

**Proposal P293 Nutrition, Health and Related Claims
Summary of submissions to the Draft Assessment Report**

13. DISQUALIFYING CRITERIA FOR GENERAL LEVEL HEALTH CLAIMS

Submitter	Group	Comments
Joss Shawyer	Consumer – New Zealand	<ul style="list-style-type: none"> • Supports new health warnings on high content of sugar occurring naturally in fruits. • Is diabetic, found through internet research that fruit is bad for diabetics so cut out all fruit and high GI vegetables from her diet and her diabetes cam under control very quickly. • Flour is also a major problem for diabetics; has cut out grain product also and will remain on a low CHO diet for the rest of her life. • Is a member of the Dr Bernstein’s diabetic forum which endorses low carbohydrate, high fat and low protein diet which helps keep their diabetes under control. • New Standard will help diabetics understand that naturally occurring sugar is not good for their health. • FSANZ will now need to stand against the commercial opposition to the new standards, which will be backed by very big money. Hopes FSANZ will stand up for what they know is right.
John Birkbeck (Massey University)	Academic – New Zealand	<ul style="list-style-type: none"> • Has already and justifiably come under fire since some common and clearly ‘healthful’ foods, e.g. apples and bananas, are excluded. • The numbers have no meaning except in context. A pickled olive may have very high sodium content, but a few olives once a day with a meal may be irrelevant/not constitute a health risk, and only a proportion of the population are sodium-sensitive anyway. • If it also had some potential health benefit [e.g., rich in a vitamin] it would unjustly be prohibited from making such a claim even if technically true. • Some totally ridiculous conclusions can be drawn from these numbers, as has already been pointed out in the media. • If a food provides many and diverse other essential or healthful components, these criteria may have little meaning in terms of the whole diet. Contrariwise, a sugar sweet may contribute nothing in the way of useful components yet be deemed ‘healthful’ because it contains only 15g of sugar. • This entire concept needs much more debate. • It is not possible or valid to categorise any given food as ‘good’ or ‘bad’ [determined by energy content per serve, saturated fat or salt content). This is strenuously opposed. • Foods can only be categorised in terms of their relation to the total diet. It is possible that reference to levels of intake determined by total diet surveys could be used as a guide.

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Dairy Farmers Group	Industry - Australia	<ul style="list-style-type: none"> • Disadvantages dairy products by virtue of their lactose content. • Compliance with the limit of 16g of total sugars per serve is virtually impossible. • 16g of total sugars per serve means that healthy milks such as Shape (16.8g lactose per 250mL) (good source of protein and one of the best sources of calcium of any product) and Farmers Best (15.8g lactose per 250 mL) (low fat modified milk with MUFA vegetable fat and omega-3) would be ineligible for even a general level claim, despite their significant contributions of calcium, protein and riboflavin. • Products such as fruit yoghurts will always contain more than 16g of lactose, fruit sugars and sucrose in a 200g serving, except where artificial sweeteners are used. This precludes general level claims such as the benefits of protein or calcium or probiotic bacteria and would create a bias towards the use of artificial sweeteners. • Expect this is an unintended consequence of the clause and suggest the limit on sugars be either deleted entirely or at least amended to indicate that it refers to sugars other than lactose. • Limits on saturated fatty acids also means that regular milk (5.8g SFA per serve) would be precluded from making a general level claim for calcium or protein and again assume that such is unintended. • Recommend the SFA limit be increased to 6g per serve. • The clause as it stands is inconsistent with current national nutrition guidelines so they trust that appropriate amendments can be made.
Mike Gidley (University of Queensland)	Academic – Australia	<ul style="list-style-type: none"> • Agrees with the principle of disqualifying criteria for health claims, as the focus should be on whole foods in the context of a balanced diet. • Appreciate that any attempt to set specific limits based on specific components will throw up anomalies. • A foodstuff that just avoided all three disqualifying criteria is very likely to be judged less nutritious than one that failed a single criterion. • Total sugars is the most problematic of the three disqualifying criteria. • Rationale for each would seem to be their potential physiological consequence. • Section 3.6.6 (attachment 5) suggests that total sugars is an alternative to energy density that is more acceptable as otherwise high protein foods would be disqualified. • Although it could be argued that non-saturated fats and protein are nutritionally preferred to carbohydrates, there is general agreement that total energy intake is the single most important predictor of obesity. • If the intention is to protect against obesogenic choices, why not set a disqualification based on energy density? If the emphasis is on specific physiological effects of high sugar intake, the measure of total sugars is inappropriate in his opinion for two reasons: <ol style="list-style-type: none"> 1. total sugars measures the sum of all mono- and disaccharides, which don't all have equal physiological consequences, e.g. lactose vs. sucrose; 2. of more concern, many starch-derived polysaccharides would not be analysed as total sugars, but are rapidly

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Mike Gidley (University of Queensland)	Academic - Australia	<p>converted to glucose during digestion and have very similar physiological effects to an equal portion of ingested glucose.</p> <ul style="list-style-type: none"> • If ‘sugar’ content is to be used as a disqualifying criterion, the only nutritionally-valid approach is to count both free sugars and digestible starches as contributing to the total. With the current 16g/serve this would disqualify e.g. many cereals, breads and other baked products. • Submits that given the difficulties in agreeing on how to measure digestible starch, the disqualifying criterion for total sugars be replaced by an appropriate measure of energy density, or be removed altogether until such time as an agreed analytical method for determining digestible starches in food stuffs is available.
New Zealand Food Safety Authority (NZFSA)	Government – New Zealand	<ul style="list-style-type: none"> • Supports the principle behind the use of ‘per serve’ for disqualifying criteria. • NZFSA and the Ministry of Health are concerned that some products, e.g. confectionery and snacks such as biscuits which, because of their small serving size, would often meet the disqualifying criteria, could have substances added to them in order to make health claims. • This would be contrary to the Policy Guidelines on Nutrition, Health and Related Claims as it would not be ‘consistent with and complement Australian and New Zealand national policies and legislation relating to nutrition and health promotion...’ namely the Food and Nutrition Guidelines. • This is a particular concern for products targeted at children, as these tend to have smaller serving sizes. • Recommends further consideration is given to whether health claims should be permitted on those foods. • The proposed approach in the Draft Assessment Report for specific disqualifying criteria for general level health claims applying to meals and main dishes does not take into account any allowances for snacks in the daily intake. NZFSA and the Ministry of Health suggest that snacks be taken into account when determining these values. • Supports the disqualifying criteria for the level of fat in a product to refer to the total level of saturated fatty acids and trans fatty acids. This is consistent with both the evidence for high level claims that reducing both saturated and trans fatty acids is beneficial in reducing the risk of coronary heart disease, and with the requirements for nutrient content claims around fat. • In line with this, recommend rewording (i)(B) to read ‘4g of saturated and trans fatty acids per serve; and’ and rewording (ii)(B) to read ‘7g of saturated and trans fatty acids per serve; and’.
Community and Public Health, Canterbury District Health Board	Public Health – New Zealand	<ul style="list-style-type: none"> • Proposal relies on the use of serving sizes but does not differentiate between food groups. • Lack of standard serving sizes and ability to manipulate serving sizes provides a significant advantage for the food industry allowing claims on highly processed products, e.g. Coco Pops, by using a serving size likely to be much smaller than that realistically eaten. • This is of serious concern from a public health perspective and will potentially become a significant marketing tool for the food industry, rather than a strategy allowing members of the public the make more informed food choices. • Understand that the DAA is working on serving size criteria with FSANZ and look forward to seeing this.

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Agencies for Nutrition Action (ANA) (members except NZ Nutrition Foundation)	Public Health – New Zealand	<ul style="list-style-type: none"> • Is problematic to base the disqualifying criteria on serving sizes as New Zealand and Australia don't have standard serving sizes. • Are concerned that manufacturers will be able to manipulate the recommended serve size of products so they can make claims. • Is of particular concern that foods such as coco pops and sponge cake can make health claims due to serve size, but others such as baked beans and large servings of fruit are disqualified. • Support the establishment of separate criteria for different food categories and recommend that standard serving sizes should be developed in consultation with key stakeholders and incorporated into Standard 1.2.7 to avoid consumer confusion. • Understand that the system needs to be practical and easily applied to the food industry but the fact that unhealthy foods can slip through to make inappropriate claims is unacceptable. • Do not believe that the proposed disqualifying criteria will assist consumers to select foods for healthy diets or protect consumers from misleading claims, hence contravening the primary objectives of FSANZ of protection of public health, provision of adequate information relating to food to enable consumers to make informed choices and prevention of misleading and deceptive conduct. • Urge FSANZ to consider the implications of this regulatory system and its adverse potential to encourage consumption of processed non-core foods and to discourage consumption of the core foods, such as fruits and vegetables, milk and bread.
Australian Fruit Juice Association (AFJA)	Industry - Australia	<ul style="list-style-type: none"> • Disagree with the introduction of disqualifying criteria. • Question why remove products such as milk, yoghurt, fruit juices and fruit from making general level or high level claims. This is contrary to a health diet (i.e. the Fruit Pyramid). • 16g sugar per serve would exclude the majority of 'No added sugars' fruit juices. • Fruit juice is widely consumed and provides a wide range of nutritional benefits (IFU Nutritional Policy) • Wide consumption of fruit juice presents an opportunity to positively influence consumers' health. Innovation by the fruit juice industry will be of immense benefit, minimising the impact of diseases of affluence. • Fruits, fruit juices, milks and their derivatives are high in naturally occurring sugars, most low GI. If any criteria were to be set for sugars it should be for 'added sugars' only. • Understand the use of sugars as disqualifying criteria is not considered appropriate by the Dietitian's Association of Australia.

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<p>Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)</p>	<p>Industry – New Zealand Industry – Australia</p>	<ul style="list-style-type: none"> • Understand that FSANZ would like to follow general public health guidance to encourage lower consumption of dietary sugar and fat. However, applying qualifying and disqualifying criteria to claims on food is a heavy-handed and unnecessarily restrictive initiative, which they strongly oppose. • A positive approach to address these public health issues involving strong educational campaigns on dietary practice would be more effective than the indirect method of prohibiting certain foods from depicting nutritional and health claims. <p>Negative impact on dairy consumption</p> <ul style="list-style-type: none"> • The criteria will negatively impact the food industry through discrimination against whole foods such as milk, resulting in exclusion of claims on a significant section of dairy foods including whole milk, most yoghurts and hard cheeses. • The enforced removal of nutritional messages from dairy produce consumed daily that are important contributors to a staple and varied healthy diet does not make sense. The negative message being sent to the public is that these products are either harmful or at least not beneficial to the diet. This inference is not true (refer to Attachment 1 to submission, Dairy Foods in Health, IDF Bulletin No. 336/1998) and could result in reduced consumption of dairy. • Submits that dairy-based foods should be excluded from the disqualifying criteria, given that dairy is a food group that is supported by the dietary guidelines. <p>Negative impact on improving indulgent foods</p> <ul style="list-style-type: none"> • Manufacturers would no longer have an incentive to improve their products from a nutritional health perspective, leading to the food industry not producing healthier types of foods within a food category. The effect would be the unnecessary limitation of a wider variety of foods as well as consumption of the less healthy option within a food group or product range through lack of availability of choice and awareness. • Allowing claims would not only would encourage industry to improve the nutritional profile of foods within particular categories but mean the overall diet could be potentially improved through distinguishing modified versions from standard ‘unhealthy’ products that tend to be consumed in large quantities. • People have the right to be completely informed, without exception, on the content and possible benefit of all foods. <p>Unsupported policy decision</p> <ul style="list-style-type: none"> • Submits that there is no consumer research that would support the assertion that claims on particular products would skew the diets towards unhealthy foods. This has not been demonstrated overseas where claims are allowed on all products. Market research indicates that claims help consumers distinguish between comparable foods, and do not generally influence a move from one food type to another. • By proposing such measures, FSANZ is communicating to consumers that they should assess the individual components of a food and not take the food as a whole into consideration. This does not make nutritional sense and will lead to people limiting aspects of their nutritional regime resulting in an imbalanced diet.

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<p>Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)</p>	<p>Industry – New Zealand Industry - Australia</p>	<ul style="list-style-type: none"> • Overall, the decision is a clear movement away from general FSANZ principles that encourage industry innovation, rely on scientific substantiation and promote consumer choice for increased public health and safety benefits. Withholding beneficial information from the public does not comply with standard FSANZ practice. • Supports the removal of general qualifying and disqualifying criteria altogether based on its inconsistent premise and conflict with FSANZ policies and principles. • Submit that the disqualifying criteria should not apply to products marketed towards growing children, who should not be focusing on diet foods. <p>Sugars and fats</p> <ul style="list-style-type: none"> • There are damaging implications being made through this ruling that insinuates all sugars and fats themselves are harmful. Again this is not true, if they are not consumed in excess. • Although there is evidence to show that some fats and sugars may be linked to certain health problems, there is no substantiation to show the harm in consuming these nutrients in the context of whole foods. Therefore, as long as the messages are accurate and these products are consumed in moderation and in the context of a healthy diet, there should be no restrictions on stating the nutritional benefit of a food or food group. • Exclusion of the basis of these nutrients levels removes all motivation for industry to perform further research and development in this area. • Many foods that constitute a significant part of a normal healthy diet (e.g. fruit yoghurt and cheese) are naturally high in sugars and fats. The criteria imposed therefore demonstrate unfair exclusions and will adversely impact on the dairy industry due to the natural fat levels in some – nutritious - dairy products. In addition, there is emerging scientific evidence showing that there may be distinct health benefits associated with milk consumption and fatty acids. • To combat these irregularities, the preferred option would be removal of disqualifying criteria from the proposal altogether. A second option would be the exemption of dairy-based products from these criteria, in recognition of their nutritious role in the diet and recommendations for dairy consumption in the dietary guidelines. <p>Lactose</p> <ul style="list-style-type: none"> • (pg 45 – exceptions) strongly agree that lactose should be excluded from the disqualifying criterion. • Approves that lactose not be encompassed and regulated as other natural sugars such as sucrose and fructose as there is strong evidence showing the lactose in milk or yoghurt has a low glycaemic index and is much less cariogenic than sucrose. Lactose has also been demonstrated to enhance calcium absorption.

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Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry - Australia	<p>Formulated meal replacements and formulated supplementary foods</p> <ul style="list-style-type: none"> • There is feeling that the disqualifying criteria are not appropriate for products as defined in the Code: Standard 2.9.3 – Formulated Supplementary Foods which have specific energy requirements. • Claims will be limited for foods under this classification due to their increased energy levels that necessitate the deliberate addition of sugars and fats. These qualifying criteria directly contradict the disqualifying criteria set in the proposed claims standard. • Would like to point out the inconsistency and resulting problem to manufacturers with stipulating higher sugar and fat levels and then excluding them from making claims based on their nutrient profile. • Due to the restrictions surrounding fortification of foods in Australasia, which are much stricter than in other countries, supplemented products sold generally overseas are required to be placed under this category. Limiting claims made here therefore has a particularly negative impact for industry and product choice. • Presumably there is a rationale for the higher energy level for foods in this category, which is the category which permits the most fortification of nutrients. To restrict claims on the category due to perceived negative impacts on weight is a direct conflict of policy underlying the formulated foods regulations. • Proposes foods classified under the Formulated Supplementary Foods category be exempted from the disqualifying criteria regulations. • Also supports a review of the energy requirements under the Formulated Supplementary Foods category.
National Heart Foundation of Australia National Heart Foundation of New Zealand	Public Health – Australia Public Health - New Zealand	<ul style="list-style-type: none"> • Sugars content is not an ideal surrogate measure for energy – is only one factor affecting the energy density of a food. • The values selected for the disqualifying criteria are limiting for some fruits and dried fruits and many foods that are higher in fats or sugars but which provide positive nutritional contribution. By being ‘one size fits all’ a single set of disqualifying criteria does not recognise the differing nutritional contribution and composition of different types of foods. • Manufacturers will reformulate to meet nutrition criteria, so it is important that positive nutrition is not compromised in the effort to only reduce the content of ‘negative’ nutrients. • If a category-linked approach is not possible, recommends FSANZ <i>reconsider the assumptions and bases</i> on which the disqualifier were developed. <u>Energy:</u> Draft Nutrient Reference Values for Estimated Energy Requirements (EERs) are used as an alternative to the 8700 kJ/day reference level; <u>Saturated fat:</u> applying the same formulation as has been applied by FSANZ but using an energy value of 11,250 kJ/day results in a saturated fat disqualifier of about 5g/serve; • If cause related marketing statements are to be permitted, then due to the potential for them to be considered quasi-endorsements or implied health claims, it is important that products carrying these statements comply with the disqualifying nutrient levels.

