a court of law would be problematic. When considering the systematic reviews, the impact of multiple publication, selective publication, and selective reporting needs to be considered. Has concerns about the quality and transparency of systematic reviews.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Also concerned about enforcement issues. • If included as a method, the review must be conducted by suitably qualified and experienced reviewers. • FSANZ should give clear guidelines on the process required to conduct a systematic review, including the types of studies that must be included and appropriate sources (reference material listed in the submission).
Department of Human Services - Victoria	Government (Australia)	<ul style="list-style-type: none"> • Method 4 proposes the use of systematic reviews to assess emerging evidence. Under the current wording, dubious and ambiguous information could be used to support a nutrition-health hypothesis. • For Method 4 to be acceptable all corroborating sources must be from published, peer-reviewed journals. • Adherence to this methodology should not result in significantly different results if conducted by different parties. It is unclear whether the current framework is sufficiently robust to achieve this.
Fonterra Co-operative Group Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Is essentially a cut and paste from the high level health claim Substantiation Framework. • Consider that whilst appropriate for a high level health claim that consumers might put a higher degree of trust in, that for a general level health claim, the method could be amended to be equally stringent but more open to new innovative nutrient functions. • E.g. the requirement for human intervention trials could be replaced with the ability to substantiate general level health claims with animal trials that can adequately be translated to humans providing supporting evidence is also available.
George Weston Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> • The Consultation Paper notes method 4 is only used to substantiate a health claim if methods 1, 2 and 3 cannot be used. • Recommends it be up to the discretion of the individual company to choose which method is most appropriate for the claim in questions and which fits within the company's internal processes for substantiation.
National Centre of Excellence in Functional Foods (NCEFF)	Research and Academia (Australia)	<ul style="list-style-type: none"> • The reference to systematic review is appropriate and well aligned to evidence based nutrition practice. • There might be some consideration of the link between theoretical positions from in vitro and animal model studies, (usually studies of food components, including nutrients) and hard evidence of effects from food consumption. • 4.2 (a), for example, might relate to a strong theoretical position rather than just being supportive. • It may be that in managing the risk associated with health claims, a strong theoretical position has a great value in the absence of food based research. This might well reflect practice to date in giving nutrition advice. • There needs to be strong consideration of the quality of clinical trials with food. • Reference could be made to the CONSORT statement which defines quality standards for RCT design. • Reference should also be made to appropriate statistical analyses and this goes to step 4 (iii) which puts quality meaning to the term 'statistically significant'.
The National Heart Foundation of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Notes that only the Cochrane database and the UK JHCI are accepted. • It also states that submitters can conduct their own systematic review of the current scientific literature. • Recommends that FSANZ also consider other high quality methods of conducting systematic review, such as QUOROM for RCTs or MOOSE for epidemiological studies.

Submitter	Group	Comments
The National Heart Foundation of New Zealand	Public Health (Australia)	<ul style="list-style-type: none"> With respect to Method 4 (page 27), notes that only the Cochrane database of systematic reviews and the UK Joint Health Claims Initiative are accepted for substantiation. It also states that submitters can conduct their own systematic review of the current scientific literature. The Heart Foundation suggests that FSANZ also consider other high quality methods of conducting systematic review, such as QUOROM for randomized controlled trials or MOOSE for epidemiological studies.
New South Wales Centre for Public Health Nutrition	Public Health (Australia)	<ul style="list-style-type: none"> Current wording may allow the substantiation of a general level health claim while the food-health relationship is still under investigation or emerging, and has not yet been published in textbooks or undergone scientific review as stated in the related table. Concerned that allowing claims of a food-health relationship to be issued prematurely has the potential to put consumers' health at risk. To prove a food-health relationship normally requires many years of research and health effects thought to be substantiated may be completely disputed subsequently, e.g. beta-carotene supplementation and the risk of lung cancer. Disagrees with the current wording of Method 4. Acknowledges a systematic review may be appropriately conducted on an established topic. It should be clear in the Framework documentation that substantial body of peer-reviewed evidence needs to be considered. The review should be undertaken by authors that are independent of the food industry.
NSW Food Authority	Government (Australia)	<ul style="list-style-type: none"> Opposes method 4. Does not consider it appropriate for health claims to be substantiated by unpublished data that has not been subject to a credible peer review process. Recommends that sources of evidence used for substantiating health claims must be credible, published, scientific documents that have been subject to a rigorous peer review process to be acceptable.
New Zealand Dietetic Association (NZDA)	Public Health (New Zealand)	<ul style="list-style-type: none"> Recommends that other high quality databases be considered for substantiation, in addition to the Cochrane database of systematic reviews and the UK JHCI (no examples given).
New Zealand Food Safety Authority (NZFSA)	Government (New Zealand)	<ul style="list-style-type: none"> In this method, there is no requirement for systematic reviews to be published in an international peer reviewed journal or report. Shares the Ministry of Health's concerns that despite guidelines for conducting systematic reviews, not all systematic reviews are reliable, particularly if reputable peer review and publication is not a feature. Findings of systematic reviews can be manipulated by varying the criteria for identifying and including (or excluding) research studies. Recognises that publication could mean access to data by competitors and while this would not be desirable, some peer review mechanism to address unreliability could significantly reduce the enforcement burden. Supports the use of systematic reviews that are funded and undertaken by independent organisations and individuals such as the JHCI and the Cochrane database as listed for method 3.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Suggests that if method 4 is to be included, a model example of a general level health claim dossier prepared by means of method 4, be included in the User Guide being developed for Standard 1.2.7.
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> • Very concerned with method 4. • Strongly recommends this option is not permitted, particularly if there is no requirement for systematic reviews to be published in an international peer-reviewed journal or report. • Not all systematic reviews are reliable (Moher, 2007). • Findings of systematic reviews can be easily manipulated by varying the criteria for identifying and including (or excluding) research studies. • It is very important that systematic reviews are funded and undertaken by organisations and individuals that are unbiased. • Many systematic reviews are out of date within two years of being published. • Nutrition and health associations are particularly hard to substantiate (difficult to measure exposure; lag time; confounders), and there are several examples of associations that were widely accepted as beneficial but later found to be harmful or of no real benefit.
Parmalat Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports the proposal by FSANZ that details on how to conduct a systematic review be included in supporting documentation to the Standard.
Public Health Association of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • If FSANZ proposes (and they agree) that only a few internationally recognised bodies should be acceptable for conducting rigorous scientific reviews to support claims, and those found in general scientific literature are not suitable for use in method 3, how can they deem a systematic review completed by a submitter as acceptable for method 4? • Suggests some reputable, independent scientific organisations be listed as suitable for conducting reviews for submitters. • In theory, this should not cost industry any extra, as it is likely they would need to outlay funds to do such a review anyway.
Queensland Health	Government (Australia)	<ul style="list-style-type: none"> • The use of rigorous systematic reviews is to be encouraged. However, their use as outlined in the consultation document does not guarantee the level of rigour needed. • Strict criteria need to be applied in the conducting of reviews. • Concern has been expressed at the influence that financial support by industry can have on research results. Often this support is not disclosed. These issues would need to be taken into account in any criteria for a systematic review. • Studies have shown that the conclusions of systematic reviews can be prejudiced by those undertaking the reviews. • The comments made above (method 3 and general comments) in relation to the long term substantiation of emerging food-health relationships also apply here. • Does not support the inclusion of method 4 in the Scientific Substantiation Framework.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Conducting rigorous and unbiased systemic reviews is a complex and time consuming process as is the checking of such reviews. • Is yet to see the guidelines being prepared by FSANZ for conducting systematic reviews and it not clear if these guidelines are to be reference in the Standard.
Sanitarium Health Foods	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Justification of general level health claims via systematic review would appear to be only available if methods 1, 2 and 3 are not capable of substantiating the food-health relationship. • The provision of this restriction is unnecessary on the basis that a systematic review is more costly than the other methods and would not stand up to scrutiny if it ran counter to the authoritative methods. • However, it may cause confusion as to whether this method can be used to supplement less conclusive evidence from methods 1, 2 and 3. Consequently, this restriction should not be stated.
Dr. Rosemary Stanton	Public health (Australia)	<ul style="list-style-type: none"> • It will be important for FSANZ to exclude those with vested interests or potential conflicts of interest from any list of reviewers. • Recent studies in the pharmaceutical field have shown that more positive results are published from researchers who have been funded by companies that stand to benefit from the research. • FSANZ may need to provide a list of reliable, independent experts that could be available to give guidance to companies as to whether their systematic review is adequate (gives an example of poor-quality evidence wrongly being judged to be acceptable in the complementary health industry).

4.5 Comments on substantiation issues that were not for consultation at this time

Submitter	Group	Comments
Australian Nut Industry Council (ANIC) and Nuts for Life	Industry (Australia)	<ul style="list-style-type: none"> • Would prefer to see the new nutrition content claims criteria for sat and trans fats flow on to the criteria for sat fat high level health claim also (including any future saturated fat high level health claim) as nuts other than chestnuts do not meet the low saturated fat criteria for the saturated fat/cholesterol lowering high level health claim. • A P:S ratio greater than 1 is required to reduce heart disease risk. Replacing sat fat with poly and mono will lower heart disease risk and blood cholesterol. However, lowering the sat fat content by itself will not achieve the desired ratio. Eating foods rich in poly and mono fats are also required (cites 1999 National Heart Foundation Position Paper on Dietary Fats).
The Bell Tea Company	Industry (New Zealand)	<ul style="list-style-type: none"> • This submission requests additional clarification within the proposed Standard on the status of beverages. • Notes, 'within the tea industry in particular, there is a general belief, supported by a wealth of scientific literature, that tea, whether black or green, is a significant source of polyphenols generally referred to as antioxidants. Further, scientific literature supports the contention that the consumption of these polyphenols is beneficial to human health across a wide range of conditions. • Herbal beverages have long been associated with health benefits known ones being camomile or fennel to aid digestion, ginger to aid circulation and elderflower to treat colds and bladder problems. It is unclear whether general level health claim will be possible for such products under the proposed Standard.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Specific clarification is sought relating to: <ul style="list-style-type: none"> - Are polyphenols recognised as a class of micronutrients under the proposed standard? - Are polyphenols recognised as having antioxidant properties in relation to human health/ - Is it possible to make nutrition and general level health claims based on polyphenol content? - Are there minimum and/or maximum levels for total polyphenol or specific compounds that set boundaries to an ability to make a claim? - Can general level health claims be made for herbal teas under the proposed standard? - Can the NPSC method be used to assess herbal beverages, teas and coffee?
The Cancer Council Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Concerned about the way in which false, misleading, deceptive or unconscionable, or simply misunderstood, marketing practices can contribute to the development of obesity and therefore the risk of cancer. • With rates of obesity escalating and obesity a significant risk factor for cancer, these issues are extremely important to The Cancer Council. • Concerned about the possibility of food manufacturers making specific health claims in relation to cancer, as well as nutrition claims about the healthiness of foods. • Concerned that there is a lack of evidence that a system for nutrition, health and related claims, such as proposed in P293, leads to behaviour change and improved public health through healthier food choices. • At the same time there is a substantial risk that nutrition and health claims can confuse or mislead the public. • If a system is introduced, it should be accompanied by strong safeguards such as mechanisms for rigorous substantiation. • Very concerned about the shift to more processed energy dense diets in the Australian population, and declining fruit and vegetables intakes.
CHOICE	Consumers (Australia)	<ul style="list-style-type: none"> • At minimum, nutrition content or general level health claims about biologically active substances should be substantiated according to the requirements outlined in Method 3 or Method 4 of the Scientific Substantiation Framework.
Comvita	Industry (New Zealand)	<ul style="list-style-type: none"> • Submitted a list of published articles to support request to create a category to allow health claims to be made on (natural) honey. Two examples of claims are suggested by the submitter, with journal articles listed against each of these: • Comvita proposes - Honey helps support and maintain a healthy digestive system. • Comvita proposes – Honey helps support and maintain respiratory health.

Submitter	Group	Comments
Commonwealth Scientific and Industrial Research Organisation (CSIRO)	Research & Academia (Australia)	<ul style="list-style-type: none"> The principle that the data needs to be derived from human studies, with amounts of the food/supplement that are realistically consumed needs to be more explicitly stated. Data from controlled (preferably placebo-controlled) human studies published in reputable international peer-reviewed journals is optimal for substantiation. Data from animal and in vitro studies provides valuable supportive evidence. Whilst the gold standard is the RCT, such data may not always be feasible in nutrition. Data from population studies as well as short-term human interventions may also provide a framework for substantiation More explicit guidelines on such an approach would be welcome in assisting researchers and industry and CSIRO is well placed to advise on such approaches. Elaboration on key biomarkers that are considered acceptable by FSANZ in the substantiation process would enhance the clarity to researchers and food industries regarding appropriate methodologies for human studies. Only results with validated biomarkers (i.e. shown to be prospectively associated with health outcomes) would be acceptable for the substantiation process. Elaboration on key biomarkers that are considered acceptable by FSANZ in the substantiation process would enhance the clarity to researchers and food industries regarding appropriate methodologies for human studies.
Go Grains Health and Nutrition Limited	Industry (Australia)	<ul style="list-style-type: none"> At least one accepted authoritative source document listed in Table 3 – the Australian dietary guideline reports – document evidence to support an association between wholegrains and coronary heart disease, whereas the proposed high level health claim has been rejected by FSANZ. JHCI (an authoritative source document) believes that scientific substantiation for health claims should be based on studies that have been peer reviewed and published in a reputable scientific journal.
Goodman Fielder Home Ingredients	Industry (Australia)	<ul style="list-style-type: none"> Recommends the following additional nutrient function claims: Omega-3 fatty acids play an important role in heart health.
Department of Health & Human Services TAS	Government (Australia)	<ul style="list-style-type: none"> The level of substantiation for biologically active substances is less rigorous than the science underpinning vitamin and mineral claims. Under the current proposal, the presence of the substance is sufficient. Suggests that manufacturers be required to hold evidence that the amount (of biologically active substance) contained in the product is 10% of an efficacious amount to fulfil the nutritional purpose.
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> Recommends that consideration be given to pre-approval of all general level health claims in addition to high level health claims. It is noted as one of the major issues left unresolved which may ultimately lead to a review request.
Innovations & Solutions – Wendy Morgan	Industry (Australia)	<ul style="list-style-type: none"> FSANZ has declined to permit a high level health claim for omega-3 and CVD despite the evidence being stronger than that for other pre-approved high level health claims. Until a high level health claim for omega-3 is permitted, a general level health claim for long chain omega-3 fatty acids should be included in the pre-approved nutrient function statements (refer comments against Method 1).

Submitter	Group	Comments
The National Heart Foundation of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Proposes that the principle of a ‘low proportion’ of sat fat and maximum trans fat level flow through to apply to general level and high level health claims. • Recommends FSANZ reconsider amending the conditions for the high level health claim for the relationship between saturated fat and trans fat and LDL cholesterol and CHD. • Believes there is a need to take into consideration the proposal for the new nutrient content claim based on ‘low proportion of saturated and trans fatty acids’, and to consider these conditions for inclusion for the high level health claim. • With reference to conclusions in the review by Mann and Booker, contends the evidence from the review supports the importance of being able to communicate to consumers changes in dietary fats- not just for those foods that have a low fat content but even more importantly to influence the choices in foods that have a significant fat content.
The National Heart Foundation of New Zealand	Public Health (New Zealand)	<ul style="list-style-type: none"> • Recommends FSANZ amend the conditions for the high level health claim for the relationship between saturated fat and trans fat and LDL cholesterol and coronary heart disease. • Believed there is a need to take into consideration the proposal for the new nutrient content claim based on ‘low proportion of saturated and trans fatty acids’, and to consider these conditions for inclusion for the high level health claim. • Sites several conclusions from the Booker/Mann review. • Contends the evidence from this review supports the importance of being able to communicate to consumers changes in dietary fats – not just for those foods that have a low fat content but even more importantly to influence the choices in foods that have a significant fat content.
New South Wales Centre for Public Health Nutrition	Public Health (Australia)	<ul style="list-style-type: none"> • Although full cream milk is a good and significant source of dietary calcium, allowing full cream milk to carry health claims (e.g. calcium and osteoporosis) may promote excessive consumption which in turn increases the total dietary fat (mostly saturated fat) intake. • There is no reason to promote/support the use of full cream milk/dairy products in helping to meet calcium RDI by allowing full cream milk to carry a health claim when there are lower fat alternatives available with similar or even higher calcium content.
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> • Would like to see that all general and high level health claims are pre-approved using a rigorous process, to ensure health claims are accurate and consistent. • Consumers do not understand the difference between general level and high level health claims and believe that all claims should be approved by the government (Ni Mhurchu and Gorton, 2007, Williams 2005). • Understands that many authoritative bodies including the American Dietetic Association, the American Medical Association, and the Public Health Association of Australia do not support health claims that have not been pre-approved. • The substantiation process should include analytical nutrient concentration data from an accredited laboratory for both general level and high level health claims. • There should also be a requirement for nutrient concentration data to be from Australian and New Zealand sources.