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<p>National Heart Foundation of Australia</p> <p>National Heart Foundation of New Zealand</p>	<p>Public Health – Australia</p> <p>Public Health - New Zealand</p>	<ul style="list-style-type: none"> • Main problems with disqualifiers proposed in section 5(2)(a) are: ‘per serve’ disqualifying criteria favour foods with smaller serve sizes. Because healthy eating recommends an upper daily limit of sodium independent of energy levels, the ‘per serve’ approach could be considered more relevant to sodium than to other nutrients. An advantage of having sodium criteria ‘per 100g’ is that it can be an indicator of the relative saltiness of the product for consumers. Heart Foundation suggests that serve sizes can be controlled to an extent by including criteria both ‘per serve’ and ‘per 100g’. • Recommends a new set of disqualifying criteria. A useful compromise between current proposal and ‘best possible’ disqualifiers is: <ul style="list-style-type: none"> – 5-8 category specific criteria (covering, as a minimum, main food groups) – Indicative lists of category inclusions; – Re-assessment of nutrients addressed in each category; – Consideration of using ‘positive’ criteria (e.g. fibre) in relevant categories; – More flexibility in the base of the criteria e.g. ‘per 100g’, ‘per serve’, a combination of these, % of total fats or even ‘per kJ’. • References and recommends consideration of submission by Dieticians Association of Australia mentioning category-specific disqualifying criteria. Would like to see addition of minimum fibre criteria for bread and cereal products.
<p>Parmalat Australia Ltd</p>	<p>Industry, Australia</p>	<ul style="list-style-type: none"> • Conversion to ‘serve size’ will prevent products in smaller size packs from making the same content claims even though the consumer is advised on the quantity and %RDI of the claimed vitamin and/or mineral present in the pack. • Rejects the proposal that disqualifying criteria based on saturated fat, total sugars, and sodium be applied to all foods in order to make health claims, with the exception of general level health claims that refer to lactose and gluten. This requirement clearly imposes penalties on many dairy products currently making valuable contributions to a well balanced diet. • Provides a table demonstrating dairy products that will not be able to place general level health claims based on proposed disqualifying criteria. • These products are unable to claim health benefits through a ‘one size fits all’ approach in applying disqualifying criteria to health claims. • Opposes the application of disqualifying criteria for health claims applied equally across all food groups and recommends that these criteria be removed and that health claims be permitted on all foods for which a substantiated health claim can be made. • Recommends an alternative option to removing disqualifying criteria for general level claims, based on category specific disqualifying criteria. • Further clarification is recommended as to the application of disqualifying criteria to Dietary Interaction Claims.

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SPC Ardmona	Industry - Australia	<ul style="list-style-type: none"> • Proposed disqualifying limit of 16g per serve of total sugars will cause many processed fruit products to be excluded. Concerned this will lead to the exclusion of basic items such as canned fruit juice. • The Dietary Guidelines referenced in the Draft Assessment Report define a ‘serve’ of canned fruit as a ‘cup’. This would place a ‘serve’ well over the current 16g limit for making any health claim = an unintended negative consequence of the current draft legislation wording and should be addressed. • Suggests changing ‘disqualifying’ levels to: Div 2 5.2.a.ii.c 16g of total sugars per serve EXCEPT where: <ul style="list-style-type: none"> – The source of the sugars is from fruits or vegetables – The product contains no added sugars defined in standard 2.8.1.1a-f. – The product does not contain any ingredient listed in Standard 2.8.1.1.h-i. – The product contains no more than 31g total sugars per serve. • The intent of point 4 is to prevent the use of highly concentrated juices as sugar supplements whilst still allowing common fruits and fruit products to qualify.
Jenny Robertson Consulting Services (Jenny Robertson & Dan Southee)	Industry - Australia	<ul style="list-style-type: none"> • FSANZ in developing generic ‘one size fits all’ disqualifying criteria have not clearly set out the risks which are intended to be managed by this approach. Attachment 5 suggests that they may include <ul style="list-style-type: none"> – Protection of public health – Over-consumption (and by inference under-consumption) of some foods and nutrients – Food selection consistent with national dietary guidelines – Enforcement and monitoring • Application of a generic one size fits all disqualifying criteria is illogical and fails to recognise the differences between foods and the need for a balanced diet. It would exclude many staple foods from the diet (e.g. milk, dairy, bread, fruits and vegetables etc) and have a negative impact on public health. They also do not take into account the varying needs of different age groups or genders or even different genetic pool requirements or that Australia is a multicultural society. • Recommends that the disqualifying criteria are removed on the basis that: <ul style="list-style-type: none"> • They are not underpinned by good science • They are not in the interests of public health as they exclude staples such as dairy, bread, fruits.
Department of Human Services Victoria	Government – Australia	<ul style="list-style-type: none"> • The draft disqualifying criteria preclude a number of core foods from making nutrition and/or health claims e.g. dairy, some fresh fruits and vegetables, many cuts of meat, nuts, bread and oily fish. The effect would be to promote consumption of highly processed foods above fresh and core foods, which is contrary to national dietary guidelines and government public health policy.

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Department of Human Services Victoria	Government – Australia	<ul style="list-style-type: none"> • The derivation of disqualifying criteria data appears to lack scientific strength and is therefore difficult to support. Proposes that an appropriate working party be set up to establish a robust, scientific set of disqualifying criteria, regardless of the final model selected by FSANZ.. • Proposes two alternative models as follows: <ul style="list-style-type: none"> Total energy would be included in addition to the current disqualifying criteria set by FSANZ. This allows a food to be assessed more completely in terms of total energy contribution and is consistent with current trends and preferences by industry in Australia and the UK. Most core foods would be exempted from this model and recommends that the primary foods closely resemble the NHMRC Dietary Guideline e.g. low fat and unsweetened milk and dairy products, raw and unsalted nuts, trim cut meats, all fruit and vegetables without added sugar or salt, lower sodium varieties of wholegrain breads and cereals. Foods for which a restricted consumption is recommended (i.e. non-core foods which are low in nutrients/high fat/high energy) would be ineligible to make health claims regardless of whether they meet the disqualifying criteria or not. This ensures that health claims are used responsibly. Disqualifying criteria are set for each food product category i.e. similar to NHF’s Tick programme. Disqualifying criteria would consist of upper limits for energy, saturated fat, sodium, sugar and added sugars specific to each food group. Only relevant nutrients and/or energy would be applied to each food category. Examples of some of the food categories in this model (adapted from the NHF Tick programme) include cereal and cereal products, and dairy and alternatives. This model requires more development but would resolve the inequity issues inherent in the current draft proposal between fresh and processed foods and is potentially easier to enforce. The model would also need to consider composite products.
NSW Food Authority	Government – Australia	<ul style="list-style-type: none"> • Disqualifying criteria per serve may give the manufacturer the opportunity to unfairly manipulate the serve size to meet the criteria.
Queensland Health	Government – Australia	<ul style="list-style-type: none"> • A more robust system of disqualifying criteria must be developed with a more clearly understandable scientific basis. The current criteria would allow highly sweetened breakfast cereals, plain sweet biscuits, confectionery and other ‘extra’ foods to make health claims (particularly via voluntary fortification) but not some fresh fruits, low fat fruit yoghurt, low fat high calcium milk, some canned vegetables and legumes and other core foods. • Recommends the following options be considered by FSANZ: <ul style="list-style-type: none"> – Standardised serve sizes rather than manufacturer serve sizes which can be easily manipulated to meet disqualifying criteria. – If standard serve sizes are not used, develop per 100g/100 ml base criteria to ensure consistent application of disqualifying criteria. – A blanket approval be given for some core foods to carry nutrition, health and related claim, particularly fresh fruit and vegetables. – A blanket disqualification for some ‘extra’ foods to carry nutrition, health and related claims, e.g. confectionery,

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Queensland Health	Government – Australia	<p>soft drinks, potato/corn crisps.</p> <ul style="list-style-type: none"> – Separate criteria be developed for each core food group and for ‘extra’ foods. – A calorie/kilo joule criterion be used as a measure of energy density rather than sugar, as energy density is affected by all macronutrients, not just sugar (which has the lowest kJ/g value of all macronutrients). <ul style="list-style-type: none"> • Is happy to work with FSANZ to develop a suitable set of disqualifying criteria. • Recommends that core foods as defined (e.g. fresh fruit and vegetables, fresh seafood, raw unadulterated nuts and dried and fresh legumes) be exempt from the proposed disqualifying criteria.
South Australia Department of Health	Government - Australia	<ul style="list-style-type: none"> • Is concerned that disqualifying criteria as proposed may result in a greater range of health claims on energy dense foods processed foods than on ‘core foods’, thereby encouraging substitution of foods such as dairy, fruit and vegetables, with nutritionally poor convenience foods. • Should aim to exclude foods which are both high in energy density and have poor nutritional value. • Should not exclude whole foods such as nuts, fruits and vegetables, meat and fish, or foods with a good nutritional profile such as milk and cheese. • A list of ‘inclusions’ and ‘exclusions’ using proposed disqualifying criteria should be included in the next round of consultation to give stakeholders a better idea of the realistic outcomes of applying the proposed framework. • Recommends that all fruit and vegetables (including frozen, tinned with no added ingredients) be exempt from the disqualifying criteria. • The use of ‘per serve’ in the disqualifying criteria for fats, sugars and sodium is confusing and scientifically unfounded. Standard serve sizes for each food category need to be established, preferably in conjunction with DAA or other nutrition experts. To leave the determination up to industry in nonsensical, unfair and risks more confusion. International food standards such as the Canadian model could be used.
Consumers’ Institute of New Zealand Inc	Consumers – New Zealand	<ul style="list-style-type: none"> • It is problematic to base disqualifying criteria on serve size as there are no prescribed serve sizes for food and beverages. Food manufacturers will be able to manipulate the recommended serve sizes of their products so they can make claims. • Consideration needs to be given as to how disqualifying criteria will apply to unprocessed versus processed foods. It is essential that core foods, such as milk, fruit and bread are able to make claims.
New Zealand Institute for Crop & Food Research Ltd	Academic and other - New Zealand	<ul style="list-style-type: none"> • Agree with the general disqualifying criteria and consider them necessary.
Obesity Action Coalition	Public Health – New Zealand	<ul style="list-style-type: none"> • Concerned about levels set for disqualifying criteria. These criteria allow inherently unhealthy foods to bear claims and foods which offer good nutrition to be excluded. Separate criteria for different categories of food may be necessary to ensure no inappropriate food is able to bear a health claim. This is more complex for manufacturers but protection of public health is a primary objective of FSANZ.

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Obesity Action Coalition	Public Health – New Zealand	<ul style="list-style-type: none"> Disqualifying criteria must ensure foods like confectionery, alcohol, high fat (especially saturated) and/or sugar foods, very high energy foods, very high salt foods, soft drinks and infant foods cannot bear any sort of claim, including content claims but that staple or core foods can.
Australian Consumers' Association	Consumers - Australia	<ul style="list-style-type: none"> Major concern is the application of nutrient disqualifying criteria. Whilst, the notion of prohibiting some products is well founded, modelling indicates the proposed criteria does not achieve this aim with many core foods disqualified from making health claims (e.g. large serves of some fresh fruits, cheeses and other dairy foods). Provided examples of eligible foods including Uncle Toby's Fruit Roll-up (15.6g) and ineligible foods including 1 green apple being illogical. This is based on FSANZ dietary modelling, DAA modelling and ACA's own assessment. Understand the need for criteria but the fact that unhealthy foods such as biscuits and jam would be eligible is unacceptable. Consider such criteria could contribute to over consumption of unhealthy foods and under consumption of healthier foods. Propose FSANZ consider developing specific disqualifying criteria for different categories of foods and/or some core foods being exempt from meeting the disqualifying criteria. The Dietitians' Association of Australia (DAA) has developed a proposal that identifies seven separate food categories and specific disqualifying criteria for each category. Whilst believe further work needs to be done on this, commend the DAA for its work to date and encourage FSANZ to work with DAA to further develop this concept. Believe this will address the issue of core foods such as fruit, wholegrain bread and dairy products being excluded from making health claims. Believes 'kilojoules' should replace 'sugar' as disqualifying criteria. While sugar is an indicator of energy density there is no distinction between added sugars and the sugars naturally present in fruit and milk. Understand that groups such as the NSW School Canteen Association and the Federation of Canteens in Schools have experienced difficulty when using total sugars as disqualifying criteria. As disqualifying criteria is based on a serve of a product rather than the amount of each nutrient per 100g means sugary products can make health claims. For example, Kellogg's Coco Pops and Uncle Toby's Roll Ups could make health claims due to the small serving size. Whilst FSANZ has undertaken to monitor the situation, ACA does not believe this is sufficient to deter manufacturers from manipulating serving sizes and will not protect consumers from inappropriate claims. The Australian Guide to Healthy Eating establishes a serve of milk as 250ml and a serve of bread as 2 slices. While these serve sizes are not prescribed in regulation they are appropriate serve sizes for optimal nutrition. Manufacturers of core foods will have the scope to manipulate serve sizes as manufacturers of highly processed foods will. If FSANZ continues to recommend disqualifying criteria based on serves of food it must also commit to developing standard serving sizes. ACA supports the development of standard serve sizes to underpin disqualifying criteria. Failing this ACA supports application of disqualifying criteria based on the amount of nutrient 'per 100g', rather than 'per serve'

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Australian Nut Industry Council	Industry - Australia	<ul style="list-style-type: none"> • Do not agree with disqualifying criteria as they affect the ability of many healthy whole foods, such as nuts and some fruits to make general level health claims. • Specifically does not support the criteria for saturated fat as this will disqualify certain types of nuts from making claims. One third a cup of Brazil nuts and macadamia nuts would exceed the disqualifying criteria. This creates a discrepancy between foods promoted by Nuts for Life and by national health eating guidelines and those proposed by FSANZ to have health claims restricted. This is also contrary to FSANZ policy principles to support government, community and industry initiatives that promote healthy food choices. • The ability of some nuts and not others to make health claims may cause confusion among consumers who see claims made on some nut varieties but not others, when nuts as a food group are highly nutritious. • Supports Horticulture Australia's position which does not support the use of generic disqualifying criteria for certain whole foods such as fruit, vegetables and nuts, as certain fruits such as bananas, mangoes and grapes will be unable to meet the total sugar criteria. • If an exemption to the disqualifying criteria for whole foods such as fruit, vegetables and nuts is not acceptable, supports the Dietitians Association of Australia and the National Heart Foundation's suggestions for creating criteria for each food group. Recommends a separate classification be made for 'nuts' (which may also include other healthy high fat but low saturated fat foods such as avocado and olives), as the nutritional profile of nuts does not allow them to fit well into either an oil or a fruit or vegetable group. • The use of criteria suggested by the Dietitians Association of Australia for each food group, where 'nuts' would be classified with oils and spreads, being = 3,700 kJ per 100 g; saturated fat = 20 g per 100g; Sodium = 450mg per 100g, does allow all nuts to make claims. • With new dietary modelling based on different assumptions to those developed by FSANZ, the National Heart Foundation's recommendations changing the disqualifying criteria to 5 grams of saturated fat per serve and 23 grams of sugars per serve will allow all nuts to make claims per 30g serve. • Propose that a definition of whole foods be included in Standard 1.2.7 to enable whole foods that meet the definition to be exempt from complying with the disqualifying criteria outlined in the draft standard. • As fruit and vegetables are currently defined in Standard 2.3.1, consider FSANZ need to develop definitions for other whole foods that may be exempt from the disqualifying criteria.
Fonterra Brands Australia (P&B)	Industry – Australia	<ul style="list-style-type: none"> • Oppose any disqualifying criteria that exclude core food groups such as dairy from making claims. • Proposed criteria would not permit health and nutrition claims on most dairy foods as outlined in the submission by Dairy Australia. • Further work on the suggested disqualifying criteria is required. • Fonterra Brands Australia has many successful consumer brands in the dairy category, such as Brownes Calcium Plus.