Submitter	Group	Comments
Nu-Mega Ingredients Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Believed the scientific evidence for a high level health claim for long chain omega-3 and an inverse relationship with CVD is stronger than that for a high level health claim for fruits and vegetables and an inverse relationship with CVD. • Believed that there has been an inconsistent approach by FSANZ in the level of evidence required for these two high level health claims. • As a high level health claim (omega-3) has not been allowed, we strongly recommend inclusion of a general level health claim in table 1 (refer Method 1 above).
Obesity Policy Coalition	Public Health (Australia)	<ul style="list-style-type: none"> • Calls for FSANZ to address the other issues in relation to P293 set out in the Cancer Council Australia's submission that have not been addressed in the Consultation Paper.
The Omega-3 Centre	Industry (Australia)	<ul style="list-style-type: none"> • Lists Dr Laurence Eyres as one of five advisers to the Omega-3 Centre. • Believes there has been an inconsistent approach in assessing the level of evidence required for high level health claims. • After assessing the scientific reports provided to FSANZ, believe that the scientific evidence for a high level health claim for long chain omega-3 fatty acids and an inverse relationship with CVD is stronger than that for a high level health claim for fruits and vegetables and an inverse relationship with CVD. • Requests that FSANZ reassess the evidence for a high level health claim for long chain omega-3 fatty acids and an inverse relationship with CVD. • In the absence of a high level health claim for long chain omega-3s and CVD, recommends that FSANZ gives urgent consideration to a high level health claim on the association of consuming fish and reduced risk of CVD.
Dr. Rosemary Stanton	Public Health (Australia)	<ul style="list-style-type: none"> • As new research becomes available and companies seek to make high level health claims, it will be important that those who assess the claim are not involved in any commercial relationship with those seeking to have the claim approved. • With regard to biological substances... issues of efficacy are relevant and some assurance that the quantities of substances used is sufficient to produce the claimed effect. Some companies involved in marketing these products do not use the same type of evidence of efficacy as is required in traditional scientific research and it would be wise to ensure firm rules about appropriate evidence for claims are in place before claims are made. • Obesity and overweight – considerable discussion during 2007 (including SDAC) about the division of overweight and obesity into general level and high level health claims. There was much support for both being in the same category, overweight being a precursor (or biomarker) to obesity. • Concerned that overweight being considered as a general level health claim and therefore subject to a lower level of scrutiny. • As few companies would be likely to prefer overweight or excess weight to the terms obese or obesity, this means that one of Australia's most serious health problems will move out of the area of high level health claims and into the level of a general level health claim. Has FSANZ looked into the widespread concern about this issue?

4.6 General comments regarding substantiation

Submitter	Group	Comments
Australian Food and Grocery Council (AFGC)	Industry (Australia)	<ul style="list-style-type: none"> • Supports FSANZ including a list of pre-approved general level and high level health claims within the Code’ (page 8 of 11). • ‘FSANZ has already moved material from Scientific Substantiation Framework into supporting documentation and the AFGC considers the rest should follow’ (page 9 of 11). Such an approach aligns with other regulatory systems, e.g. complementary medicines. • Further clarification in guidelines is recommended to distinguish between the level of substantiation required from authoritative texts being ‘definitive’ versus the level required from a scientific review being ‘consistent’. Refers to NHMRC grades for recommendations for developers of guidelines (2005). • Recommends FSANZ move the Scientific Substantiation Framework from the proposed Standard to the user-guides. • Recommends FSANZ include a provision in the proposed Standard that requires all claims to be truthful and scientifically substantiated, and that foods are capable of delivering benefits according to the claim in the context of a balanced diet.
Australian Nut Industry Council (ANIC) and Nuts for Life	Industry (Australia)	<ul style="list-style-type: none"> • Supports FSANZ’s choice of four methods for substantiating general level health claims.
Australian Publishers Bureau	Media (Australia)	<ul style="list-style-type: none"> • ‘It must be the sole responsibility of the advertiser to ensure that all criteria which must be met, for each of the different level of health claims. • ‘It must not fall to publishers to ensure that the required substantiation exists’.
Australian Self Medication Industry (ASMI)	Therapeutic (Australia)	<ul style="list-style-type: none"> • Supportive of the recommendation to institute the Scientific Substantiation Framework as this is consistent with the requirements required of complementary medicines to support general level health claims.
Bayer Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • The four methods presented are sensible but raise certain concerns (as listed by submitter). • Given 10% of a nutrient’s RDI is required to make a claim and efficacious levels are not clearly defined, claims could be misleading in their perceived ‘health benefits’ for consumers. • Suggests limiting wording that can be used in claims to ‘may’, ‘assists’ or similar to place perspective on the claim. • Suggests the requirement for companies to employ suitably qualified personnel (to analyse data to substantiate claims) and for this to be supported by relevant training courses on understanding scientific documentation to be supplied by FSANZ or FSANZ-approved suppliers. • Suggests adding clarity in the food standard around products which carry the ‘scientifically proven’ claim to clarify whether it is the ingredient or the product formulation that is relevant. • P293 will allow claims based on specified levels of an individual nutrient at the time of product manufacture and will not consider the interactions within the food as a whole. • Suggests that the extrapolation of claims be justifiable and relevant to the nutrient level for the duration of the product’s shelf life.

Submitter	Group	Comments
Cadbury Schweppes Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> Industry should be compiling their substantiation dossier as a discipline in the overall product development process.
Campbell Arnott's Asia Pacific	Industry (Trans Tasman)	<ul style="list-style-type: none"> Recommends FSANZ develops a simple guide outlining the requirements for 'acceptable reviews' to ensure a consistent approach is maintained when assessing the validity of current and future substantiation for general level health claims. Supports FSANZ proposal in providing guidance on substantiation requirements for general level health claims.
The Cancer Council Australia	Public Health (Australia)	<ul style="list-style-type: none"> There are some further considerations that FSANZ must address. An important consideration is that any assessment for claims, whether they be general level or high level health claims, is based on the totality of the evidence base and not just some emerging studies. The requirements and processes in conducting a systematic review may address this for high level health claims, but it is also important that FSANZ address this for general level health claims.
Cereal Partners Worldwide (CPW)	Industry (Australia)	<ul style="list-style-type: none"> Does not support FSANZ proposal that the Scientific Substantiation Framework becomes a schedule to the Standard. Recommends that the Scientific Substantiation Framework should be available as supporting documentation only.
Cerebos Foods	Industry (Trans Tasman)	<ul style="list-style-type: none"> Supports the clarification around the alternate substantiation requirements for general level health claims offered in Attachment 1 (the schedule). The approach will assist in providing confidence to manufacturers, consumers and enforcement agencies that claims are credible and substantiated. Supports including the list of nutrient function statements as part of the draft Standard. Does not support the other three methods for substantiation being part of the standard. Recommends the Scientific Substantiation Framework (with the exception of nutrient function statements) be referenced from within the standard but not be incorporated as part of the Code to allow for more flexibility and timeliness of response for future updates.
Chamber of Commerce & Industry WA	Government (Australia)	<ul style="list-style-type: none"> The regulatory burden (cost of compliance) for small and medium enterprises remains disproportionate compared with large enterprises. Any regulatory requirement of the Code should not be onerous. Whilst they are supportive of the proposed Framework, it is understood that access to information and research is often costly. Seeks to ensure that methods made available for obtaining information to substantiate claims remain accessible to small and medium size businesses and that they do not provide unfair advantage to larger organisations.