Submitter	Group	Comments
Fonterra Brands Australia (P&B)	Industry - Australia	<ul style="list-style-type: none"> • Many of these would not be permitted to carry general level or high level health claims based on the proposed disqualifying criteria. • Further work is required so that these products can stay in the market place.
Nestle Australia Limited and Nestle New Zealand Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> • (section 5.3.2.1) The proposed disqualifying criteria (except for nutrient function claims for vitamins and minerals) are too simplistic. • In some cases, foods that are considered wholesome and recommended for consumption within the Australian Dietary Guidelines, such as milk products, will not be permitted to carry general level health claims. • Foods that are regulated in standard 2.9.3 (formulated supplementary foods) are compositionally based on the made up product for protein, energy and vitamins and minerals. Products within this group, such as MILO and Malted Milk, that are made up with milk will not meet the disqualifying criteria for sugars due to lactose from the milk. Recommend that while these claims about the product would be based on the standard requirements, the disqualifying criteria could be based on the food as sold. • The requirement for general level claims is more stringent than for some of the pre-approved high level claims, for example a general level claim about the culture in a product would not be permitted on a 200g serve of low fat yoghurt with added sugar (sucrose) because of the sugar level, however this product would be able to make a high level claim about osteoporosis. Both claims are acceptable to consumers, It would not make sense to disqualify a yoghurt from claiming about the health benefit calcium provides nor does it make sense to disqualifying that same product from a claim about the health effect of the cultures in it. • Some fruits would not meet the disqualifying criteria. • Some claims are subject to ‘double’ disqualifying criteria. Whole foods must meet the disqualifying criteria as well as being 90% primary foods, meaning milk could claim it is good for you, but sweetened, low fat fruit yoghurt (88% primary food) could not. • Many nutrient function claims will need to be removed from food labels as they are not currently subject to disqualifying criteria. There is no evidence that consumers are currently misled by claims currently appearing on food. • Support AFGC position that the application of national recommendations about the overall diet with respect to saturated fat, salt and sugars to individual foods is inappropriate. • AFGC has a set of principles for serving sizes that its members have agreed to follow. These ensure that serving sizes are not misleading to the consumer. • Note that manipulating serve sizes to ensure disqualifying nutrient targets are met will mean the nutrient that is subject to the claim may not meet the qualifying conditions.

Submitter	Group	Comments
New Zealand Food and Grocery Council (FGC)	Industry – New Zealand	<ul style="list-style-type: none"> • Note that the Policy Guidelines states “the standard may contain disqualifying criteria”, thus they were not to be considered mandatory. • Do not support the inclusion of disqualifying criteria because: <ul style="list-style-type: none"> – Nutritional Content Claims have been in place for many years without disqualifying criteria and have caused no difficulties; – General Level Claims would be treated more stringently than some High Level Claims; – Many products on which claims can currently be made will be precluded from making claims (e.g. cheese, breads, yoghurt and some fruits), which will disadvantage many manufacturers and confuse consumers who find such claims useful. – Consumers will have access to useful information about fat, sugar and salt content via Nutrition Information Panels.. – The ‘Pick the Tick’ Heart Foundation endorsement has not given rise to the concerns that FSANZ is seeking to address by the adoption of disqualifying criteria. – Consumers must be given the choice to determine whether a product containing a claim meets their requirements. – The selection of sugar, fat and salt as disqualifying criteria is questionable. The recommended contribution sugar, saturated fats and salt makes to the diet must be highlighted and conveyed in the context of the total diet. – The scientific evidence about the role of sugars, saturated fats and salt in the diet is complex and contentious which questions the usefulness of providing disqualifying criteria. For example, sodium intake is a biomarker of increased blood pressure, but only in respect of people with hypertension; high intakes of sugar make no greater contribution to weight gain than any other dietary energy source; there is evidence showing that the presence of saturated fat in some products, such as milk and cheese, does not raise cholesterol levels. • If retained, the blanket ‘one size fits all’ approach is unacceptable and flawed. • They unfairly discriminate products carrying claims from products carrying nutritional function claims for vitamins and minerals. • The requirement that the disqualifying criteria and conditions for General Level Claims will apply to claims on whole foods has been controversial and epitomises the difficulty of setting the same generic disqualifying criteria across all categories of food. FSANZ sought to clarify this situation in its Fact Sheets but by stating (20 January) “the proposed upper limit would not apply to the majority of healthy eating claims about fresh fruit” etc only confuses the situation and shows an inconsistency of approach that does not sit well with regulation.

Submitter	Group	Comments
Glycaemic Index Ltd (GIL)	Public Health – Australia	<ul style="list-style-type: none"> Manufacturers’ can manipulate serve sizes and therefore recommends that standard serve sizes be developed in consultation with key stakeholders. Australia and New Zealand would be the only two countries in the world to implement a nutrition and health claim system where standard serve sizes are not legislated. Consideration should be given to the use and extension of the ‘reference quantities’ stipulated in Standard 1.3.2 (Table to clause 3).
Dietitians Association of Australia (DAA)	Public Health – Australia	<ul style="list-style-type: none"> Has conducted modelling for over 9,000 generic (AusNut) and brand name foods for disqualifying criteria. Many nutritious foods will be excluded from making a claim based on criteria for salt (breads and canned legumes) and sugars (e.g. pears, bananas, mangoes). Allow foods such as biscuits, cakes, table sugar, many sugar based confectionery and foods low in sugar but high in total fat and energy, such as butter (small serve size) to make claims.
New Zealand Dietetics Association (NZDA)	Public Health – New Zealand	<ul style="list-style-type: none"> Lists of foods that meet or fail to meet criteria are provide in submission(s) appendices. Lack of specificity in disqualifying criteria is largely due to the fact that the criteria are not based upon food groups. The proposed system is too simplistic, which will create confusion in consumers’ minds. The use of sugar as a disqualifying criterion is not considered appropriate. Page 44 of Appendix 5: “...both total and added sugars both contribute to energy intake, and are digested, absorbed and processed by the body through the same mechanism.” is incorrect and misleading. There are significant differences in the way monosaccharides are digested compared to disaccharides. Some monosaccharides are actively transported across the intestinal lumen while others are passively absorbed. The pentose fructose is metabolized via a different mechanism than hexoses like glucose. The net effect of the differences in digestion, absorption and metabolism of the various sugars can be quantified physiologically by the glycaemic index, as recommended by the World Health Organisation/Food and Agriculture Organisation (Carbohydrates in human nutrition. 1998. Report of a Joint FAO/WHO Expert Consultation. FAO Food and Nutrition Paper – 66.). If any criteria is set for sugar it should be for ‘added’ sugars only as they are ‘empty kilojoules’ and have a greater glycaemic impact. The only disease associated with high sugar consumption independent of energy intake is tooth decay. This should not be the sole rationale for setting a sugar disqualifying criteria, particularly because it is strongly related to frequency of consumption rather than just total amount consumed. From a total energy intake perspective, a disqualifying criterion for kilojoules is the most logical alternative, as energy density is much more strongly correlated with total body weight. DAA does not understand why FSANZ is recommending the use of a surrogate when the causal factor is readily known, and the information is equally available on nutrition panels?

Submitter	Group	Comments
<p>Glycaemic Index Ltd (GIL)</p> <p>Dietitians Association of Australia (DAA)</p> <p>New Zealand Dietetics Association (NZDA)</p>	<p>Public Health – Australia</p> <p>Public Health – Australia</p> <p>Public Health – New Zealand</p>	<ul style="list-style-type: none"> • Has conducted detailed modelling and suggests cut-offs for disqualifying criteria based upon food groups: <ul style="list-style-type: none"> (a) bread and other cereal products (Breakfast cereals, Cakes, Biscuits, Noodles, Pasta, Rice, Savoury biscuits, and Snack foods); <ul style="list-style-type: none"> ≤1600 kJ per 100 g; saturated fat ≤3 g per 100g; Sodium ≤500 mg per 100 g (b) fruit and vegetables (fresh, frozen and pickled) <ul style="list-style-type: none"> ≤1100 kJ per 100 g; saturated fat ≤3 g per 100g; Sodium ≤300mg per 100 g (c) milk, milk products and alternatives (cheese, yoghurts, milk and soy based drinks, etc....with a min of 50% dairy or ingredients); <ul style="list-style-type: none"> Cheese – saturated fat ≤18g per 100 g; Sodium ≤600mg per 100 g; Other milk, milk products and alternatives - ≤500 kJ per 100 g; saturated fat ≤2 g per 100 g; calcium > 100 mg per 100 g. (d) meat, fish, eggs, and legumes (including fresh and processed meat, poultry and seafood, with minimum 50% meat/poultry/seafood); <ul style="list-style-type: none"> ≤800 kJ per 100 g; saturated fat ≤4 g per 100g; Sodium ≤450mg per 100g (e) fats, oils, edible oil spreads, cream, dressings, nuts, seeds and their spreads <ul style="list-style-type: none"> ≤3,700 kJ per 100 g; saturated fat ≤20 g per 100g; Sodium ≤450mg per 100g (f) All other foods (not covered by (a) – (e)) <ul style="list-style-type: none"> ≤1000 kJ per 100 g saturated fat ≤2 g per 100g; Sodium ≤300 mg per 100 g (g) Beverages (cordials, soft drinks, fruit and vegetable juices, and dairy drinks with < 50% dairy) <ul style="list-style-type: none"> ≤ 175 kJ per 100 g; Sodium ≤150mg per 100g • For meal/main dish products: <ul style="list-style-type: none"> ≤800 kJ per 100 g; saturated fat ≤4 g per 100g; Sodium ≤450 mg per 100 g • Detailed modelling suggests that these will not be overly restrictive for food industry, and experience with existing endorsement programmes would suggest that they will promote industry innovation. • DAA would be happy to discuss the rationale and further development/ refinement of these criteria with FSANZ. • Recommends disqualifying criteria set for fibre for the ‘bread and other cereal products’ group. However, due to the breadth of this category modelling, suggested this was not practical. It would be possible to add in specific disqualifying criteria for sub-categories (if deemed practical by FSANZ) within the bread and cereals so that disqualifying criteria for dietary fibre could be set.

Submitter	Group	Comments
Coles Myer Ltd	Industry - Australia	<ul style="list-style-type: none"> • Conducted a nutrition audit of over 300 House brand food products manufactured for CM Supermarkets. Data provided as attachment to submission – results against the proposed standard and particularly qualifying and disqualifying criteria are presented to provide examples of implementation of the proposed draft standard. • Nutrient and current on-pack claims compared against the Claims Classification Framework and qualifying and disqualifying criteria • Conducted a nutrition audit of over 300 House brand food products manufactured for CM Supermarkets. Data provided as attachment to submission – results against the proposed standard and particularly qualifying and disqualifying criteria are presented to provide examples of implementation of the proposed draft standard. • Nutrient and current on-pack claims compared against the Claims Classification Framework and qualifying and disqualifying criteria • Of all current House brand food products that are currently making nutrition claims, 51 products would be unable to continue to make these claims under the new P293 criteria. • Of all the current House brand products that do not currently make nutrition claims, 70 products would be unable to make any nutrition content or health claims under the new P293 criteria.
Unilever Australasia	Industry – Trans Tasman	<ul style="list-style-type: none"> • Where products meet the qualifying criteria for making truthful claims about the content and/or role of foods in the body there should be no requirement for disqualifying criteria. • If disqualifying criteria is the only option, we suggest the fall back position of working with industry to establish a set of criteria. Criteria suggested by FSANZ are advantageous to foods with small serving sizes and disadvantage foods with larger serving sizes. Criteria based on a per serving quantity are better for foods with smaller serving sizes and do not adequately allow for foods with larger serving sizes; Criteria based on a per 100g quantity are better for foods with larger serving sizes and do not adequately allow for foods that may have a higher nutrient density but are consumed in smaller quantities. • Vigorously oppose the disqualifying criteria of ‘claimable foods’ being brought across from the Vitamin and Minerals standard to be used in the Nutrition, Health and Related claims standard to prevent truthful content and other General level health Claims being made about food. • Strongly object to the concept of claimable foods being used as a vehicle to perpetuate an advantage to certain types of foods that are permitted to be fortified over those that are not, in being able to make truthful and substantiated claims about their vitamin and mineral content. • We contend that any food that contains a claimable amount of vitamin and/or mineral content should be able to declare this. • Strenuously oppose the concept of ‘primary foods’ being used as a disqualifying criteria to only allow primary foods to make ‘whole of foods’ claims, where the substantiation for the health claim is based on the whole food. Some examples of foods that would be excluded from making such a claim because of this criterion are: tea, yoghurt, cereal products, and oils.

Submitter	Group	Comments
Unilever Australasia	Industry – Trans Tasman	<ul style="list-style-type: none"> • We therefore strongly recommend that this disqualifying criterion is removed. • We also have major concerns with the criteria for a ‘Low saturated fat’ claim being used as a disqualifier for cholesterol claims (both free and low) Again this is an area where the combination of claims helps to educate consumers. • The final major concern in this area is how the qualifying criteria for a ‘low saturated fat’ claim have been used as the disqualifying criteria for the one high level claim for fat that has been reviewed for introduction with this standard. • To permit this claim only on foods that are intrinsically low in total fat, and therefore low in saturated fat, is not contributing to the education of consumers or helping them to choose products that give them the essential nutrients they require from fat while ensuring that the less healthy fats are minimised. • We therefore also urge consideration of amended criteria for this high level claim in conjunction with a re-consideration of the qualifying criteria for the ‘low saturated fat’ claim.
Go Grains Health and Nutrition Limited supported by George Western Foods Limited/AB Food and Beverages	Industry – Australia	<p>Sodium</p> <ul style="list-style-type: none"> • Disagrees with the proposal to assign one set of disqualifying criteria to all foods. • Specifically, the sodium disqualifying criteria of less than 325mg / serve is unworkable for bread and means that few bread products will be able to make a general level claim. • Sodium is present in bread for essential technical reasons as well as taste, and substantially reducing sodium content can be difficult. History is littered with examples of low salt breads that have been launched and failed due to lack of consumer acceptance. • Specifically, claims will not be possible on Tip Top 700g white, wholemeal and grain breads, which comprise 34% of the total bread category in Australia. This includes the ‘enriched’ category containing Goodman Fielder’s Wonder White and Helgas Breads, Wonder White, Tip Top UP Omega 3 DHA and Tip Top 9 Grains. These breads have a long history in the marketplace and are known by consumers as breads which are a healthier alternative to regular white bread and are recommended by health professionals as nutritious breads for the whole family. • On commencement of the Heart Tick programme George Weston Foods (GWF) worked closely with the Heart Foundation to determine the minimum amount of sodium required to be added to a mainstream bread formulation. 450mg per 100g was the lowest level of sodium that could be achieved whilst still producing a good quality product. • Bakers Delight would not be able to make claims on their white, wholemeal and country grain breads and Goodman Fielder will be disqualified from making claims on various wholemeal and multi-grain loaves. • Taking into account that bread and other cereal foods are currently the leading source of fibre in the Australian diet (NNS 1995), and that fibre intake in Australia is considered to be sub optimal, it would seem counterproductive to prohibit general level claims on bread.

Submitter	Group	Comments
<p>Go Grains Health and Nutrition Limited</p> <p>supported by George Western Foods Limited/AB Food and Beverages</p>	<p>Industry - Australia</p>	<ul style="list-style-type: none"> • Any moves that could lead to reduced intake of bread would not be consistent with public health recommendations including the Dietary Guidelines for Australian Adults -‘Eat plenty of cereals (including breads, rice, pasta and noodles), preferably wholegrain’. • It is possible that consumers will perceive the deletion of claims on familiar brands as an indication that bread is not as healthy as it used to be. • In an environment of declining confidence in the healthiness of high carbohydrate foods like bread (Go Grains research Feb06), regulation that discourages consumption is inconsistent with the dietary guidelines that encourage higher consumption. • Believe that, if disqualifying criteria are required at all, they should be established on a category by category basis. • The criteria proposed for sodium are not commercially achievable for bread and at very least, should be changed to 450mg per serve. <p>Sugar</p> <ul style="list-style-type: none"> • The disqualifying criterion for sugar disadvantages some bread and breakfast cereal products that are made with fruit or dried fruit. • Bakers Delight Apricot Delight products would not meet the sugar disqualifying criteria, however these products contain no added sugar but are made using dried fruits. • Recommends amending the disqualifying criteria for sugar to apply only to ‘added sugars’ using the sugar descriptors specified for a ‘no added sugar’ claim including honey, malt, concentrated fruit juice etc.
<p>George Western Foods Limited and AB Food and Beverages</p>	<p>Industry - Australia</p>	<ul style="list-style-type: none"> • Strongly disagree with the proposal to assign one set of disqualifying criteria to all foods for the purposes of making general level claims. • Are concerned that the ‘one size fits all’ approach takes no account of variation in serving sizes. • Sodium – see comments under Go Grains. <p>Sugars</p> <ul style="list-style-type: none"> • This criterion is very low for products designed to be added to other foods, for example, formulated supplementary foods such as Ovaltine®, where the milk itself contributes significant amounts of (naturally occurring) sugars and the serving size is relatively large (200mL).
<p>Health Promotion Unit, Taranaki District Health Board</p>	<p>Public Health – New Zealand</p>	<ul style="list-style-type: none"> • The new Standard must include disqualifying criteria for general level and high level claims to reduce risk and public confusion of potentially misleading claims. • Have serious concerns about the levels set for disqualifying criteria. • Disqualifying criteria for sugars should be based on added sugars not total sugars, to allow for intrinsic sugars such as in fruits and milk. • Consideration and consultation is needed regarding how disqualifying criteria apply to basis foods compared to processed.