Submitter	Group	Comments
CHOICE	Consumers (Australia)	<ul style="list-style-type: none"> • The same level of evidence should be required for general level and high level health claims. • Any general level or high level health claim must be based on an assessment of the total body of evidence rather than that a selection of studies that support a claim. • The sources selected by manufacturers to substantiate general level health claims must be consistent with the totality of evidence. • Emerging studies should not be sufficient to support a general level or high level health claim.
Consumers NZ	Consumers (New Zealand)	<ul style="list-style-type: none"> • The same level of evidence should be required for general level and high level health claims. • Any general level or high level health claim must be based on an assessment of the total body of evidence rather than that a selection of studies that support a claim. • Emerging studies should not be sufficient to support a general level or high level health claim.
Department of Agriculture, Fisheries and Forestry (DAFF)	Government (Australia)	<ul style="list-style-type: none"> • Acknowledges that changes proposed to the draft standard address concerns relating to the enforceability of the Scientific Substantiation Framework and remove redundancy in the documentation (e.g. removal of reference to qualifications ‘probable’ for general level health claims and ‘convincing’ for high level health claims). • Considers that this (removal of ‘probable’ and ‘convincing’) will better facilitate consistent use and enforcement of the Scientific Substantiation Framework across jurisdictions due to the removal of a degree of subjectivity. • Believes the Scientific Substantiation Framework in the Standard should be limited to requiring that information sources used to validate claims meet a number of essential criteria, including that they be credible, supported and up-to-date. • In particular, it is suggested that, rather than including a prescriptive list of scientific source documents, it may be preferable for the standard to be limited to referencing a list which could be more readily updated.
Dairy Australia	Industry (Australia)	<ul style="list-style-type: none"> • In general, supports the proposed changes and inclusion of the Scientific Substantiation Framework into the standard with further detail provided in a user guide.
Dairy Farmers	Industry (Australia)	<ul style="list-style-type: none"> • Supports FSANZ recommendations to the Scientific Substantiation Framework but recommends there is a process for regular review.

Submitter	Group	Comments
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> • Recommends that consideration be given to pre-approval for all general level health claims, an issue that has been raised previously but has not been satisfactorily dealt with. • Pre-approved claims would enable equitable enforcement action. • There is still potential for a large amount of confusion and subjective interpretation (re general level health claims). • From an enforcement perspective, this will be exceedingly difficult. • It also creates an uneven playing field for small business with the likelihood that they will simply use the same claims as their larger competitors. • A more equitable system would be that all general level health claims are pre-approved. • The proposed standard still places a huge onus on enforcement bodies to assess and weigh evidence to substantiate claims. • All food health relationships upon which claims are based need to be proven beyond reasonable doubt. • If there is any doubt or confusion in interpreting evidence, it will make the law unworkable. • Health claims are a voluntary system and the onus of responsibility to prove or not prove a claim should be on the manufacturer not on the enforcement body. • Cannot support the proposed draft substantiation framework guidelines without knowing how these will be incorporated into the standard.
Department of Human Services - Victoria	Government (Australia)	<ul style="list-style-type: none"> • Cannot support the proposed draft Scientific Substantiation Framework without knowing how these will be incorporated into the Standard. • Recommends that the substantiation framework be incorporated into guidelines that accompany the standard, rather than be included in the standard itself. • Supports the removal of the terms ‘probable’ and ‘conclusive’ to define evidence. • The phrase ‘the food-health relationship must be confident and definitive’ needs to be clearly defined so that it can be proven beyond reasonable doubt under the law for this to be enforceable. This applies to both methods 3 and 4. • Has previously recommended FSANZ obtain independent legal advice on what constitutes compliance for the substantiation of general level health claims. It remains unclear whether an organisation can be deemed to comply as long as it has adhered to the methods outlined, regardless of whether enforcers disagree with the conclusions drawn. • The Standard will be unworkable if jurisdictions are expected to measure compliance by assessing the scientific evidence and the validity of the claim. • It is unclear who will retain the responsibility for assessing the evidence for compliance. • There has been no estimation of the cost of enforcement.
Fonterra Co-operative Group Ltd	Industry (Trans Tasman)	<ul style="list-style-type: none"> • The Scientific Substantiation Framework in the format presented for comment is, in our opinion, not as tight as it might be and as such would be better suited to a user guide.

Submitter	Group	Comments
Food Technology Association of Australia (FTA)	Industry (Australia)	<ul style="list-style-type: none"> • The recommendation in paragraph 3.1 (Scientific Substantiation Framework to be a schedule to the Standard and relate only to general level health claims with four methods) is acceptable. • It should be the responsibility of FSANZ to assess support data supplied in an application which may be uniquely held but still scientifically acceptable, even for a general claim. This same data may at a later time be used to support a high level health claim but a company may seek to use a general level health claim to gain or test market acceptance prior to the expense of providing the data required for a high level health claim. For example, this could apply to a novel food held exclusively by one company. • These substantiation recommendations would probably and preferably be included in the Guidelines that will be prepared in conjunction with the new Standard. • The 4 methods probably would not be legally enforceable as part of ANZFSO. • Methods 1 & 2 could possibly be included as definitions in the introduction of the new Standard. • Methods 3 & 4 are purely descriptive.
Fruco Beverages Ltd	Industry (New Zealand)	<ul style="list-style-type: none"> • Supports the insertion of the Scientific Substantiation Framework into Standard 1.2.7.
Go Grains Health and Nutrition Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Does not support the proposal to insert the Scientific Substantiation Framework as a schedule into the Standard. • Recommends the Scientific Substantiation Framework be available as supporting documentation.
George Weston Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Does not support the recommendation that the Scientific Substantiation Framework be inserted into the draft standard as a schedule. • Recommends the Scientific Substantiation Framework be placed in a user guide and be used as a model for substantiating general level health claims. • The current framework is overly prescriptive and omits other credible sources of scientific substantiation.
Goodman Fielder Home Ingredients	Industry (Australia)	<ul style="list-style-type: none"> • Goodman Fielder supports FSANZ including a list of pre-approved general level and high level health claims within the Code. • The Code need only require claims to be truthful and scientifically substantiated, and that foods are capable of delivering benefits according to the claim in the context of a balanced diet. • It is the role of enforcement agencies to assess any particular claim. • The FSANZ user guide can provide information to assist enforcement agencies and industry in assessing claims. • Recommends that FSANZ move the Scientific Substantiation Framework from the proposed Standard to the user guides. • Recommends that FSANZ include a provision in the proposed Standard that requires all claims to be truthful and scientifically substantiated, and that foods are capable of delivering benefits according to the claim in the context of a balanced diet.

Submitter	Group	Comments
Heinz Wattie's Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports the direction provided by FSANZ in providing suggested wording and substantiation for general level health claims. • Recommends that the Scientific Substantiation Framework be provided in the user guide rather than in Standard 1.2.7. • Suggests that a statement be included in Standard 1.2.7 requiring all general level health claims be scientifically substantiated and truthful.
Horticulture Australia Ltd (HAL)	Industry (Australia)	<ul style="list-style-type: none"> • Supports FSANZ's preferred approach. • Wishes to support the issues raised in the submission made by the Australian Nut Industry council (ANIC) and Nuts for Life.
International Chewing Gum Association	Industry (International)	<ul style="list-style-type: none"> • Generally supports the proposed claims Scientific Substantiation Framework.
Innovations & Solutions – Wendy Morgan	Industry (Australia)	<ul style="list-style-type: none"> • FSANZ proposal is too restrictive. • Including the Scientific Substantiation Framework as a schedule will disallow sound scientific evidence being used as substantiation. • Including such information as guidance in a User Guide will offer more flexibility and allow more up-to-date scientific source documents to be used. • The JHCI is no longer in operation and so no further reviews will be forthcoming. • The Cochrane database is often out-of-date at publication.
Kraft Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Notes that high level health claims were to have required 'convincing' evidence, while general level health claims only required 'probable' evidence. • general level health claims, being less precise claims in that they do not reference a serious disease but are more concerned about general health will normally have more evidence from them in the literature. • Therefore, convincing at both levels is appropriate and helps to support the credibility of food claims generally. • Supports the approach to substantiation but recommends that it be removed from the Standard to a User Guide and replaced with a simpler requirement in the Standard for all claims to be truthful scientifically substantiated, not misleading, and capable of delivering the benefits (in its normal consumption occasion) in the context of a balanced diet. • Thanks FSANZ for the progress made thus far, but strongly recommends that the positions put forward by Kraft are adopted.

Submitter	Group	Comments
Murray Goulburn Co-operative Co. Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports inclusion of the Scientific Substantiation Framework into the proposed standard with the exception of Table 3 which specifies permitted authoritative sources. • Recommends authoritative sources be included in a users guide to provide guidance on the type of sources which are acceptable, as it is unreasonable to assume that those listed in table 3 are the only suitable authoritative sources. • Supports development of a standard to provide a Scientific Substantiation Framework which is flexible and can take account of up-to-date scientific evidence through the use of a user guide for authoritative source guidance rather than a prescriptive regulation.
National Centre of Excellence in Functional Foods (NCEFF) (Tapsell)	Research & Academia (Australia)	<ul style="list-style-type: none"> • The new proposed Scientific Substantiation Framework is clearer and more precise. • It will still remain the case, however, that outcomes represent a value judgment, so the articulation of these values is important.
National Foods Ltd	Industry (Trans Tasman)	<ul style="list-style-type: none"> • In recognising FSANZ's intent to simplify the process, certain substantiation requirements in the Consultation paper have actually become more restrictive. • Supports including a list of pre-approved general and high level health claims into the Standard. This would provide confidence to consumers and enforcement agencies that the claims are truthful and can be substantiated. • The list of general level health claims should be indicative only. • A process should be instated committing FSANZ to continually add to the list of pre-approved health claims. • Recommends FSANZ agree to updating the list of pre-approved health claims on a regular basis • Submits that the 'conditions and criteria' for general level health claims be included in a separate User Guide or Guideline document (e.g. the list of authoritative sources). • Recommends that FSANZ clarify the difference between a 'nutrient-function' and 'food-health relationship' and the associated substantiation requirements. • Recommends levels of substantiation for general level health claims – whether via 'authoritative sources' or 'systematic reviews' be based on the 'consistency' of the evidence. • FSANZ has changed its terminology and appears to use the term 'food-health relationship' to mean a 'food-health' relationship <u>or</u> a 'nutrient-function' relationship. • Understands a 'food-health' relationship to refer to a food class and a health benefit (e.g. dairy for bone health) and a nutrient-function benefit to link a nutrient with a health benefit (e.g. calcium for bone health). • Previously a 'probable' conclusion from 'authoritative texts/sources' was sufficient to support a general level health claim. FSANZ have now proposed that the evidence for general level health claims from authoritative sources must be 'confident and definitive'. The level of evidence required from a 'systematic review' for substantiating a general level health claim is 'consistent' (page 33 of Consultation Paper) • Considers the evidence from the NHMRC guidelines for reviewing evidence and making clinical practice guidelines, that puts forward recommendations from a body of scientific evidence that is graded as 'good' or 'excellent' – 'good' being the 'body of evidence can be trusted to guide practice in most situations' and 'excellent' meaning the 'body of evidence can be trusted to guide practice'.

Submitter	Group	Comments
		<ul style="list-style-type: none"> • Recommends a consistent substantiation approach be adopted for general level health claims and the level of evidence, whether validated through either authoritative sources or from a systematic review and proposes the word ‘consistent’ be adopted. ‘Consistent’ then aligns with the need for a ‘food-health relationship’ to be substantiated from ‘two corroborating sources’.
The National Heart Foundation of Australia The National Heart Foundation of New Zealand	Public Health (Australia) Public Health (New Zealand)	<ul style="list-style-type: none"> • In general agreement with the proposed framework. • Pleased to learn that supporting documentation will be developed to accompany the release of the standard which describes in more detail how to conduct a systematic review and additional information on the use of methods one, two and three.
Nestle Australia Ltd.	Industry (Australia)	<ul style="list-style-type: none"> • Does not support the proposal that the Scientific Substantiation Framework becomes a schedule to the standard. • Recommends that the Scientific Substantiation Framework should be available as supporting documentation only.
New Zealand Beef & Lamb Marketing Bureau	Industry (New Zealand)	<ul style="list-style-type: none"> • Having a strong scientific evidence base is essential for maintaining the credibility of all nutrition messages. It ensures they are accurate and science-based, underpinned by a wealth of research. The proposed framework appears to facilitate this process.
New Zealand Commerce Commission	Government (New Zealand)	<ul style="list-style-type: none"> • Queries why the substantiation provisions do not extend to nutrient content claims, on the basis that consumers may be misled by such claims as to the composition, nutritional quality/quantity or health benefits of a food.
New Zealand Food and Grocery Council	Industry (New Zealand)	<ul style="list-style-type: none"> • Supportive of the intent of the Scientific Substantiation Framework. • Opposed to the Scientific Substantiation Framework being included within the Standard. • It is accepted that the Standard must provide that all claims are scientifically substantiated to the highest standard. • It is also a given that all standards must be truthful and not misleading. • When assessing the strength of evidence, the following points must be applied (summarised from the Consultation Paper): 1. consistent association...; 2. supportive, good quality human studies...; 3. biological plausibility...; and 4. most weight given to experimental studies to assess causality. • How substantiation can be achieved is however better positioned in supporting documents such as user guidelines. • It is logical, consistent and clearer to incorporate all the explanatory information about substantiation in the supplementary documentation (that the Consultation Paper notes is currently being developed). • It is overly prescriptive and unnecessary to include this documentation within the standard.
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> • Allowing only methods 1 and 2 would make enforcement of these claims much easier. • Having pre-approved claims and prescribed wording would eliminate the requirement for industry to prepare a dossier and hold the evidence.

Submitter	Group	Comments
Nu-Mega Ingredients Pty Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports a system which encourages the use of scientifically substantiated general level health claims which do not mislead consumers in regard to the nutritional value of the food. • Specifically, supports the application of current conditions of use for omega-3 fatty acid nutrition content claims (Standard 1.2.8 clause 13) to the new Standard. These should also be used as the minimum conditions of use for general level health claims making a scoring criteria system redundant for omega-3 fatty acid general level health claims. • Supports the need for scientific substantiation of all health claims.
Obesity Policy Coalition	Public Health (Australia)	<ul style="list-style-type: none"> • Shares the views submitted by the Cancer Council of Australia • Agrees that assessment of health claims must be based on the totality of the evidence base.
Parmalat Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Believes that information provided at Draft Assessment had not explicitly stated nor clearly defined the type of documentation required in the substantiation of general level health claims, which would be a major concern to enforcement bodies. • Welcomes the recommendations proposed by FSANZ in the Consultation Paper whereby four methods for the substantiation of general level health claims are outlined. • The key requirements to a sound substantiation framework are: 1) evidence required for general level health claims is explicitly stated; and 2) substantiation requirements must be able to be uniformly interpreted and enforced by the jurisdictions.
The Public Health Association of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Any substantiation process should be based on the totality of evidence, not just one or two emerging studies.
Queensland Health	Government (Australia)	<ul style="list-style-type: none"> • Has concerns in relation to Methods 3 and 4. • These concerns relate to ensuring rigour in evidence in relation to substantiating food-health relationships and to the enforcement of general level claims. • It is not clear that the Scientific Substantiation Framework as it stands would guarantee that some food-health relationships are ‘clear, confident and definitive’ and thus whether the same conclusions about the evidence would be reached by different manufacturers. • This has consequences for monitoring and enforcement about which Queensland continues to have serious concerns. • These must be adequately addressed on a national basis prior to further consultation with the jurisdictions. • The evidence for a food-health relationship needs to be defensible in a court of law. • Therefore a definition of what constitutes a ‘clear and definitive food-health relationship’ is required. • This Standard will be difficult to enforce if the process of assessing evidence is too complex and open to interpretation.