Submitter	Group	Comments
Health Promotion Unit, Taranaki District Health Board	Public Health – New Zealand	<ul style="list-style-type: none"> • It is not in the interests of the public to restrict the use of claims on foods such as milk, fruit and bread when less-healthy processed foods may appear healthier. • Support the approach of establishing separate criteria for different food categories, such as that suggested by the Dietitians Association of Australia. • Are concerned that manufacturers will be able to manipulate the recommended serve sizes so they can make claims. This could result in overeating of less healthy foods, contributing to the obesity epidemic.
Heinz Australia/Heinz Wattie's New Zealand	Industry – Trans Tasman	<ul style="list-style-type: none"> • Recommends FSANZ reconsider nutritional rationale behind current disqualifying criteria or consider disqualifying criteria against 100g/100ml or as a percentage rather than per serve to better represent the overall nutrient profile of a food. • Recommend consideration be given to having specific disqualifying criteria for food categories as suggested by the Dietitians Association of Australia or similar to the National Heart Foundation criteria. • Suggests that the rationale for establishing these values is flawed. • They disqualify many 'primary foods' (Standard 1.3.2) which are supposed to make up the bulk of our diet and tend to have high serving sizes compared to snacks, but permit many non-primary foods such as biscuits, which have a smaller serving size. • Comparisons based on serving sizes misrepresent values of foods when compared across categories. • Appendix D in submission gives a list of their products that are currently considered "claimable foods" but are excluded by the disqualifying criteria. • To progress with the current draft criteria but allow 'exclusions' such as fresh fruit, will not solve the problem. • Regard must be given to national dietary guidelines which in New Zealand encourage consumption of at least 5 serves of fruits and vegetables a day, which may include canned and frozen varieties and juice. Food standards must be consistent with dietary guidelines and no disadvantage recommended foods based on their packaging. • Are concerned because baked beans are classed under the meal category and they meet the disqualifying criteria for the 220g, 420g, and 820g cans, however the 130g can does not meet the meal definition of >175g. This means one of the cans in a range will not be able to bear the health claim. • It would be easier to have set criteria for food categories rather than 'food' or 'meal'. • Having one sodium cut off value for all products is not feasible as sodium also is used for functionally or stability, e.g. preservative.

Submitter	Group	Comments
New Zealand Nutrition Foundation	Public Health – New Zealand	<p>Serve size</p> <ul style="list-style-type: none"> • There is no information defining FSANZ’s concept of a serve, a course in a main meal and a main meal, and no indication of the size of these or how they relate to the disqualifying criteria. • The NZ Nutrition Taskforce (1990), recognising the need for a diversity of foods daily to ensure energy and nutrient adequacy, designated a daily number of servings based on the daily common eating pattern and the daily ingestion of food from each food group but did not propose recommended serve sizes. • It is evident that each food should have its food-specific recommended serve size which is determined by the food group, energy content and, in this case, the current three nutrient contents of the food. • Current serving sizes on packaging have no consistent reference standard. • The energy density, fat content, sugar and salt content can be the reference standard against which serving size can be determined. • Suggested solution is to develop criteria for determining serving size of individual foods taking cognizance of density of energy, fatty acids, total sugars, and sodium limitation, based on the 24 hour intake. <p>Levels of disqualifying criteria</p> <ul style="list-style-type: none"> • There is no evidence given for the derivation of the levels of disqualifying criteria, both for single foods and meals. • The chosen levels would exclude accepted healthy foods such as an apple, pear or other fruit suggesting there is a major flaw in the derivation of the figures. • When determining these values, FSANZ should apply to itself the same criteria of credible evidence that it requires of those applying for a high level claim. • It is difficult to understand the logic of these three nutrient criteria to a single food when most commonly the food will be associated with other foods particularly in a main course or throughout the day when accompanying a meal. Foods eaten together vary in energy and nutrient content, reducing or increasing one or more of the identifiable nutrients.
Nutrition Australia	Public Health – Australia	<ul style="list-style-type: none"> • Has concern for levels set. • Further consideration should be given to unprocessed vs. non-core foods as it is not in keeping with standard dietary advice to restrict the use of claims on core foods such as yoghurt, fruit and bread. • Concerned that foods such as cocoa pops and sponge cake do not meet the disqualifying criteria but other foods such as baked beans and large serves of fruit are disqualified. • Support the approach of establishing separate criteria for different food categories, such as the approach developed by the Dietitians Association of Australia. • Understand that groups such as the NSW School Canteen Association and FOCIS have experienced difficulty when using total sugars as disqualifying criteria. • Further consideration should be given to using energy density rather than total or added sugars.

Submitter	Group	Comments
Nutrition Australia	Public Health - Australia	<ul style="list-style-type: none"> • It is easy to manipulate the serve sizes to avoid meeting disqualifying criteria and the food industry are already manipulating them, for example the serve size for most margarines is 5g but for sterol containing margarines, the serve size is 10g. • Consumers have a poor understanding of serve sizes and do not view them in the same technical way as nutritionists. A serve is what you eat or drink ‘in one go’. • Recommends that FSANZ consult key stakeholders to develop standardised serve sizes, to incorporate into Standard 1.2.7. • A simpler option is to develop disqualifying criteria per 100g rather than per serve. This would stop health claims on energy dense products. • Do not believe that the proposed disqualifying criteria will assist consumers to select foods for healthy diets or protect consumers from misleading claims. The disqualifying criteria have a significant impact on FSANZ’s primary objectives. • Misinformation to consumers will inhibit their capacity to make informed and healthy food choices . • Urge FSANZ to consider the implications of this regulatory system and its potential to encourage consumption of processed non-core foods and to discourage the consumption of the core foods, such as milk, bread and fruits and vegetables. • The job of nutrition educators would be made more difficult if regulations do not support the Healthy Eating Guide and Healthy Living Pyramid. Regulations should underpin public health nutrition objectives.
Public Health Dietitians	Public Health – New Zealand	<ul style="list-style-type: none"> • Has concern for levels set. • Further consideration should be given to unprocessed vs. non-core foods as it is not in keeping with standard dietary advice to restrict the use of claims on core foods such as yoghurt, fruit and bread. • Concerned that foods such as cocoa pops and sponge cake do not meet the disqualifying criteria but other foods such as baked beans and large serves of fruit are disqualified. • Support the establishment of separate criteria for different food categories (like the approach developed by the DAA). • Concerned that manufacturers will be able to manipulate serve sizes and recommends that serve sizes should be developed in consultation with key stakeholders and incorporated into Standard 1.2.7. • Do not believe that the proposed disqualifying criteria will assist consumers to select foods for healthy diets or protect consumers from misleading claims. The disqualifying criteria have a significant impact on FSANZ’s primary objectives. • Misinformation to consumers will inhibit their capacity to make informed and healthy food choices. • Urge FSANZ to consider the implications of this regulatory system and its potential to encourage consumption of processed non-core foods and to discourage the consumption of the core foods, such as milk, bread and fruits and vegetables.

Submitter	Group	Comments
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • The ‘one size fits all’ criteria preclude certain core foods such as milk, fruits and bread from making health claims. • FSANZ has proposed these criteria without evidence of regulatory failure and knowing certain core foods will be eliminated from making such health claims. • Application of a generic ‘one size fits all’ disqualifying criteria is illogical and fails to recognise the differences between foods and the need for a varied, healthy diet. Application of this would exclude many staple foods from making health claims (i.e. milk, dairy foods, bread and fruits – which the Australian Dietary Guidelines encourage because of their nutritional benefits). Furthermore, criteria do not take into account the varying needs of individuals. • The risks have not been substantiated and the proposed management tool not based on rigorous scientific analysis. On their own admission in public meetings around Australia, FSANZ staff have said that the methodology used to develop the proposed values for disqualifying criteria was not scientifically based, rather an ad hoc midpoint between ‘a lot’ and ‘a little’, and a response to the mounting pressure from public health lobbyists. • The rationale and assessment for including sodium, saturated fat, sugars as disqualifying criteria are inconsistent with a ‘whole of diet’ approach to public health recommendations on nutrition and food consumption – and therefore inconsistent with national nutrition policies and broader strategies to improve nutrition outcomes in Australia and New Zealand (i.e. Eat Well Australia; Healthy Weight – 2008). • FSANZ propose the focus for disqualifying criteria should be on the ‘whole’ food. If true, why does the disqualifying criteria relate to certain ‘risk-increasing’ nutrients, only (i.e. total fat, saturated fat, sugar, salt)? The ‘totality’ of the diet, the role of food within the total diet, and the presence of ‘risk-reducing’ nutrients (i.e. dietary fibre, calcium and iron), has not been considered. • FSANZ’s objective is to ensure that food labels with nutrition, health or related claims provide adequate information to the consumer to enable informed food choices. National Foods believes the suggested disqualifying criteria do not achieve this goal and may in fact mislead consumers. • Mandatory nutrition information currently on pack is not fully understood and used by the consumer; the per serve column is often favoured to the 100g column; the 100g column allows consumers to compare between products but this is rarely used – and yet education has been shown to facilitate learning (FSANZ 2003). FSANZ have increased mandatory criteria and labelling instead of first employing education initiatives, which could enhance consumer understanding and choice. • FSANZ claims the criteria provide manufacturer’s an incentive to develop healthier foods. National Foods questions the substantiation to this statement? What is the incentive to the manufacturer, if core foods such as dairy foods, breads, and fruits, are prohibited from making health claims? Manufacturers do respond to consumers needs, and innovate in response to these needs (as opposed to increased regulatory requirements). Minimal regulation that maximises public health and safety will drive product innovation. Innovation is driven by consumer needs. Hence, it could be suggested that consumer education strategies targeting appropriate food selection, are a more effective and encouraging motivator for manufacturers to produce healthier foods.

Submitter	Group	Comments
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • National Foods questions the scientific rigour behind the proposed methodology for disqualifying criteria and the evidence that positive outcomes will result for the consumer. • Provides extensive scientific evidence opposing disqualifying criteria (i.e. questions the scientific rigour behind the proposed methodology and the evidence that positive outcomes with results for the consumer). • National Foods acknowledges that vitamin and mineral nutrition content (and function) claims are widely used by the consumer as a quick, simple reference, to facilitate informed food choice. The nutrition information panel lists nutrients per 100g or per serve for verification, if required. Such claims are consistent with international regulation. • In considering the impact of the disqualifying criteria, National Foods presents a case for white milk – a core-food: <ul style="list-style-type: none"> – Pura regular milk: Pura milk currently claims for certain vitamins and minerals, as well as protein. Under the proposed disqualifying criteria, the protein nutrition content claims will be prohibited, as milk fails the saturated fat criteria. The vitamin and mineral claims can remain on pack at present, although the outcome of reviewing Standard 1.3.2 may require changes in the future. The implications to the consumer are mixed information on pack; the manufacturer incurs packaging and opportune costs; and, there are inconsistent public health messages being delivered. What is the scientific evidence to justify such implications? • National Foods questions FSANZ’s rationale for ‘considering’ disqualifying criteria when FSANZ acknowledge vitamins and minerals as ‘risk-reducing’ nutrients – that can benefit the total diet. • Provides extensive scientific evidence opposing defective evidence base for saturated fat – this criterion has the potential to exclude foods currently carrying substantiated health claims whereby the nutrition content claim is unrelated to saturated fat – e.g. milk, claiming for protein; meat, claim for protein. • Provides extensive scientific evidence opposing defective evidence base for sodium – has potential to exclude foods currently carrying substantiated claims from making them regardless of whether the claim is unrelated to sodium – e.g. baked beans and fibre claims. • Provides extensive scientific evidence opposing defective evidence base for sugar – FSANZ has dismissed the physiological differences between extrinsic and intrinsic sugars – such as those found in milk and fruit. • Recommends that the disqualifying criteria for health claims be removed on the basis that: They are not underpinned by good science They are not in the interests of public health as they exclude staples such as dairy foods, bread and fruit A consumers’ ability to make personal food ‘choices’ has been tampered. • Proposed criterion has the potential to negate consumer’s food choices and dietary habits. FSANZ has focused on the individual nutrients as opposed to the ‘whole of diet’, and has been selective in those critiqued. National Foods sees no evidence of market failure or performance benefits to warrant introduction of such criteria and recommends their removal. • If FSANZ persists with the area of disqualifying criteria, further consultation with affected parties must occur.

Submitter	Group	Comments
Adecron Food Tech Consulting	Industry – New Zealand	<ul style="list-style-type: none"> • Agree with the disqualifier principle as it avoids things such as potentially healthy botanical extracts being added to soft drinks and sugar laden juices. • Agree with the reasoning balance for using per serve/serving, rather than per 100 grams. • Inconsistency between these proposals and Pick the Tick where rather than focusing on sugar levels (as a de facto nutrient density measure) as in P293, the focus is on energy density. For instance, a low fat dairy dessert fails on the disqualifier criteria whilst it currently meets Pick the Tick on fat level and energy density. Who is right? • Disadvantage of energy density is that it is per 100g and does not reflect actual eating habits (as per table 5.3.1). Pick the Tick overcomes this by having different standards for different foods; this would be too descriptive and limiting for encouraging innovation in foods. • On balance, keep the sugars disqualifier and suggest that the Heart Foundation might need to adjust their criteria.
<p>Confectionery Manufacturers of Australasia Supported by CMA NSW Branch CMA Queensland Branch CMA SA Branch CMA Victoria Branch Langdon Ingredients CMA NZ Branch</p> <p>International Confectionery Association</p>	<p>Industry – Australia</p> <p>Industry – New Zealand</p> <p>Industry – International</p>	<ul style="list-style-type: none"> • Recommends that the proposed disqualifying criteria with respect to sugars, saturated fat and sodium be removed and that health claims be permitted on all foods for which a substantiated health claims can be justified. • FSANZ has no evidence to suggest that disqualifying criteria will influence consumption patterns, and therefore the disqualifying criteria are unjustifiable. FSANZ has incorrectly implied that processed foods have a lower nutritional value but there is no evidence of this. • In applying the sugar, saturated fat and sodium disqualifying criteria to confectionery, FSANZ is wrongly applying national recommendations about the overall diet to individual foods. Confectionery, as a treat food has an acknowledged and legitimate place and contribution to a balanced diet and may be legitimate vehicles for the delivery of health benefits which may benefit consumers. • Confectionery makes a small contribution to the overall diet, approximately 2-4% (1). The CMA promote healthy eating of confectionery in the spirit of Australian and New Zealand dietary, healthy eating and nutrition guidelines, accompanied by regular physical activity. • These same disqualifying criteria do not apply to Standard 1.3.2 – Vitamins and Minerals. Some inconsistency exists with respect to the qualifying/disqualifying criteria applied in Standard 1.3.2 and draft Standard 1.2.7 and the types of foods regulators believe are ‘acceptable’ as being suitable for health, vitamin and mineral claims. <p>(1) 1995 National Nutrition Survey</p> <p>Lack of innovation</p> <ul style="list-style-type: none"> • The current proposed disqualifying criteria will exclude most confectionery products from making health type claims thereby restricting innovative opportunities for the confectionery industry. • Reformulating confectionery would potentially achieve compliance with the sodium and saturated fat criteria, however the lactose content would generally exceed the sugars criteria.