Submitter	Group	Comments
Sanitarium Health Foods	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Supports providing a list of pre-approved general and high level health claims within the Code. • This will provide clarity to manufacturers, consumers and enforcement agencies that the most common claims are truthful and can be substantiated. • These pre-defined health claims are unlikely to be open to systematic abuse, as companies will still need to demonstrate that sufficient amounts of the claimed component(s) would be incorporated into the diet within realistic serving sizes in order to make a claim. • Final position on these proposals may alter depending on how the changes are actually drafted in the legislation. Sanitarium noted concern that in the consultation, draft changes to the legislation are not available. Consequently, comments on the proposals are based on our interpretation of the stated intent within the consultation paper. • Companies should also be free to choose the method of justification on a ‘best fit for the claim’ basis.
Simplot Australia Pty. Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Supports the AFGC submission. • Supports the movement of the Scientific Substantiation Framework to a User Guide.
Dr. Rosemary Stanton	Public Health (Australia)	<ul style="list-style-type: none"> • The framework as proposed is useful but needs some refinement that will protect citizens from misleading claims and assist food companies, especially those who do not have employees skilled in nutritional science or scientific method. • Adequate scientific substantiation is just as important for general level health claims as it is for high level health claims. This needs to be emphasised. • Rules about scientific substantiation must be clear and unambiguous. • FSANZ needs to ensure that companies understand these rules and that issues regarding conflict of interest are avoided where possible and revealed where this is not possible. • FSANZ needs to refer companies to independent experts who can guide them before they make claims that would be costly to retract.
Unilever Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Fully supports the comments in the submission of the AFGC on behalf of industry. • Also active participants of FBIA, and ABC and support their submissions on behalf of their industry members. • Does not support the FSANZ recommendation to insert the Scientific Substantiation Framework into the Standard as a schedule for general level health claims. • Fully supports the two high level principles in the DAR, the disagreement arises from the method of implementation of these principles – in particular mandating in detail methods to be used for substantiation in a Standard. • Also supports the inclusion of a list of pre-approved general and high level health claims within the Code as this provides a credible starting point for health claims and helps establish this area with a solid regulatory foundation.

5. GENERAL COMMENTS ABOUT ISSUES NOT UNDER CONSULTATION

Submitter	Group	Comments
ADECRON Food Tech Consulting Ltd	Industry (New Zealand)	<p>ESADDI/%RDI declarations</p> <ul style="list-style-type: none"> • Some clarification is needed in relation to %ESADDI as currently the % cannot be shown, only the absolute amount (1.3.2.9). Hardly any consumer would know how to interpret the amounts. Seems to be more of a scientific rather than consumer based focus just because there are no clear RDIs established. Suggestion to allow % ESADDI declaration. The difference to a consumer between RDI and ESADDI is largely semantic. Making all 3 terms (DI, RDI, ESADDI) one as in US system, i.e. Daily Values or similar, would be most helpful too. • There is still a need to specify maximum % RDI/ESADDI claims per serving, especially for added vitamins and minerals (in contrast to naturally present levels) (see clause 5 of Standard 1.3.2). This in conjunction with guidelines for sensible serving sizes. • % RDI declarations should be part of the NIP if claims are made, not an optional as in the 2nd example under 1.3.2.9. • Will permission be given now to caffeinated beverages to claim %RDI or will this still be prohibited in 2.6.4.? <p>Addition of vitamins and minerals</p> <ul style="list-style-type: none"> • Current permitted additions should be maintained at least until the full review of vitamin/mineral additions and new NRVs and the Complimentary Foods category have taken place.
Australian Nut Industry Council (ANIC) and Nuts for Life	Industry (Australia)	<p>Good source of mono and polyunsaturated fatty acids</p> <ul style="list-style-type: none"> • Proposes that criteria for good/rich source of mono and polyunsaturated fatty acids be included as exist for omega-3 fats. • The only option for these fats is ‘increased in’ which is useful for commercially manufactured foods such as margarine but not possible for natural whole foods which will be disadvantaged over processed foods. • Submission notes the precedence in the Standard for criteria for ‘good source’ claims for other nutrients such as fibre (100% increase from ‘source’ claims) and vitamins and minerals (25% of RDI per serve). There is an AI value for omega-6 fats and long chain omega 3 fats but no NRV for monounsaturated fats. • Suggests a figure of 50% of either mono- or polyunsaturated fats of total fats for a ‘good source’ of mono or polyunsaturated fats claim. To suggest a value above 80% would greatly limit many healthy high fat foods including nuts (see table 2 in submission – amount and percentage of fats as a proportion of total fats). • To be able to make a ‘source’ claim for both polyunsaturated and monounsaturated fats, suggest more than 72% of total fats as polyunsaturated fats and monounsaturated fats (i.e. the remainder after less than 28% of total fats as saturated fat) and for a <i>good source</i> of both combined - more than 80% of total fat. • Alternatively, a per serve approach could be used. I.e. foods to have a low proportion of saturated fat and: <ul style="list-style-type: none"> – ‘source’ claim of either monounsaturated or polyunsaturated fat: 2.5g of either per serve – ‘good source’ claim of either monounsaturated or polyunsaturated fat: 5g of either per serve – ‘source’ claim of both monounsaturated and polyunsaturated fat: 4g combined per serve

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		<ul style="list-style-type: none"> – ‘good source’ claim of both monounsaturated and polyunsaturated fat: 8g combined per serve • Refers to Table 3 in the submission for dietary modelling of these proposed criteria. • The per serve approach allows for greater flexibility and more healthy high fat foods such as seeds and fish have a better fit than with percentage system, e.g. fish can be described as a good source of polyunsaturated fat which the percentage system doesn’t allow. <p>Macadamia nuts and NPSC</p> <ul style="list-style-type: none"> • Macadamias achieve a score of 4 meaning this one nut will not be able to make general level health claims. Macadamia nut oil does meet the NPSC cut off which paints a confusing picture for consumers. Macadamia nuts qualifying for the NHF Tick Program. • Propose solutions so that macadamias pass the NPSC: <ul style="list-style-type: none"> (i) Adding additional criteria for the healthy unsaturated fat content of products. <ul style="list-style-type: none"> • Suggests that if i) a food/ product contains more than 10g of saturated fat and ii) achieves maximum points for a. protein, b. fibre and c. percentage of fruits vegetables, nuts and legumes (%FVNL); then they should be able to use another set of criteria and cut off points for the levels of monounsaturated and polyunsaturated fats they contain to offset their higher saturated fat points. Developing a scoring system including mono and polyunsaturated fats would require access to dietary modelling which ANIC does not have, however an example is provided (see submission). (ii) Changing the NPSC for fibres and sugars. <ul style="list-style-type: none"> • Suggests including another level for fibre – up to 6 points for greater than 5.6g per 100g. This would increase the subtotal for protein, fibre and %FVNL and give macadamias a final score of 3 (pass). • The Australian Macadamia Society is planning a re-analysis of the nutrient content of macadamias with the next crop by variety and location. It is possible the official levels of fat and saturated fat of macadamias may rise if the USDA Standard Release 20 data for macadamias now available sets precedence. • Refer to appendix 2 of the submission for the Australian macadamia Society nutrient analysis for macadamias 2002.

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Sanitarium Health Foods	Industry (Trans Tasman)	<p>Draft Standard</p> <ul style="list-style-type: none"> Concerned that draft changes to the legislation were not available with this consultation. Their comments are therefore based on their interpretation of the stated intent within the consultation paper and their final position may alter depending on how the changes are actually drafted into the legislation. <p>NPSC and general level health claims</p> <ul style="list-style-type: none"> Has previously recommended that the eligibility criteria be removed from the Standard or be revised to allow a wider range of healthy food options to make claims. Still concerned that the NPSC does not appear to be based on rigorous science and still creates arbitrary boundaries between products that can and can't make claims. Notes that some products that may be healthy in the context of the total diet will still not be eligible to make health claims. Concedes that the revised NPSC will prevent obviously unhealthy products from making claims and provide an incentive to innovate, which may result in some improvement to the nutritional profile of the overall food supply.
The National Heart Foundation of New Zealand	Public Health (New Zealand)	<ul style="list-style-type: none"> Supports giving permissions for substantiated health and nutrition claims on food labels and in advertisements as a form of public health intervention to support public health nutrition priorities. Recommends an adequate education campaign to reinforce key messages of national nutrition guidelines and improve consumer and food manufacturers understanding of food labels in general, and nutrition and health claims. Believes that tighter controls on nutrition and health claims via inclusion in a standard rather than a guideline will particularly assist smaller food companies to improve the quality and accuracy of the nutritional information they provide. Also believe this is the better approach with respect to imported foods. Recommends further consideration be given to scoring cut-off levels in the NPSC to address inconsistencies – specifically macadamia nut, which is unable to make a general level health claim, versus macadamia nut oil which passes the NPSC.
Tomox Pty Ltd (Susan Thompson, Consultant Dietitian)	Industry (Australia)	<ul style="list-style-type: none"> Concerned that NPSC limits the ability of some basic foods to make health claims, e.g. nutrient dense foods such as regular cheese and flavoured milks. Without changes to the NPSC many nutritious dairy products are disadvantaged in making bone health claims despite these foods being consistent with dietary guidelines, being the predominant source of calcium in the Australian diet and calcium being a nutrient of concern in the Australian population. It is important that the NPSC balances the positive attributes of such basic traditional foods against the levels of saturated fat, sugar and salt in achieving a balanced diet overall. The appropriateness of allowing a claim regarding types of fats (despite concerns about total fat intake and energy density) could be extended to allow calcium claims in some foods that do not currently meet the NPSC.
National Health and Medical Research Council (NHMRC)	Government (Australia)	<ul style="list-style-type: none"> Supports comments in Section 1.4 of the document relating to NRVs.

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Parmalat Australia Ltd	Industry (Australia)	<ul style="list-style-type: none"> Comments that it is essential that the review of the NRVs is completed before the end of the transition time to minimise cost to industry.
South Australia Department of Health	Government (Australia)	<ul style="list-style-type: none"> Concerned that the consultation only addresses three issues when the department has raised several other issues at previous stages and has received no feedback regarding these concerns. <p>1) General level health claims</p> <ul style="list-style-type: none"> States that many concerns raised in relation to general level health claims are still largely unresolved which may ultimately lead to a review request (recommend pre-approval of all general level health claims). Comments that current proposals is exceedingly difficult from an enforcement perspective and creates and uneven playing field between large and small businesses. <p>2) Drafting</p> <ul style="list-style-type: none"> Strongly recommends that the jurisdictions have opportunity to see the drafting prior to Final assessment. Comments that this is necessary to give opportunity to clarify wording and intent with FSANZ prior to making recommendations to the Minister. <p>3) Enforcement</p> <ul style="list-style-type: none"> ‘The enforcement aspect of the proposed health claims Standard is particularly concerning. In particular, the proposed Standard still places a huge onus on enforcement bodies to assess and weigh evidence to substantiate claims.....If there is any doubt or confusion in interpreting evidence, it will make the law unworkable’
CHOICE	Consumer (Australia)	<ul style="list-style-type: none"> Believes that the proposed regulatory approach for products containing biologically active substances will not adequately protect consumers. Until such time as policy guidelines and corresponding standards have been developed for the addition of substances other than vitamins and mineral, and/or safe and appropriate levels of individual biologically active substances have been established, CHOICE supports the prohibition of all claims about biologically active substances or regulation of these claims as high-level health claims. Concerned that it will be the responsibility of manufacturers to determine an efficacious level of that substance. Research supporting the health benefit of biologically active substances may not be advanced and manufacturers may not have the expertise to assess the available evidence and determine an efficacious amount. Believes that manufacturers that choose to make a nutrition content or general level health claim about biologically active substances should meet the substantiation requirements outlined on Method 3 and Method 4 or the Scientific Substantiation Framework. While products carrying a general level claim about a biologically active substance have to meet qualifying criteria and the NPSC, a product carrying a content claim about a biologically active substance need only have a trace amount of the claimed substance. This is inconsistent with the regulation of products carrying vitamin and mineral claims. These products must contain at least 10% of the recommended dietary intake (RDI) of the claimed vitamin or mineral.

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		<ul style="list-style-type: none"> • While there are no RDIs for biologically active substances, for the sake of consistency and to avoid misleading claims, CHOICE believes that content claims about biologically active substances should also be required to meet the 10% qualifying criteria, by requiring these products to contain 10% of the efficacious amount. • Believes that FSANZ has not adequately addressed the issue of product endorsements and how these would be regulated under the new standard. In particular, if endorsement programs are not regulated appropriately under this standard, products that are ineligible to carry health claims because they fail to meet the NPSC may be marketed with a health endorsement if the endorsement scheme establishes less stringent nutrition criteria. This is particularly concerning given that in 2005 FSANZ's own research found that consumers attributed a higher degree of promise to products carrying endorsements, compared to other high level health claim, general level health claim or nutrition content claim. Products that are deemed by the NPSC to be ineligible to carry health claims should not be able to carry a health-related endorsement, unless the claim relates to an allergy or intolerance. • Concerned that the proposed enforcement system for the new standard will not be sufficient to deter food manufacturers from intentionally breaching the standard. Strict enforcement is vital to protect consumers against misleading claims and advertisements that contravene the health claims standard and overstate the health benefit of individual food products. • The new Standard should be accompanied by a well funded, far reaching and nationally consistent public education campaign that promotes healthy eating messages consistent with the Australian Guide to Healthy Eating and the Australian Dietary Guidelines. It should also improve consumer understanding about how to interpret food labels, as well as address consumer understanding of nutrition and health claims and the role of individual foods in a healthy diet.
New Zealand Ministry of Health	Government (New Zealand)	<ul style="list-style-type: none"> • Pleased to read that FSANZ considers the work of incorporating the new NRVs into the Code as a high priority and should, if possible, be undertaken prior to the end of the transition period for Proposal P293. • While they would prefer all components of the NRV review were completed before standard 1.2.7 is finalised, pleased that FSANZ will at least incorporate the new vitamins and mineral NRVs into standard 1.2.7 to ensure claims reflect the most up-to-date recommendations. This is particularly important for nutrients such as sodium, for which the new NRVs are substantially lower than before.
National Centre of Excellence in Functional Foods (NCEFF)	Research & Academic (Australia)	<ul style="list-style-type: none"> • Note that the focus is on <i>food</i>, and recognize that the impact of the Standard will be seen through food consumption and its impact on health. However, despite the fact that most of the available scientific knowledge is on <i>food components</i>, the principles on which this knowledge is applied should ideally defer to the concept of foods, and not food components. • Argues that food eligibility criteria should be driven by a concept of <i>food</i>, not nutrients, that claims regarding fat content should help consumers identify the best '<i>fat rich foods</i>' and the substantiation framework should privilege evidence based on <i>food</i> consumption.

Submitter	Group	Comments
Horticulture Australia Ltd (HAL)	Industry (Australia)	<ul style="list-style-type: none"> • While making claims about the existence of monounsaturated and polyunsaturated fats in nuts is essential, the Australian nut industries would like to propose that criteria for a good/rich source of these types of fats be included as exist for omega 3 fats. • Macadamias do not pass the NPSC and the Australian nut industries would like to propose possible solutions which include altering the criteria of the nutrients in the calculator. Failure to achieve the inclusion of macadamias would mean the category of nuts could not be promoted in a consistent way which may result in confusion and misunderstanding.
National Foods Ltd	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Believes the proposed nutrition, health and related claims Standard is overly complex and flawed in its current form, particularly with regards to the proposed NPSC for general level health claims. • The intent of the Standard is to enable consumers to make informed choices based upon clear, validated information. Therefore, in its current form, does not support the introduction of the Standard for Nutrition, health and related claims.
Australian Self Medication Industry (ASMI)	Therapeutic (Australia)	<ul style="list-style-type: none"> • Concerns with enforcement of the health claims standard. • Interface between health claims and therapeutic claims.
Australian Publishers Bureau	Media (Australia)	<ul style="list-style-type: none"> • Must be the sole responsibility of the advertiser of health claims to ensure that all criteria are met. Publishers of this information should not be held accountable for compliance with the standard.
Comvita	Industry (New Zealand)	<ul style="list-style-type: none"> • Requests that health claims be permitted on honey. Cites 19 studies in support of this position.
Consumers NZ	Consumer (New Zealand)	<ul style="list-style-type: none"> • Expresses disappointment that NPSC will not be applied to nutrient content claims (all types). Provides 1 page of comments on this subject. • Supports the mandatory declaration of trans fatty acids in the nutrition information panel. • Comments on endorsement programs • Concerns on enforcement of the health claims standard. • Makes comments that an education campaign should accompany the changes to nutrition and health claims.
Commonwealth Scientific and Industrial Research Organisation (CSIRO)	Research and Academia (Australia)	<ul style="list-style-type: none"> • The requirement of only 10% of the RDI to carry a vitamin/mineral nutrient content claim appears too low given that no information on bioavailability is required. This could be reconsidered if the claimable food criteria are removed as FSANZ proposes.