Submitter	Group	Comments
<p>Confectionery Manufacturers of Australasia Supported by CMA NSW Branch CMA Queensland Branch CMA SA Branch CMA Victoria Branch Langdon Ingredients CMA NZ Branch</p> <p>International Confectionery Association</p>	<p>Industry – Australia</p> <p>Industry – New Zealand</p> <p>Industry – International</p> <p>Industry – Australia</p>	<ul style="list-style-type: none"> • In responding to the growing obesity concerns, public health policy encourages the food industry, including the confectionery industry, to innovate by offering a wide and varied product range for consumer choice. Prohibiting most health claims on confectionery fails to demonstrate support of the confectionery industry. • It has been well established that the cocoa butter in chocolate does not raise blood cholesterol, despite being two-thirds saturated fat. This is due to the unique properties of stearic acid. From a nutritional perspective 50g, one adult serve, of milk chocolate contributes the following: - 0.75mg iron (about 10% RDI for men and 5% RDI for women), - 0.65mg zinc (about 5% RDI), - 125mg calcium (about 15% of the RDI), - 28mg magnesium (about 10% RDI), - 1.2mg niacin (about 5% RDI), - 0.21mg riboflavin (about 10% RDI), - 0.05mg thiamine (about 5% RDI), - 50mcg vitamin A (about 5% RDI). In addition, confectionery products may also contain other nutritious foods including fruit, nuts and cereals. • Must not be restricted by our traditional perspective of confectionery, recognising that given the opportunity to innovate through increased flexibility in regulation, a new wave of confectionery may emerge. Key to innovation is the ability to communicate characteristics of confectionery products and their potential benefits to the consumer. • Regulation is inhibiting the food industry’s ability to move forward in line with consumer expectations. CocoaVia has been recently launched in the US. This product relies on ingredient and labelling permission not currently available in Australasia. This chocolate product contains phytosterols associated with lowering cholesterol.
<p>National Starch Food Innovation</p> <p>Solae Australia Pty Ltd</p>	<p>Industry – Australia</p>	<ul style="list-style-type: none"> • Believes the proposed generic exclusion criteria set out in Division 2 (Conditions for General Level Claims) is too simplistic and will have the effect of preventing health claims for healthy food items. • E.g. the sugars claim will exclude nutritious foods like bananas and mangos due to their larger size. Likewise, many breads and canned legumes will not be able to make claims due to their moderate sodium levels. • Intention to link the exclusion criteria with serve size is problematic due to lack of standardised serve sizes. • Recommends that a set of disqualifying criteria be established for specific food categories in consultation with industry and key stakeholders and in doing so, establish standardised serve sizes. • Recommends separate criteria be developed in consultation with industry and other stakeholders for the following food categories: <ul style="list-style-type: none"> – Bread and other cereal products (Breakfast cereals, Cakes, Biscuits, Noodles, Pasta, Rice, Savoury biscuits, and Snack foods); – Fruit and vegetables (fresh, frozen and pickled) – Milk and milk products (cheese, yoghurts, milk based drinks, etc); – Meat, fish, eggs, and legumes (including fresh and processed meat, poultry and seafood); – Fats, oils, oil spreads, dressings, nuts and seeds – All other foods (not covered by (a) – (e)) – Beverages (cordials, soft drinks, fruit and vegetable juices, and dairy drinks)

Submitter	Group	Comments
National Starch Food Innovation Solae Australia Pty Ltd	Industry - Australia	Disqualifying criteria would be required for meal/main dish products.
The Omega-3 Centre	Industry - Australia	<ul style="list-style-type: none"> • Arbitrary, generic disqualifying criteria are not relevant to general level health claims and would limit useful consumer information on foods which provide a significant source of a nutrient or other substance. This applies specifically to packaged/advertised food currently highlighting the presence of a significant source of Omega-3 fatty acids. • Examples of products that would be disqualified by making a general level health claim: <ul style="list-style-type: none"> – TipTop Up Omega-3 DHA Wholemeal <ul style="list-style-type: none"> ○ Omega-3 EPA & DHA content: 33mg/serve ○ Disqualifying barrier: 333mg sodium/74 g serve ○ Source of Omega-3, good source of fibre, contains thiamine (mandatory), low in fat & cholesterol – Jalna Pro-Heart Blueberry Yoghurt <ul style="list-style-type: none"> ○ Omega-3 EPA & DHA content: 30mg/serve ○ Disqualifying barrier: 22.2g sugars/200g serve ○ Source of Omega-3, protein, calcium, vitamin A, low in fat – Bertocchi Omega-3 Pure Leg Ham <ul style="list-style-type: none"> ○ Omega-3 EPA & DHA content: 31mg/serve ○ Disqualifying barrier: 1200mg sodium/100g serve ○ Source of Omega-3, good source of protein, low in fat • Many foods contributing positive nutritional value will not be permitted to make general level claims. There is a risk that an arbitrary emphasis on only 'negative' nutrients will distort the diet towards foods of low nutritional value. Concerned that foods which offer an Omega-3 benefit will be prohibited from communicating these benefits and helping to raise consumer awareness and understanding of these important nutrients. • The nutrition information panel informs consumers of saturated fat, total sugars and sodium levels; nutrients that are required on food labels of all packaged foods. Recommends that a requirement for a statement to the effect that the nutrition information panel should be checked for nutrition information to be linked to general level health claims. • National Health & Medical Research Council (NHMRC) recommendations for whole of diet have been inappropriately applied to setting disqualifying criteria for individual foods. Their recommendations took account of the wide variety of food combinations which can be included in such a diet (NHMRC. Dietary Guidelines for Australian Adults. Commonwealth of Australia, 2003).

Submitter	Group	Comments
The Omega-3 Centre	Industry - Australia	<ul style="list-style-type: none"> • The Ministerial Policy for health claims did not specify that disqualifying criteria were required for general level health claims. Strongly recommend that that FSANZ reconsider the need for arbitrary disqualifying criteria based on negative nutritional components which risk skewing the diet. • The Trade Practices Act will cover claims made on food packaging and advertising related to general level claims. It is therefore unnecessary to use arbitrary negative disqualifying criteria to prevent false or misleading representations about food. • Although removal of disqualifying criteria for general level health claims was previously recommended, if criteria are to be retained, then the following changes are recommended: Subclause 5(2)(a)(i)(B) No more than 28% saturated fatty acids and trans fatty acids as a proportion of the total fatty acids content; or No more than 4 g saturated fatty acids and trans fatty acids per serve. Subclause 5(2)(a)(ii) for meal/main dish products (B) (i) No more than 28% saturated fatty acids and trans fatty acids as a proportion of the total fatty acids content; or (ii) No more than 7 g saturated fatty acids and trans fatty acids per serve.
Simplot Australia Pty.Ltd.	Industry - Australia	<ul style="list-style-type: none"> • Is concerned that the disqualifying criteria would exclude claims for nutrients such as protein and omega 3 fatty acids for fresh fish, value added frozen fish fillets and some canned seafood due to either the sodium or saturated fat criteria (examples of foods that fail to meet the proposed disqualifying criteria provided at Appendix 1 of the submission). • Atlantic salmon, barramundi and ocean trout exceed the saturated fat criteria based on a 150 g serving size (uncooked) while other aqua cultured fish contain higher levels of fat than their wild counterparts. Fatty fish are excellent sources of marine omega-3 fatty acids. • Canned seafood exceeds the sodium criteria and some sardine products in vegetable oil exceed the saturated fat criteria and are also good sources of marine omega-3 fatty acids.
Australia Banana Growers' Council Inc.	Industry – Australia	<ul style="list-style-type: none"> • Understands the need for guidelines for processed or modified fruit e.g. canned fruit but cannot understand the need for nutrient (e.g. sugar) guidelines for fresh fruit or vegetables. • All bananas sold in Australia are branded as Australian Bananas. There is no discernable nutritional difference between an unbranded banana and one with a sticker denoting a particular orchard/producer. • There needs to be a clear definition of “branding” e.g. some fruit may have stickers to indicate that the fruit is locally grown or grown in a certain fashion (e.g. organic), or comes from a certain producer. Others will carry the government-endorsed ‘Go for 2&5’ branding. • Notes that in the case of a ‘branded’ banana, its right to carry a health claim changes depending on its degree of ripeness. • Strongly believes that bananas and all fresh fruit should be allowed to make health claims, independent of whether it carries the producer’s name, area, and country of origin or the method of growing.

Submitter	Group	Comments
Australia Banana Growers' Council Inc.	Industry - Australia	<ul style="list-style-type: none"> • Making separate guidelines for branded and unbranded bananas does not make nutritional sense. It will only confuse the consumer and the Standard will be extremely difficult to implement and police. • Believes that the Standard needs to be focussed on the issues it was originally asked to address, namely, spurious and unsubstantiated claims on the labels of processed and value added produce.
Horticulture Australia Ltd (supported by Horticulture Australia Council and SPC Ardmona)	Industry – Australia	<ul style="list-style-type: none"> • Considers that in the case of fruit and vegetables in Australia, serve sizes could be justified using the Australian Guide to Healthy Eating or the ‘Go for 2&5’ campaign criteria. • Under these definitions of a serve, fruits such as apples, grapes, pears, mangoes and bananas would be excluded due to their total sugar content. Similarly, a serve of Brazil nuts and macadamia nuts exceeds the disqualifying criteria for saturated fat yet the overall fatty acid profile and nutrient content is consistent with a healthy diet. Avocados and olives are also affected. This highlights the unintended bias towards manufactured products as manufacturers are able to vary serve sizes in order to make claims. • The proposed generic disqualifying criteria are inappropriate for some food groups, possibly because the method for the derivation of the criteria lacks scientific rigour. The introduction of health claims under the draft standard may lead to a proliferation of claims on nutritionally unsound products, resulting in consumer confusion and possibly deterioration of the national diet. • The general intent of qualifying and disqualifying criteria is largely directed at the packaged and manufacturing product sector. Fruits, vegetable and nuts are largely purchased as whole, fresh product and the consumption of these products is recommended as part of a balanced diet. Even when partly processed, these products do not carry added sugar, added fats or added salt. • The development of qualifying and disqualifying criteria for fruit, vegetables and nuts may cause confusion among consumers who are being provided with a range of whole food, healthy eating messages by government (e.g. the Go for 2&5 campaign). • Accepts that evidence exist for the need to limit foods high in fats and salt, however does not believe there is unanimous support for using total sugars as a disqualifying criteria. The greater problem to public health lies with refined added sugar. A more logical approach would be to use energy density (kJ/g) as a disqualifying criterion, given the concern about ‘empty kilojoules and the increasing prevalence of overweight and obesity. • Recommends that a general exemption from qualifying and disqualifying criteria be allowed for all: <ul style="list-style-type: none"> – Unprocessed fruit, vegetable and nut products; and – Fruit, vegetable and nut products that have undergone a processing treatment that has firstly, not substantially changed the nutritional quality of the food (other than removal of water through drying) and secondly, that has not resulted in any added sugar, salt or fats. • Standard 2.3.1 contains a definition of fruit and vegetables and Standard 1.4.2 further defines and lists individual food commodities and classes. These can be used to determine those products that would be covered under a general exemption.

Submitter	Group	Comments
Horticulture Australia Ltd (supported by Horticulture Australia Council and SPC Ardmona)	Industry – Australia	<ul style="list-style-type: none"> • Products that have undergone a processing treatment that has not substantially changed the state of the food are recognised within Standard 1.3.1, although the definition does not explicitly include drying or canning, which need not change the nutritional benefits of fruit and vegetables. • 100% juice including pulp and without added sugar has similar nutrient content to the whole fruit or vegetable and therefore should be eligible for exemption, whereas sweetened diluted juices would not be eligible. • Supports the alternative option proposed by the Australia Nut Industry Council, which picks up the definition of whole foods defined in the Draft Assessment Report (p60). It also defines fruit and vegetables as per Standard 2.3.1 but includes the caveat that fruit and vegetables include fresh, frozen, canned and dried varieties with no added sugar, salt or fat. • A general exemption for fruit, vegetable and nuts offers the following advantages: <ul style="list-style-type: none"> – Allows these products the opportunity to compete on an equitable footing with processed products and to make health claims that will encourage and reinforce eating habits in line with the Dietary Guidelines for Australians and the Australian Guide to Healthy Eating. – Allows the development of innovative partially processed products and is in keeping with the general intention of the disqualifying criteria – to promote foods that are low in sugar, salt or fat. • If a general exemption is not possible, qualifying and disqualifying criteria specific for fruit, vegetable and nut food categories should be developed in consultation with industry. • Notes the statement made in the FSANZ Fact Sheet ‘Health claims proposal and sugar levels of fruit’ (20 January 2006) which states that the proposed upper limit of sugar would only apply when a general level health claim is linked with a specific company brand of fruit. The horticultural industry is increasingly developing new varieties that are subsequently marketed with their varietal name (e.g. Calypso Mango and Pink Lady Apple). In these examples there is no difference between a particular generic variety of product and the product brand. Under the proposed standard, these companies would be seriously disadvantaged and would hinder future marketing opportunities for branded fruit and vegetable products.
Horticulture New Zealand	Industry – NZ	<ul style="list-style-type: none"> • The current framework is geared towards manufactured processed foods. • Fruit and vegetables need to be exempt from the health claims framework to allow for their unique contribution to the health of New Zealanders. • The benefits of (increased) consumption of fruit and vegetables are well documented and government should support initiatives to encourage New Zealanders to make better food choices, such as including fruit and vegetables. • Government should encourage the fruit and vegetable industry to undertake robust research. Industry will see little point in supporting nutrition research if it is unable to make health claims. • When robust research highlights specific benefits then the industry undertaking the research should be able to present this information to the public e.g. the link between increased consumption of fruit and vegetables and decreased risk

Submitter	Group	Comments
Horticulture New Zealand	Industry - NZ	<p>of, or protection against, forms of cancer, heart disease and obesity.</p> <ul style="list-style-type: none"> • Having to use terms such as ‘lifestyle’ diseases is vague and unacceptable. • Sugar content cannot be considered in isolation – the nutrient density of food products must also be considered.
Murray Goulburn Co-operative Co Ltd	Industry - Australia	<ul style="list-style-type: none"> • Does not support disqualifying criteria as proposed by FSANZ. Provided that a general level claim is truthful and not misleading, disqualifying criteria are not required. The following reasons were provided: <ul style="list-style-type: none"> – Whole of diet recommendations have been inappropriately applied to individual foods. Whole of diet recommendations from the NHMRC took account of the wide variety of food combinations which can be included in such a diet. – Staples such as milk and bread are disqualified from making general level health claims despite their significant contribution to many essential nutrients. – Positive nutritional contributions of individual foods have not been taken into account. An emphasis only on ‘negative’ nutrients may distort the diet towards low nutritional value foods. – The Ministerial Policy did not specify that such disqualifying criteria were required. – ACCC regulations will cover truthful and not misleading requirements for general level claims. • Supports the Dairy Australia submission that if disqualifying criteria re introduced, added sugars should replace a criterion for sugar so that intrinsic sugars found in fruit and dairy products are not included.
National Council of Women of New Zealand	Consumers – New Zealand	<ul style="list-style-type: none"> • Some members expressed concerns regarding the sugar content of fresh fruit, but the committee viewed that fresh fruit is seldom labelled so may not be an issue.
New Zealand Beef and Lamb Marketing Bureau	Industry - New Zealand	<ul style="list-style-type: none"> • The proposed disqualifying criteria will disadvantage certain consumers for whom a ‘healthy’ diet is inappropriate e.g. those who have special or increased dietary needs may not be able to recognise valuable sources of nutrients because foods are excluded due to the saturated fat or sugar content. • The criteria have the potential to exclude foods widely acknowledged as being part of a healthy, balance diet, thus confusing consumers by giving mixed messages.
NSW Department of Health	Government – Australia	<ul style="list-style-type: none"> • Is concerned about the “one size fits all” approach to disqualifying criteria and the use of total sugars as a disqualifying criterion. • Refers to modelling undertaken by the Dietitians Association of Australia indicating that under FSANZ’s approach, many ‘unhealthy’ food products would qualify to make a health claim while many core foods would not. • Endorses the DAA approach to the development of food group nutrient criteria (i.e. kJ/100g, saturated fat g/100g and sodium mg/100g) and encourages FSANZ to work with DAA to further refine this criteria for content, general level and high level claims. • Supports DAA’s use of energy density rather than total sugars for the following reasons: <ul style="list-style-type: none"> – Total sugars is problematic as it disadvantages core foods that are high in intrinsic sugars e.g. fruits, milks and

Submitter	Group	Comments
NSW Department of Health	Government - Australia	<p>their derivatives which are low in glycaemic index.</p> <ul style="list-style-type: none"> - Added sugars contribute to empty kilojoules and need to be limited, however determining the amount of added sugars by independent analysis is problematic. - Using energy density as a disqualifying criterion offers an indirect way of controlling the amount of sugar that can be added to a product. - Energy/100 g is readily available on food labels and be verified independently by laboratory analysis. <ul style="list-style-type: none"> • Recommends that standard serve sizes be developed in consultation with key stakeholders and be incorporated in the Standard, or that the nutrient criteria be based on per 100 g of food.
Public Health Association of Australia	Public Health - Australia	<ul style="list-style-type: none"> • Is concerned about the ‘one size fits all’ approach to disqualifying criteria. Modelling indicates that this does not achieve the aims of the disqualifying criteria with many core foods (e.g. large serves of fruit, cheeses and other dairy foods) disqualified from making health claims and cocoa pops and sponge cake are not disqualified. • Believes FSANZ needs to further consider how disqualifying criteria apply to unprocessed core foods vs. processed non-core foods. • Recommends that standard serve sizes be developed in consultation with key stakeholders and be incorporated in the Standard. Alternatively, disqualifying criteria could be based on per 100g of food rather than per serve to negate the need for standard serve sizes and to prevent some energy dense products from carrying health claims.
Ray Winger Ray Winger	Academic and other – New Zealand Academic and other – New Zealand	<ul style="list-style-type: none"> • What is the scientific justification for incorporating perceived dietary restrictions on foods, or food categories when all modern nutrition is about total diet? An individual item composition, in moderation as part of a balanced diet, should not be regulated as part of this proposed standard. • What is the absolutely minimum requirement for a Standard that meets public health needs and which components of the Standard are an attempt to address perceived ideals of public health, many of which are still under scientific debate? E.g. controlling the level of sodium, fatty acids or carbohydrates in an individual food when we are looking at a total diet. • There is a perception with the Standard of substantial over-regulation and is based on an assumption that there is an ‘average’ consumer but no such ‘person’ exists. Many people consume a lot of salt but have normal blood pressure. It is not essential for every food to have low fat, trans or saturated fat content and some foods with high levels may be consumed as a microscopic part of a total diet. Is it appropriate that these foods should be declined a health claim, either because of their ‘poor’ nutritional content or their microscopic usage? In 5 years time will these micro-details recommended in the Standard be proven wrong, or irresponsible?

Submitter	Group	Comments
5 + A Day United Fresh	Industry-NZ	<ul style="list-style-type: none"> • Cut-off criteria should not apply to fresh fruit and vegetables. • Note the sugar level will preclude many varieties of fruit from making claims. • There is the need to be able to associate specific fruit and vegetables and their phytochemicals with specific health benefits. This will fall outside of dietary advice. • Due to the nature of fruit and vegetables in protection of health request that fruit be excluded from the sugar level criteria. • Request that a specific set of criteria for fresh fruit and vegetables be established. • Criteria for sugar, as currently proposed should only pertain to processed/manufactured foods as at present an all-inclusive approach does not create a level playing field with unprocessed foods. • The fruit and vegetable industry is unable to change their product to manipulate serve sizes or the energy density of serve sizes to meet FSANZ criteria. • Fresh fruit and vegetables provide a natural nutrient rich but low energy food source and confer many scientifically established health benefits • Processed food industry has the ability to produce new foods with phytonutrients with undetermined bioavailability and mode of action, whereas fruit provides a natural source, with bioavailability designed by nature, yet unable to qualify due to sugar content. • Any restriction of the fruit and vegetable industry's ability to make health claims is seen as undermining the work that United Fresh do and is directly in contraction of the New Zealand Governments Healthy Eating-Healthy Action strategy and dietary guidelines. • The Government's report, Nutrition and the Burden of Disease, New Zealand 1997-2011, estimates that 1559 deaths in 1997 per year could be directly attributed to low fruit and vegetable consumption. • the media may run misleading articles on nutrition and health, regardless of their basis in science, and they are as effective in selling as any ad or packaging label. By contrast, industry is limited in what may or may not be said, and even if the science is robust, fruit may be excluded due to its inherent carbohydrate nature.
CSIRO	Government - Australia	<ul style="list-style-type: none"> • 325 mg salt/serve should remain as may encourage manufacturer to reduce weight of slice of bread. • Saturated fat should include trans fat in the 4g as well. • Sugars should increase to 24g as this excludes many fruit juices, which are considered as healthy.
New Zealand Dietetics Association (NZDA)	Public Health – New Zealand	<ul style="list-style-type: none"> • Although agreeing in general with the disqualifying criteria proposed by the Dietitian's Association of Australia, NZDA suggest that for the fresh fruit and vegetables category, in their natural and unaltered state they should be exempt from disqualifying criteria.

Submitter	Group	Comments
Tomox Pty Limited	Public Health – Australia	<ul style="list-style-type: none"> • Qualifying criteria is unnecessarily restrictive to some basic nutritious foods such as milk, dairy and fruit based products (e.g. cheese and full cream milk, flavoured milk, yoghurt, custards). • Based on standard serves for dairy (250ml milk, 40g cheese, 200g yogurt) the criteria exclude: <ul style="list-style-type: none"> – cheese and full cream milk (>4g saturated fatty acids) – flavoured milk, yoghurts, custards (unless artificially sweetened) and some modified low fat milks (>16g sugar). • Although claims for vitamins and mineral are currently exempt, the intent (page 87) suggests these will be brought into line later. This will mean many dairy foods wont be able to make a general level claim for calcium on products for children, but would be able to make a high level claim for calcium and bone density. • In developing the concept of ‘claimable foods’ FSANZ included dairy foods as “foods consistent with healthy eating guidelines”. In Attachment 6, page 127, claimable foods are discussed as having a similar purpose to generic disqualifying criteria, which is clearly not the case. The criteria do not take into account total nutritional contribution of these foods or the whole food effect. • The criteria do not take into account the increasing scientific evidence, for example that (see submission for further examples): <ul style="list-style-type: none"> – Milk drinkers have a reduced risk of cardiovascular disease despite the saturated fat content (Elwood PC et al Eur J Clin Nutr 2004 58, 718-724). – Dairy appears to protect against metabolic syndrome (JAMA 2002 287 201-89) – Dairy intake appears to protect against the development of Type 2 diabetes (Cho, HK et al. Archives of Internal Medicine. 2005;165:997-1003) • The barrier to making general health claims on nutritious dairy foods is counter productive to nutrition education and national nutrition guidelines. This is particularly so in dairy products for children: <ul style="list-style-type: none"> – <i>Parents want these products to be healthy and nutritious so it is common for manufacturers to include claims on the label.</i> – The criterion for total sugars is inconsistent when Dietary Guidelines suggest that “small amounts of sugar can promote the intake of nutritious foods”. – Low calcium intake was the micronutrient most commonly low in the diets of school age children and adolescents in the National Nutrition Survey. – Milk and dairy products contain nutrients essential for dental health. – The Dietary Guidelines suggest that cheese is “a natural product that may provide anti-cariogenic effects and can provide an alternative to high-sugar snacks”. • Milk and dairy products, unlike fruit, are branded products so the impact of the criteria will be greater than on the fruit. • Even whole food claims are restricted (page 60).

Submitter	Group	Comments
Tomox Pty Limited	Public Health - Australia	<ul style="list-style-type: none"> • If the proposed criteria become gazetted there are 4 scenarios: <ol style="list-style-type: none"> 1. The public do not receive information on pack about the nutritional value of milk and dairy products which is inconsistent with healthy eating guides and could impact on intake of calcium and other essential nutrients; 2. The manufacturers could reduce serving size so that a product fits within the criteria, which conflicts with public health serving sizes; 3. Manufacturers will be pushed into using the current endorsement programmes to achieve a nutrition message; 4. There is potential for increased use of artificial sweeteners (of particular concern for phenylketonurics). • <i>There are several potential solutions:</i> <ul style="list-style-type: none"> – The criteria allow core food groups to make health claims; – There could be separate criteria for different food groups. The amber criteria of the NSW school canteen association would be a good starting point; – The criteria for saturated fat be increased say to 6g per serve with lactose and natural fruit sugar excluded from sugars; – If criteria are widened to be needed for nutrient claims then care needs to be taken to avoid loss of innovation for say reduced fat products which may not meet criteria, but could have an adverse effect on nutrient and energy intake (e.g. reduced fat cream, reduced fat pastry products)
Rosemary Stanton	Public Health – Australia	<ul style="list-style-type: none"> • Levels of sodium, saturated fat and total sugars proposed will provide many anomalies. Modelling (Attachment 5, Table 5.3.4) shows some highly nutritious foods are disqualified, e.g. baked beans, some fruits, cheese and milk, while other foods of low nutritional value, high sugar content or low serving size are not captured, e.g. cocoa pops, semi-sweet biscuits – these would be permitted to make claims for any added vitamins/minerals. • This is confusing and potentially misleading, and makes health promotion using the Australian Guide to Healthy Eating, with its long-established five food groups approach, difficult. • Criteria for different categories of food may need to be established. Any group given this task should be overseen by an independent body free from commercial interests, for example if the Dietitian’s Association of Australia would need to be overseen as they have commercial sponsors. • Disqualifying criteria should be applied to ‘added’ sugars. Dietary Guidelines seek to limit intake of added sugars but not the naturally occurring sugars in fruit, milk or yoghurt. P293 needs to be in line with these guidelines. • Consumers frequently seek information about added sugars. Manufacturers know exactly how much added sugars are in the product so there is no problem in restricting disqualifying criteria to added sugars. Unless the nutrition information panel lists added sugars the consumer would not be able to check the veracity of the claim, but then the consumer won’t be able to check any claim. • Realises the quantity of added sugar varies slightly, e.g. ‘pure’ fruit juices many add sugar to adjust for ripeness in the fruit, however it would not be difficult for the disqualifying criteria to accommodate for these products.

Submitter	Group	Comments
Rosemary Stanton	Public Health – Australia	<ul style="list-style-type: none"> Added sugars could include concentrated fruit juices such as de-ionised pear juice, as well as fructose, maltose. Added sugars could be expressed as extrinsic sugars. It is easy to distort the serve sizes to avoid meeting disqualifying criteria. Recommends FSANZ, in consultation with industry and consumer groups, develops standardised serve sizes. An alternative is to develop disqualifying criteria per 100g rather than per serve. This would work against some energy dense products but that would be a good thing, given the rise of overweight/obesity. Consumption of core food rather than highly processed foods should be encouraged. Health claims could encourage consumption of foods that are of general poor nutritional quality but with addition of nutrients. The proposed standard needs to keep in mind the primary objectives of FSANZ.
Campbell Arnott's Asia Pacific	Industry - Australia	<ul style="list-style-type: none"> Recommend removal of disqualifying criteria for all general level health claims. Generic disqualifying criteria will limit useful consumer information on foods that provide a significant source of nutrients or beneficial substances. Many staples will be excluded using these criteria such as dairy, fruit soups and breads. Contend that the disqualifying criteria attempt to apply whole-of-diet measures to individual foods. Pre-prepared soups are good source of vegetables, pulses, grains and meat but would fall outside the specified criterion for sodium. Do not agree that sugar is a risk increasing nutrient and should not be used as a surrogate for energy. Notwithstanding rejection of disqualifying criteria, Clause 5(2)(A)(i) disqualifying criterion of saturated fat should be modified to no more than 28% saturated fatty acids and trans fatty acids as a proportion of the total fatty acids content; or no more than 4g saturated fatty acids and trans fatty acids per serve. Clause 5(2)(A)(ii) disqualifying criterion of saturated fat for meal/main dishes should be modified to no more than 28% saturated fatty acids and trans fatty acids as a proportion of the total fatty acids content; or no more than 7g saturated fatty acids and trans fatty acids per serve.
Rebecca Kendrick (Paraparaumu College)	Consumer – New Zealand	<ul style="list-style-type: none"> Manufacturers should not be allowed to put health claims on other wise unhealthy food product like confectionery and high fat/sugar snacks.
Manufactured Food Database	Government – New Zealand	<ul style="list-style-type: none"> Per 'serve' unit measure. Concerns that serve sizes are currently determined by the manufacturer and therefore open to modification to meet disqualifying criteria. Suggests a guide for standardised serve sizes to address this. <p>Notes international consensus on concern over trans fatty acids effect on LDL cholesterol. Consideration should be given to trans fats in addition to saturated fats as a limitation.</p>
New Zealand Dietetics Association (NZDA)	Public Health – New Zealand	<ul style="list-style-type: none"> Serve sizes should be stated and they should meet per 100g criteria

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Brismark/Brisbane Markets Limited (BML)	Industry – Australia	<ul style="list-style-type: none"> • Serve sizes can be manipulated to suit the criteria. • Standard serve sizes should therefore be developed for manufactured products. • Serve sizes of fruit and vegetables cannot be changed; they are rarely labelled for nutrient content. Consumers do not differentiate between nutrient claims and a general level health claim which could lead to choosing manufactured goods over the natural product • Heavy promotion of fruit and vegetables and a constant government push to keep reminding consumers of the benefits of eating these products is essential, e.g. ‘Go for 2 + 5’. • Branded fresh produce is in danger of being restricted from making health claims if the sugar content is 16 grams or greater in each serve. It could also deter innovative firms from continuing research and development into varieties that they would brand. • Branded fruit and vegetables should be considered in the same light as non-branded produce. • Welcomed the announcement on January 20th 2006 that fresh fruit and vegetables are allowed to have health claims made about them even if their naturally occurring sugar content is higher than maximum requirements. • The FSANZ fact sheet did not clearly define what the size of a serve is so that the 16g sugar content can be calculated and other references such as the media release on 20 January 2006, the Nutrition Panel Calculator, throughout the draft Standard, and the Dietitians Association of Australia recommendations do not clarify this. • It is important to clarify the size of a serve because some branded produce could fall into the upper sugar limit if the serve size calculation was not aligned with FSANZ’s calculations. • Companies are investing in research to produce a new range of fruit that will be known by the name of the product. For example, ‘Honey Gold Pineapples’, ‘Pink Lady Apples’. Future development could be hindered if the new brand names are not to be used in conjunction with a general level health claim. • Branded fruit and vegetables should be considered in the same light as non-branded produce and should be allowed to make health claims.
Coalition for a Healthy Australian Food Supply (CHAFS)	Public Health - Australia	<ul style="list-style-type: none"> • Levels of sodium, saturated fat and total sugars proposed will provide many anomalies. Modelling (Attachment 5, Table 5.3.4) shows some highly nutritious foods are disqualified, e.g. baked beans, some fruits, cheese and milk, while other foods of low nutritional value, high sugar content or low serving size are not captured, e.g. cocoa pops, semi-sweet biscuits – these would be permitted to make claims for any added vitamins/minerals. • This is confusing for consumers to note that the core foods within the five food groups in the Australian Guide to Healthy Eating would be prohibited to carry claims while foods in the non-core category of ‘extras’ could make claims. • Criteria for different categories of food may need to be established (such as that suggested by the Dietitians’ Association of Australia) but this should be overseen by an independent body free from commercial interests. • It is easy to distort the serve sizes to avoid meeting disqualifying criteria and the food industry are already

Submitter	Group	Comments
Coalition for a Healthy Australian Food Supply (CHAFS)	Public Health - Australia	<p>manipulating them, for example the serve size for most margarines is 5g but for sterol containing margarines, the serve size is 10g.</p> <ul style="list-style-type: none"> • Recommends that FSANZ consult with industry, public health, consumer groups and dietitians to develop standardised serve sizes, to incorporate into Standard 1.2.7. • An alternative is to develop disqualifying criteria per 100g rather than per serve. This would stop health claims on energy dense products. • Consumption of core food rather than highly processed foods should be encouraged. The primary objective should be to protect public health and safety, prevent misleading claims and help consumers make appropriate choices, which fit with the recommendations of the Australian Guide to Healthy Eating. Health claims could encourage consumption of foods that are of general poor nutritional quality but with addition of nutrients. Fresh, unpackaged foods could be disadvantaged.
Food Technology Association of Western Australia (FTAWA)	Industry - Australia	<ul style="list-style-type: none"> • Does not support the proposed disqualifying criteria as they are not realistic and practical. • Prevents basic core food products from making health and nutrition claims e.g. dairy, whole milk and yoghurt • Further work necessary on the naturally occurring sugar levels in fruit
Environmental Health Association Australia	Government - Australia	
Cancer Society of New Zealand Inc The Cancer Council of Australia	Public Health – New Zealand Public Health – Australia	<ul style="list-style-type: none"> • Has concern for levels set. • Further consideration should be given to unprocessed vs. non-core foods as it is not in keeping with standard dietary advice to restrict the use of claims on core foods such as yoghurt, fruit and bread. • Concerned that foods such as cocoa pops and sponge cake do not meet the disqualifying criteria but other foods such as baked beans and large serves of fruit are disqualified. • As increasing fruit and vegetable consumption is both a key priority within Healthy Eating Health Action and a key component of the Dietary Guidelines for New Zealand, a system that promotes the consumption of fruit is essential. • Concerned that manufacturers will be able to manipulate serve sizes and recommends that serve sizes should be developed in consultation with key stakeholders and incorporated into Standard 1.2.7. • Current set of disqualifying criteria will encourage food manufacturers to manipulate the nutrient content of foods through the addition of artificial sweeteners and fat substitutes. • Criteria should be established based upon food categories and separate disqualifying criteria adopted for core foods including: bread and other cereal products, fruit and vegetables, milk and milk products, meat, fish, egg and legumes, fats oils spreads, nuts and seeds, beverages and all other foods not covered by these categories, as suggested by the Dietitians Association of Australia. • Do not believe that the proposed disqualifying criteria will assist consumers to select foods for healthy diets or protect consumers from misleading claims. The disqualifying criteria have a significant impact on FSANZ’s primary