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Dairy Australia	Industry (Australia)	<ul style="list-style-type: none"> • Considers that improvements could be made to the NPSC to better align it with ‘dietary guidelines recommended’ foods. These suggestions include having protein content as an additional criterion for category 3 foods, and ensuring that consumer recognised food categories (such as milks and milk drinks) are not split across different profiling scoring criteria. • The operation of the NPSC for cheese results in cheese types such as Camembert, Brie and Mozzarella being eligible to make general level health claims, while other types such as Cheddar and Parmesan are ineligible to make claims. This will result in confusion for consumers who would be justified in wondering why health claims are made for some cheeses, and not others. • A further anomaly is that regular fat milk with added omega 3 fats will be treated differently in the NPSC to regular fat milk that has been produced through agricultural practices to have higher levels of omega 3 fats. • Milk with added omega 3 fats will be assessed under Category 1, while milk with ‘natural’ omega 3 fats will be assessed under Category 2. This also has the potential to increase consumer confusion, and could be resolved through simple adjustment to the NPSC.
Dairy Farmers	Industry (Australia)	<ul style="list-style-type: none"> • Under the present NPSC, nutrient dense foods such as regular cheese and some milk products will be ineligible for general or high level claims for vitamins and minerals. • Continues to be concerned about the nutritional impact of the current NPSC. The current NPSC eliminate the following Dairy Farmers products: some custards, virtually all flavoured milks (except one that is low fat), standard yogurts and cheeses (except for reduced fat cheese). • Dairy Farmer products are consistent with national dietary guidelines and are important contributors of nutrients. The inability to provide consumers with information on the nutritional benefits of these products could impact on the intake of calcium and other important nutrients. • Supports the NPSC but proposes that: <ul style="list-style-type: none"> – ‘Milk’ be re-defined to allow all liquid milk products (including flavoured milk and other dairy beverages such as drinking yogurt), permitted within the scope of the code, to be captured under category 2; – Include a protein score in category 3 (as a marker for calcium). This would allow standard cheese with a high calcium content to make claims in line with current dietary recommendations; and – Decrease the protein grams allowed per point marginally to 1.4 grams per point which will allow claims for standard yogurts in line with current dietary recommendations.

Submitter	Group	Comments
Department of Agriculture, Fisheries and Forestry (DAFF)	Government (Australia)	<ul style="list-style-type: none"> • Further analysis needs to be undertaken to establish a clear case regarding the need for food products wishing to make general level health claims to meet eligibility criteria that relates to the overall nutritional profile of the food product. It is unclear what additional information or benefit is conferred to the consumer in applying such qualifying criteria. • The NPSC is based on the UK Food Standards Nutrient Profiling Model that was developed to assess the eligibility of foods that could be advertised during children’s airtime on UK television. DAFF notes that the purpose for which the nutrient profile model was initially developed is much narrower in scope than FSANZ’s proposed use for the model under the draft health claims standard. The appropriateness of the model being applied to this broader scope should therefore be assessed by FSANZ. • If FSANZ stands by its decision to proceed with the nutrient profile model for general level health claims, believes that an evaluation of its effectiveness in improving consumers’ capacity to make healthy dietary choices should be undertaken.
George Weston Foods Ltd	Industry (Australia)	<ul style="list-style-type: none"> • Comments supporting work that will allow NRVs to be completed within the transition period for health claims (p293) and folate fortification (p295).
Heinz Wattie’s Australasia	Industry (Trans Tasman)	<ul style="list-style-type: none"> • Raises an issue on having different claims criteria for solid foods and liquid foods in Table to Clause 11, criteria for making nutrient content claims.
New South Wales Centre for Public Health Nutrition	Public Health (Australia)	<ul style="list-style-type: none"> • Raises several issues that are considered to be unresolved: <ul style="list-style-type: none"> – Qualifying criteria for biologically active substance claims; – Full cream milk should be eligible to make health claims; – NPSC should be modified to allow claims on healthier breakfast cereals; – Manipulation of processing techniques to make foods eligible for claims; and – Hot chips and other fried takeaway foods should be ineligible to make claims.
The National Heart Foundation of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Supports giving permissions for substantiated health and nutrition claims on food labels and in advertisements as a form of public health intervention to support public health nutrition priorities. • Recommends an adequate education campaign to reinforce key messages of national nutrition guidelines and improve consumer and food manufacturers understanding of food labels in general, and nutrition and health claims. • Believes that tighter controls on nutrition and health claims via inclusion in a standard rather than a guideline will particularly assist smaller food companies to improve the quality and accuracy of the nutritional information they provide. Also believe this is the better approach with respect to imported foods. • Recommends further consideration be given to scoring cut-off levels in the NPSC to address inconsistencies – specifically macadamia nut, which is unable to make a general level health claim, versus macadamia nut oil which passes the NPSC.

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The Cancer Council Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Requests that FSANZ address the following issues: <ul style="list-style-type: none"> – Enforcement issues raised by jurisdictions in previous consultation rounds; – Ensuring that there is an education strategy to accompany the health claims standard; – Resolving concerns around biologically active substances; – Ensuring there are no nutrition or health claims on alcohol; and – Condition of food consumption and claims (e.g. claims on breakfast cereals when milk is added).
New Zealand Food Safety Authority (NZFSA)	Government (New Zealand)	<ul style="list-style-type: none"> • Without a draft Standard it is not possible to ascertain if the intent of the consultation paper has been carried through into the drafting of Standard 1.2.7
Dr. Rosemary Stanton	Public Health (Australia)	<ul style="list-style-type: none"> • Has made previous submissions on P293 and many of her original concerns remain. • To summarise, concerns on the issues in question are that the current proposal P293: <ul style="list-style-type: none"> – has the potential to confuse consumers unless disqualifying criteria are applied to all foods; – appears to favour the food industry's selling tactics rather than be principally concerned with encouraging the public to choose basic core foods, especially fruits and vegetables; – assumes that content and general level claims are somehow deserving of less principle; – ignores the need for the regulatory framework to move the national diet away from heavily processed foods that are high in fat, sugar and salt. • Remains concerned that the Standard does not have a proactive and dedicated 'watchdog' that could seek out misleading or deceptive claims. I am also concerned that insufficient resources are available (or planned) for consumer education about nutrition, health and related claims. Would like to see FSANZ propose a more proactive response and set up an education program for the public. This may be done in conjunction with the Department of Health and Ageing. • The issue of claims made about the addition of various biological substances needs to be addressed before any claims are permitted for these ingredients. • Safety issues are relevant to many substances as are issues of efficacy and some assurance that the quantities of substances used is sufficient to produce the claimed effect. • During 2007, there was considerable discussion (including at SDAC meetings) about the division of overweight and obesity into general level and high level claims areas. There was much support for both being within the same category, overweight being a precursor (or biomarker) to obesity. Many were concerned that overweight was only being considered as general level claim and therefore subject to a lower level of scrutiny. As few companies would be likely to prefer overweight or excess weight to the terms obese or obesity, this means that one of Australia's most serious health problems will move out of the area of high level claims and into the level of general level claims. Has FSANZ looked into the widespread concern about this issue?

Submitter	Group	Comments
The Public Health Association of Australia	Public Health (Australia)	<ul style="list-style-type: none"> • Concerned that a number of issues that have been previously raised are not addressed in this current Proposal. These include: <ul style="list-style-type: none"> - Enforcement – there needs to be an appropriate enforcement strategy in place to ensure that offenders are identified and penalised accordingly. - Communication strategy and education campaign – a communication and education strategy is essential in order to prevent consumer confusion. - Endorsement programs and trademarks – it is still necessary to consider how these will be regulated as consumers do not necessarily see these as any different to health claims. - Biologically active substances – PHAA remains concerned about the use of nutrition content claims for biologically active substances and that, given the lack of knowledge about many of these substances, claims can be made based on 10% of recommended amount. - Remains concerned that infant foods are included in the standard as foods that nutrition content and or health claims can be made on, and recommend these be exempt.