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Cancer Society of New Zealand Inc	Public Health – New Zealand	<ul style="list-style-type: none"> objectives. Misinformation to consumers will inhibit their capacity to make informed and healthy food choices. Consumption of core foods needs to be encouraged.
The Cancer Council of Australia	Public Health - Australia	
Food Technology Association of Victoria Inc.	Industry- Australia	<ul style="list-style-type: none"> Concern that certain foods are unable to make a general level claim such as dairy foods- yoghurt and calcium, due to the conditions in clause 5(2) of the draft Standard excluding these on a per serve basis. Revision of rationale is required and the provision for all foods to be able to make permitted claims.
Health Outcomes Team Auckland Regional Public Health Service (ARPHS)	Public Health – New Zealand	<ul style="list-style-type: none"> Energy content of the food per 100g is of much greater value to the consumer and in obesity prevention than the sugar content A sugar criterion also discriminates against foods naturally high in sugars such as fruits. Do not believe that stating the %DI of energy requirement is helpful to the consumer or an appropriate alternative criterion to disqualifying criteria. The absence of specified serve sizes provides an opportunity for manufacturers to manipulate these so as to meet disqualifying criteria All nutrient information should be provided per 100g/ 100ml to allow consumers to easily compare products. The nutrient profile per serve should also be provided but ideally these should be based on official standard serve sizes. Support the adoption of disqualifying criteria outlined in the Dietitians Association of Australia submission, specific to a food group.
Health Outcomes Team Auckland Regional Public Health Service (ARPHS)	Public Health – New Zealand	
The Cancer Society of Australia	Public Health – Australia	<ul style="list-style-type: none"> There are many problems in using total sugars as disqualifying criterion as experienced by other groups using nutrient criteria, e.g. National Heart Foundation, NSW School canteen Association and Federation of Canteens in Schools. Preferred method is energy density rather than total sugars. Expressing disqualifying criteria as per 100g rather than per serve would negate the need to develop standard serve sizes to assist consumers to interpret nutrition information panels. Support that foods making gluten and lactose claims are exempt from the generic disqualifying criteria.
Dairy Australia	Industry- Australia	<ul style="list-style-type: none"> Present criteria would disqualify most dairy foods from making a general level health claim and whole food claim Generally accepted serve sizes are 250ml milk, 200g yogurt or 40g cheese (Australian Dairy Corporation, 1999). Submission provides a table indicating which foods will be disqualified (pg 9). Education regarding calcium intake is built on these serve sizes. Submissions gives details on research that shows that a number of general practitioners and dietitians were aware of these serve sizes.
Fonterra Co-Operative Group Limited	Industry – New Zealand	

Submitter	Group	Comments
<p>Dairy Australia</p> <p>Fonterra Co-Operative Group Limited</p>	<p>Industry-Australia</p> <p>Industry – New Zealand</p>	<ul style="list-style-type: none"> • Many fruits and most stone fruits will be disqualified from making general level health claims yet some types of chips will qualify (see table 2, pg 10 of submission). • Believe the Standard has failed in regards to a “a suitable nutrient profile’ (pg 25). This illustrates the inadequacy of the present disqualifying criteria. • There will be dietary distortion if the main food groups do not have a comparable opportunity to make health claims, this should be taken into account in determining criteria. Dairy consumption is likely to be adversely affected by the proposed standard as consumption of foods making health claims will increased and consumption of these not making claims will decline. • This is inconsistent with National Dietary Guidelines. Preventing calcium rich dairy foods from making general level health claims will not meet the Policy guideline aim ‘to allow claims in order to achieve public health benefits’ or Section 10 of the FSANZ Act ‘the protection of public health and safety. • Welcome the efforts outlined in the FSANZ fact sheet to work with industry regarding the disqualifying criteria. • In relation to sugars as a disqualifying criterion there will be increased pressure from the food industry to use artificial sweeteners. Recommends a detailed risk analysis be undertaken into the effects of a large increase in the use of artificial sweeteners, particularly the effects on young children. • Notes the Roy Morgan Research Report Consumption of Intense Sweeteners (2003) which gives further weight to the need for risk assessment in young adults and children. • Questions the science on which disqualifying criteria has been set; cut off points set do not appear to be evidence based. It appears the ‘Rules of thumb’ methodology was not intended to be used in developing disqualifying criteria. • The cut-off points for ‘a lot’ (25%) and ‘a little’ (3%) of a daily intake appear quite arbitrary and further adjustments were made depending on how many foods fell into a category. It is questionable how FSANZ arrived at the chosen 14% midpoint. • In the UK experience fibre was also considered – not only risk-increasing nutrients.
<p>Dairy Australia</p> <p>Fonterra Co-Operative Group Limited</p>	<p>Industry-Australia</p> <p>Industry – New Zealand</p>	<ul style="list-style-type: none"> • Suggests a nutrient quality scoring system to set criteria for specific food categories. Categories are meant as foods listed in standard food composition tables. This would be a more holistic approach considering all nutrients not just the absence of problematic ones but also the presence of beneficial nutrients. • Nutrient quality scores (explained on page 13) should be used to determine which food categories are eligible to make general level health claims (e.g. food categories with a score of at least 1). (‘categories’ means the foods listed in standard food composition tables, not individual products/brands, e.g. doughnuts, potato crisps, wholemeal bread, whole milk). • In order for food manufacturers and enforcers to determine whether or not a food fits into a certain category that is permitted to make general level health claims, FSANZ should set bench marks for that category.

Submitter	Group	Comments
Dairy Australia Fonterra Co-Operative Group Limited	Industry-Australia Industry – New Zealand	<ul style="list-style-type: none"> • More information is provided in the submission on rationale and calculations for of nutrient quality scores (page 13 – 17). • If current disqualifying criteria are kept then further refinements are needed specifically around regular fat dairy foods which are more than just saturated fat as they contain a whole package of nutrients. There is evidence to support this (see page 17) (references provided). • If the saturated fat disqualifier criteria is kept then certain food categories should be exempt if there is good scientific evidence to support that the saturated fat present does not cause an increased in blood cholesterol levels. • Recommends that all unflavoured milk, yoghurt and cheese should be permitted to make claims under any proposed approach. • If the present disqualifier criteria remain then it should be for added sugars not total sugars. • Lactose naturally present in milk and yoghurt should not be included in the sugar disqualifying criteria. • Submission includes an attachment ‘Calculation of nutrient quantity where added sugar is used rather than total sugars’ which includes nutrient values for various foods. • Evidence relating to a particular food matrix (as outlined on P. 28 Attachment 8) should be applied to the evidence supporting the disqualifying criteria. For example, as cheese does not raise cholesterol, its saturated fat content should not disqualify it from making health claims.
Food Products Association (FPA)	Industry-International	<ul style="list-style-type: none"> • Prohibitive criteria are contrary to the basic principles in nutrition that there are no ‘good’ or ‘bad’ foods just ‘good’ and ‘bad’ diets. The requirement that claims be stated within the context of total diet reinforces that principle. Dietary guidance in the US, EU and Australia supports this. • Advocate that these nutrient levels should not constitute prohibition against claims but should trigger statements that disclose the nutrient of interest and direct consumers to the nutrition label for further information e.g. a high level claim which exceeds saturated fat content should have a disclosure statement “see nutrition information for more information about saturated fat” content in proximity to the claim (see FDA requirement 21 CFR 101.13(h)). • Many nutritious foods such as fruit juices, dairy, meat products would not be able to make claims. • In the US nether intrinsic or added sugars are disqualifying criteria; and the sodium level is set at 480mg per serve. • Recently the FDA determined that a more restrictive level for sodium would constrain product development and formulation of food and beverages related to sodium content. • Encourages FSANZ to consider the FDA determination for nutrition and health claims to facilitate product development.
Growcom	Industry-Australia	<ul style="list-style-type: none"> • Concerned that the proposed Standard does not allow claims on goods with sugar contents greater than 16g/serve • This has caused pandemonium amongst the horticulture industry as many Queensland fruit and vegetables contain sugars levels of 16g/serve or above e.g. pineapples, apples, pears, grapes and sweet potatoes. • This standard will negatively impact on many Queensland growers.

Submitter	Group	Comments
Growcom	Industry-Australia	<ul style="list-style-type: none"> • Fresh fruit and vegetables are a natural source of sugar and should be exempt from this proposed standard. • Appears to be no benefit behind introducing this standard to fresh fruit and vegetables. • The promotion of fruit and vegetables is promoted nationally for a healthy diet, with government programs promoting this through the media. • Would create confusion amongst consumers, negatively impacting upon the industry and the broader objectives of increasing fruit and vegetable consumption. • Important that FSANZ partake in ongoing engagement with industry and stakeholders to ensure the standard works for industry and the community.
HortResearch	Academic and other – New Zealand	<ul style="list-style-type: none"> • Per serve must be defined as there are several international definitions which will allow different interpretations • The final definition adopted must be appropriate to whole foods such as fruit and vegetables which are usually consumed as a unit e.g. an apple • If ‘per serve’ is left undefined there is room for ambiguity. Food and Agriculture Organisation defines a serve of fruit and vegetables as 85g; the New Zealand Ministry of health also gives example of serve sizes in their Food and Nutrition Guidelines for Health Adults; United States Drug Administration states that “ products come in defined , discrete units ...are normally listed as the number of whole units that most closely approximates the reference amount e.g. 2 medium kiwi fruit; the 5 + A Day Program specifies ‘one medium fruit’ • Recommend for whole foods such as apples and pears that the serving corresponds to a discrete unit, if sold in the whole form. • Disqualifying criteria of total sugars less than or equal to 16g/serve does not take into account the nutrient density in the food product • Criteria would exclude most apples, pears, and some other fruit from any health claim if a serve is defined as 1 medium fruit, because some cultivars are high in total sugars and 1 piece of fruit can be larger than 1 serve if a serve is defined on weight basis • Commercially an average apple is 180g per fruit with average 13% sugar content (range 13%-15 % at consumption). Apples have a wide spread of weights (80-300g per apple). Submission includes a graph of brix levels compared to weights of apple. The sugar criteria would exclude many apples. • Cultivars can differ widely. It is unclear how the beneficial health content of one cultivar against another can be established if it is not based around disease. • Recommends an exemption for whole fruit and vegetables, based on the definition of whole foods – ‘fruit or vegetables that are sold to be substantially eaten in their whole form’.

Submitter	Group	Comments
Kellogg (Aust.) Pty Ltd	Industry-Australia	<ul style="list-style-type: none"> • Does not support disqualifying nutrients for general level health claims; disqualifying criteria should only be applied if there is scientific evidence to support their inclusion based on the claim being made. All foods should be able to accurately and fully describe their substantiated claimed benefits. • Note that all food products are required to carry a nutrition information panel which provides full information about nutrients and ingredients etc. Suggests that inclusion of % Daily Intake information may do more than disqualifying criteria to provide consumers with information about foods which contribute to their overall intake • FSANZ has not demonstrated that disqualifying criteria will meet the desired outcome of providing consumers with the correct information to make informed dietary choices
Cadbury Schweppes Pty Ltd	Industry - Trans Tasman	<ul style="list-style-type: none"> • (Note – submission had this information under the heading ‘qualifying criteria’). • Do not support the use of qualifying criteria as it unnecessarily restricts claims to those foods which FSANZ have deemed to be ‘healthy foods’ rather than looking of diet as a whole • Believe Cadbury Schweppes products can play a part in a balanced diet even though the ability to make health claims on their products is limited under this proposal. • The Draft infers that processed foods are less healthy then unprocessed foods yet in remote areas there is a stronger reliance on processed foods. Processed foods may rely on fortification to restore nutrients lost in processing but these foods are no less suitable in a balanced diet. • Foods such as cheese would be unable to meet the criteria yet cheese is a claimable food so able to make vitamin and mineral claims. Cheddar cheese contains more fat and saturated fat than most milk chocolate and would exceed the saturated fat criteria (4 g per serve) in a 25g reference quantity.
<p>Australian Food and Grocery Council</p> <p>(Supported by Nestle Australia Ltd and Nestle NZ Ltd, Unilever Australasia, George Western Foods Limited/AB Food and Beverages, Simplot Australia Pty Ltd)</p>	Industry, Australia	<ul style="list-style-type: none"> • Disagrees with rationale for proposing to maintain a separate set of disqualifying criteria for vitamins and minerals based on the outmoded concepts of claimable foods and primary foods. • The origins of this provision predate the current Food Standards Code whose revision was undertaken to minimise prescriptive regulation and to move, where possible to outcome based regulation. At the time of revising the Food Standards Code, FSANZ noted that the Vitamins and Minerals Standard 1.3.2 required updating, but this has not occurred and it remains unmodified. • The AFGC recommends the removal of any restrictions on substantiated health claims for vitamins and minerals in line with our recommendation that no disqualifying criteria apply to substantiated health claims unrelated to vitamins and minerals. • Rejects the use of disqualifying criteria for foods wishing to make biologically active substance claims.

Submitter	Group	Comments
<p>Australian Food and Grocery Council</p> <p>(Supported by Nestle Australia Ltd and Nestle NZ Ltd, Unilever Australasia, George Western Foods Limited/AB Food and Beverages, Simplot Australia Pty Ltd)</p>	<p>Industry, Australia</p>	<ul style="list-style-type: none"> • From the legitimate policy objectives, the AFGC concludes that the risks FSANZ are intending to address by this regulatory measure for foods carrying health claims are: <ul style="list-style-type: none"> protection of public health; not promoting irresponsible food consumption patterns; inconsistency with policies relating to nutrition and health promotion; and failure to monitor and enforce the regulation. • The measure chosen by FSANZ to address these risks is to prohibit health claims on foods that fail to meet certain criteria for salt, sugar and saturated fat composition. The AFGC considers FSANZ have erred in their argument by applying national recommendations about the overall diet with respect to salt, sugar and saturated fat to individual foods. • The AFGC considers that, without resort to further restriction, existing measures would address the policy issues and (FSANZ identified) risks, e.g.: <ul style="list-style-type: none"> – The nutrition information panel contains all relevant information for salt, saturated fat and sugars, thus protecting public health, providing for ease of enforcement and monitoring. – The AFGC has previously addressed the issue of promoting irresponsible food consumption patterns by reference to the heart Foundation ‘Tick program’ which has evidence that the ‘tick’ promotes sensible consumption patterns, without over consumption. – There is no inconsistency with national policy which is about diets, not foods, in promoting a substantiated health benefit about a food which has full disclosure of its nutritional profile in the nutrition information panel. • The AFGC recommends that disqualifying criteria are removed and that health claims be permitted on all foods for which a substantiated health claim can be made. This does not conflict with Ministerial Council advice which provides FSANZ with the option of permitting claims without using disqualifying criteria, when the Council states, ‘Claims can be made providing the eligibility criteria, including qualifying and/or disqualifying criteria...are complied with’ • FSANZ have not used sound science in developing the values proposed. • The effect of the ‘one size fits all’ approach is to exclude staples like bread, fruit and dairy from making health claims. The AFGC considers that this does not benefit public health, as it is inconsistent with FSANZ section 10 objective: the protection of public health and safety. • Commends FSANZ in its reasoning for not requiring foods under Standard 2.9.2 and foods with gluten and lactose claims from being required to meet generic disqualifying criteria. • However, as pointed out earlier, FSANZ reasoning for requiring any disqualifying criteria for products carrying substantiated health claims was faulty and not based on sound science.

Submitter	Group	Comments
<p>Australian Food and Grocery Council</p> <p>(Supported by Nestle Australia Ltd and Nestle NZ Ltd, Unilever Australasia, George Western Foods Limited/AB Food and Beverages, Simplot Australia Pty Ltd)</p>	<p>Industry - Australia</p>	<ul style="list-style-type: none"> • FSANZ suggests that the evidence to support inclusion of sugar as a disqualifying criterion is: <ul style="list-style-type: none"> – strong evidence for the role of sugar in the aetiology of dental caries; – inappropriately high intakes of sugar may displace other nutrients from the diet; – it is also noted that high levels of sugar[s] intake contribute to weight gain, overweight and obesity, as does any excess dietary energy; and – intake recommendations...Australian consumption of 15-20% of energy as sugars is not incompatible with a healthy diet, however consumptiongreater than this could lead to undesirable decrease in nutrient density of the diet....New Zealand...added sugars should be no more than 15% of total energy, due to potential problem associated with excess energy and dental caries. • The AFGC dismisses the observation regarding sugars and overweight, as does FSANZ by acknowledging that it is no more contributory than any other dietary energy source. • The AFGC dismisses the observation regarding displacement as it is not evidence based and applies equally to any other macronutrient consumed in inappropriately high amounts. • The AFGC concludes from this that managing the risk of dental caries by disqualifying certain foods containing sugars from making substantiated health claims unrelated to dental health is an inappropriate and ineffective regulatory measure. • The AFGC recommends that the sugar disqualifying criterion is removed and that health claims be permitted on all foods for which a substantiated health claim can be made. • FSANZ suggests that the evidence to support inclusion of saturated fat as a disqualifying criterion is: <ul style="list-style-type: none"> – intake recommendations...Australian dietary guidelines to limit saturated fat intake [as it] is the strongest dietary determinant of plasma low density lipoprotein cholesterol which is the most strongly established of the diet-influenced risk factors [for] CHD...New Zealand guidelines ..prepare foods or choose pre-prepared foods, drinks or snacks with minimal added fat, especially saturated fat. • FSANZ then bases its exclusion criterion for individual foods on the median saturated fat intake (12% of daily energy from saturated fat) from population surveys of total daily intake in Australia and New Zealand. The AFGC accepts the scientific evidence that links total dietary saturated fat intake to the levels of the biomarker for heart disease risk, low density lipoprotein cholesterol, but rejects the one size fits all solution of <4g/serve proposed by FSANZ because: <ul style="list-style-type: none"> this will exclude foods currently carrying substantiated claims delivering benefits unrelated to saturated fat; and applies a whole of diet recommendation to individual foods. • The AFGC recommends that the saturated fat disqualifying criterion is removed and that health claims be permitted on all foods for which a substantiated health claim can be made.

Submitter	Group	Comments
<p>Australian Food and Grocery Council</p> <p>(Supported by Nestle Australia Ltd and Nestle NZ Ltd, Unilever Australasia, George Western Foods Limited/AB Food and Beverages, Simplot Australia Pty Ltd)</p>	<p>Industry - Australia</p>	<ul style="list-style-type: none"> • In the event that FSANZ continues to recommend the use of a disqualifying criterion for saturated fat the AFGC recommends that an alternative be considered: • the food contains as a proportion of the total fatty acids content, no more than 28% saturated and trans fatty acids. • FSANZ suggests that the evidence to support inclusion of sodium as a disqualifying criterion is: <ul style="list-style-type: none"> – intake recommendations: choose foods low in salt and....well accepted scientific evidence that a reduction in dietary sodium intake will decrease the mean population blood pressure and reduce the prevalence of hypertension. • The AFGC accepts the scientific evidence that links sodium intake to the biomarker of raised blood pressure in those with hypertension, but rejects the one size fits all solution of <325mg/serve proposed by FSANZ because: <ul style="list-style-type: none"> – this will exclude foods currently carrying substantiated claims delivering benefits unrelated to salt; and – applies a whole of diet recommendation to individual foods. • The AFGC recommends that the sodium disqualifying criterion is removed and that health claims be permitted on all foods for which a substantiated health claim can be made. • The AFGC has demonstrated through sound science that: <ul style="list-style-type: none"> – disqualifying criteria are inappropriate measures to manage the imagined risks to public health of foods carrying substantiated health claims; and – there is no evidence of market failure that would require such a measure; and – the “one size fits all” approach excludes foods such as dairy, fruit and bread from making substantiated claims. • None the less, there will remain a perception that permitting substantiated health claims on foods may in some way fail to deliver the benefits claimed in foods that contain (FSANZ defined) ‘risk increasing’ nutrients. The AFGC proposes the following options: <ul style="list-style-type: none"> – No disqualifying criteria – AFGC recommended position. – Disqualifying criteria varied by category. • The AFGC recommends that FSANZ undertake further work to explore the use of category specific disqualifying criteria, should they reject the simpler sound science based AFGC endorsed alternative of removing disqualifying criteria. • The AFGC stands ready to assist FSANZ in exploring any alternative sound science based criteria that deliver an outcome commensurate with Ministerial guidance of regulatory decisions being made commensurate with risk. • In exploring this alternative the AFGC recommends that FSANZ only use the evidence based disqualifiers of saturated fat and sodium, removing sugars from consideration for reasons explained in their submission (above).

Submitter	Group	Comments
Sanitarium Health Food Company	Industry – Trans-Tasman	<ul style="list-style-type: none"> • Believe the intent behind the criteria, that is the prevention of unhealthy foods from bearing health claims, is commendable however the current approach where one set of criteria is to be applied to all foods creates a number of issues and irregularities. These are: • A number of foods encouraged for consumption as part of Australian and New Zealand dietary guidelines (1, 2) do not meet the criteria e.g. some breads, dairy milk, flavoured yoghurts, cheeses. Notes, FSANZ’s objective of being “consistent with...Australian and New Zealand national policies and legislation including those relating to nutrition and health...” Under the proposed criteria, many nutrient-poor foods, such as cakes, biscuits, table sugar and salty snack foods would still be able to bear health claims. • Foods containing naturally-present sugars from dairy and fruit ingredients are disadvantaged by the criteria possibly encouraging the increased use of intense sweeteners by food manufacturers. 1. NHMRC, 2003. Food for Health: Dietary Guidelines for Australian Adults. AGPS, Canberra. 2. Ministry of Health, 2003. Food & Nutrition Guidelines for Healthy Adults: A Background Paper. Ministry of Health, Wellington. • Some foods require higher levels of sodium for food safety reasons (e.g. chilled vegetarian meals products) and other technical reasons (e.g. bread). These nutritious foods could be seen as unhealthy by consumers if they are disqualified from bearing general level health claims. • In keeping with Australian and New Zealand dietary guidelines, added sugar is more relevant to include as part of the criteria than total sugars. This is further supported by the 2002 Joint FAO/WHO report on diet and chronic disease (3), which recommends limiting added sugar on the basis that it provides significant energy without accompanying nutrients as well, and it’s likely promotion of positive energy balance. Added sugars criteria would be difficult to enforce unless added sugars were required to be added to nutrition panels. There are many aspects of the Code that are difficult for enforcement agencies to monitor based on reviewing packaging information only, such as percentage labelling. • Some food groups may have other relevant criteria, which should be considered as part of the disqualifying criteria. For example, fibre should be considered for inclusion in criteria for grain-based products, in keeping with Australian and New Zealand dietary guidelines which prefer wholegrain cereals; • The application of the disqualifying criteria to foods on a per serve rather than a per 100g / mL basis disadvantages foods typically consumed in larger serve sizes, and provides advantage to those eaten in smaller serve sizes. This could result in manufacturers manipulating serve sizes of foods to unrealistic amounts in order to be eligible for general level health claims. 3. WHO, 2002. Joint FAO/WHO Expert Consultation on Diet, Nutrition & the Prevention of Chronic Disease. Geneva: Switzerland • Has concerns with the methodology used to develop the numerical limits, which are not scientifically based. • The cost impact of introducing the proposed disqualifying criteria on manufacturers is likely to be significant. It is

Submitter	Group	Comments
Sanitarium Health Food Company	Industry – Trans-Tasman	<p>possible that in many cases, manufacturers will investigate reformulating products to overcome the disqualifying criteria.</p> <p>Recommendations</p> <ul style="list-style-type: none"> • Recommends that the requirement for disqualifying criteria be removed from the Standard, relying on existing regulatory measures, such as the Trade Practices Act, proposed content criteria requirements and current mandatory nutrition labelling to help ensure consumers are not misled. An additional measure could be mandatory highlighting of sodium, saturated fat, sugars and energy on nutrition panels for all products. • Or if disqualifying criteria are regarded as essential by FSANZ and the Ministerial Council, recommends that the proposed criteria are ‘relaxed’ to ensure staple foods staple foods, such as breads, dairy products and fruits are not disqualified from bearing health claims. This is a precautionary approach rather than an evidence-based approach, in that criteria are set to exclude many ‘treat’ foods, such as salty snacks, soft drinks and confectionery, from being able to bear health claims. Recommend criteria be based on added sugars rather than total sugars to prevent more nutrient-dense foods, such as dairy and fruit products, from being penalised for their natural sugar content and thus, prevent sugary nutrient-poor foods from bearing claims.
Sanitarium Health Food Company	Industry – Trans-Tasman	<ul style="list-style-type: none"> • Suggests the following revised disqualifying criteria per serve: Sodium: 400mg (allows bread while still precluding many salty snacks) Saturated fat: 6g (allows regular dairy milk) Added sugars: 10g (based on current criteria for folate health claims. It still precludes most regular size chocolate bars, soft drinks and confectionery) For meals / main dish products, they must contain no more than: Sodium: 900mg (based on Heart Tick criteria) Saturated fat: 7g (same as currently proposed) Added Sugar: 10g (based on current criteria for folate health claims.) • Dietary modelling to determine the likely effects the revised criteria will have is recommended. • If the disqualifying criteria requirements are removed, it is recommended that research specifically examining the impact of allowing general level health claims on all foods be conducted as part of the planned review 2 years after the commencement of the Standard.
Kraft Foods Ltd	Industry – Australia	<ul style="list-style-type: none"> • Do not see the benefit to the consumer of regulating disqualifying criteria. Notes that the generic disqualifying criteria are not applied to gluten and lactose claims due to diet difficulties in certain parts of the population. There should not be any disqualifying criteria as there are many in the population with other sensitivities. As long as claims are made which are truthful, then consumers can consider those claims along with any other issues they might have to come up with a diet appropriate to themselves. • Understand that there is concern that claims will be made on inappropriate foods and that there is concern about obesity. However, from experience consider consumers shy away from foods which make inappropriate claims and do not believe that disqualifying criteria will contribute anything to the resolution. • Consider the marketplace to be brutal about claims that are not relevant and inappropriate. Kraft fortified processed cheese with calcium in the marketplace did not increase consumer consumption despite all the concern about osteoporosis. In fact market share went down. Considers there are better ways of tackling these problems which major

Submitter	Group	Comments
Kraft Foods Ltd	Industry - Australia	<p>players in the industry would be happy to discuss.</p> <ul style="list-style-type: none"> • Notes that Kraft Foods have set out internal criteria for which foods cannot make a claim. This is based on what the marketplace would see as being reasonable. Believe that setting these criteria will maintain Kraft's image as a responsible manufacturer. Most major manufacturers take similar attitudes. • An issue is that only one set of qualifying criteria are set to be applied to all food, based on the assumption that all food contains average values of nutrients. This is obviously not correct, which is why a varied diet is always recommended. • These criteria are not in line with the principle of a minimal regulation, and there is no evidence of market failure. Where there may be failure is a person not eating a diet suitable for themselves rather than what food is available in the marketplace.
Meat and Livestock Australia	Industry – Australia	<ul style="list-style-type: none"> • The generic disqualifying criteria for general level health claims were made for the diet as a whole and do not consider food categories. • Does not support the disqualifying criteria for saturated fat which is based on per serve. In relation to red meat, there is no standard serve size. Therefore claims can be misleading to consumers who may have different ideas around what constitutes a serve of red meat. For MLA's marketing purposes, 1 serve of red meat is 150g. • The Dietitians Association of Australia (DAA) modelled the proposed generic disqualifying criteria on a database of over 9,000 generic (AusNut) and brand-name foods. Because the generic criteria is based on serve sizes, this will allow foods low in sugar, yet high in total fat and kilojoules, like butter, to make claims, because of their small serve size. • On the other hand, the saturated fat criteria would exclude several cuts of lean red meat because of its larger serve size. • The Smart Foods Centre, at Wollongong University, in collaboration with the Australian Government Analytical Laboratory and RMIT University conducted a retail survey of popular cuts of raw and cooked beef, lamb and veal. Nutrient composition data was developed for different cuts of lean red meat (defined as containing 10g or less total fat per 100g). Using this data which has been approved by FSANZ for use in the NUTTAB 05 database, a number of cuts of lean red meat would be excluded from making nutrition, health or related claims because they contain more than 4g of saturated fat per 150g serve. However if the disqualifying criterion was based on per 100g this would help to overcome any confusion as it is more specific, having a reference value. This would result in all cuts of lean red meat being able to make nutrition, health or related claims. • Being able to make claims for lean red meat helps the consumer differentiate between lean cuts of red meat e.g. lean beef mince (7% total fat; 2.6% saturated fat) and fattier cuts of red meat e.g. hamburger mince (16% total fat; 6% saturated fat).

Submitter	Group	Comments
Meat and Livestock Australia	Industry – Australia	<ul style="list-style-type: none"> • Recommends that FSANZ either make exceptions for lean red meat with regard to the saturated fat disqualifying criteria or modify the disqualifying criteria for saturated fat to 4g/100g for the following reasons: • FSANZ has made special exceptions for fruits with regard to disqualifying criteria for sugar. It was proposed that the disqualifying criteria for sugar would not apply to the majority of healthy eating claims about fresh fruit including: General dietary advice such as ‘eat 5 serves of vegetables and 2 of fruit each day’ or ‘eat at least five servings per day; at least 3 servings of vegetables and at least 2 servings of fruits’. Specific advice about a fruit or type of fruit such as ‘a healthy diet should include bananas’. General level health claims about a fruit or type of fruit such as ‘bananas are a good source of fibre which assists digestive health’. Vitamin or mineral claims about fruit such as ‘oranges are a good source of vitamin C’. MLA recommends that FSANZ take a similar view for all fresh, whole foods, including lean red meat. • Lean red meat is relatively low in saturated fat with the main sources of saturated fat coming from fast foods, snack foods, oils, spreads, other processed foods and the visible fat of meat (Li et al (2005)). The upper limit for saturated fat (4g/serve) is quite low, particularly when lean red meat has not been found to be a major contributor in the Australian diet. • Lean red meat is recommended in the dietary guidelines. The Australian Guide to Healthy Eating (1998) and nationally agreed dietary guidelines (2003) recommend that we should “Enjoy lean red meat three or four times each week” as part of a healthy and balanced diet. • Lean red meat provides many vital nutrients, including protein, omega-3s, iron, zinc, and vitamin B12 unlike processed foods. However, lean meat cannot make claims about these under the proposed disqualifying criteria. • Protein: Lean red meat is a good source of high quality, highly digestible protein. Protein is essential for the normal metabolic growth, repair and maintenance of cells in the body and can also be used as a source of energy (Williamson 2005). There are 23 amino acids, 8 are called ‘essential amino acids’ which humans must obtain through their diet. Animal protein like red meat provides all of these essential amino acids. • Omega-3s: Australian lean beef, lamb and veal are all sources of omega-3s. A recent survey shows red meat makes a significant contribution to the diet of the Australian population providing almost 30% of dietary omega-3s (Howe 2005). Omega-3s are important for heart health and play a key role in brain function (Dietary Guidelines for Australian Adults - 2003). • Iron: Lean red meat is one of the best sources of bioavailable iron. Iron helps to transport oxygen around the body, supports the immune system and helps produce energy from food (Dietary Guidelines for Australian Adults - 2003). • Zinc: Lean red meat is a good source of zinc and the zinc in red meat is highly bioavailable. Zinc has a number of functions in the body. It plays a major role in metabolic processes such as protein synthesis. It is also involved in immune function and cell growth and repair (Dietary Guidelines for Australian Adults - 2003).

Submitter	Group	Comments
Meat and Livestock Australia	Industry - Australia	<ul style="list-style-type: none"> • Vitamin B12: Lean red meat is a good source of vitamin B12. Vitamin B12 is predominantly found in animal products therefore vegetarians often lack this vitamin which is important to health and wellbeing. Vitamin B12, in particular helps to maintain a healthy nervous system (Dietary Guidelines for Australian Adults - 2003). • Recommendations are in line with AFGC, DAA and Heart Foundation views. • AFGC do not support the disqualifying criteria as a whole and recommend “the disqualifying criteria are removed and that health claims be permitted on all foods for which a substantiated health claim can be made.” In addition, with respect to saturated fat, AFGC recommend “the saturated fat disqualifying criterion is removed and that health claims be permitted on all foods for which a substantiated health claim can be made.” • DAA also do not support the disqualifying criteria recommending that “separate criteria are developed for food groups”. This cut-offs were based on dietary modelling conducted by DAA. They recommended the cut-offs for meat, fish, eggs and legumes (including fresh and processed meat, poultry and seafood with minimum 50% meat/poultry/seafood) should be: Energy \leq 800kJ per 100g; Saturated fat \leq 4g per 100g; Sodium \leq 450mg per 100g • The Heart Foundation (2005) in their tick criteria for red meat recommends no more than 4g saturated fat/100g. • Howe, P., Meyer, B., Record S and Baghurst, K. (2005) ‘Dietary intake of long chain omega-3 polyunsaturated fatty acids: contribution of meat sources’. Nutrition, vol. 11 (Epub ahead of print). • Williamson, C.S., Foster, R.K., Stanner and Buttriss, J.L. (2005), ‘Red meat in the diet’, Nutrition Bulletin, vol. 30, pp. 323-355.
National Centre of Excellence in Functional Foods	Academic & Other - Australia	<ul style="list-style-type: none"> • Considers the use of the disqualifying criteria runs the risk of being ‘anti-innovative’ and this risk is unlikely to outweigh perceived benefits. The benefits (reduced confusion in food choice) appear to be based on an assumption that core group classification is straightforward, unproblematic and unchanging, which is not the case. • Foods could be developed to maximise nutritional value to the benefit of the consumer. In addition, different ethnic cuisines place different emphases on different foods to meet nutritional requirements in a whole of diet model. With these changes taking place, nutrition education becomes an even greater imperative for the population and has to remain relevant to contemporary society. • Recommend that FSANZ reconsider the proposed disqualifying criteria and include a requirement for nutrition education in a whole of diet model to support claims.

Submitter	Group	Comments
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • Inconsistent approach throughout report to ‘healthy diet’ versus ‘healthy foods’ versus ‘healthy components’ within foods. Public health principles should relate to the ‘whole of diet’ rather than condemnation of some foods as unhealthy because they may contain specific nutrients and others because they are ‘processed’. • Inference that ‘processed foods’ are unhealthy is indicative of a naïve approach to a nutritious food supply for highly urbanised societies.
Community and Public Health, Canterbury District Health Board	Public Health – New Zealand	<ul style="list-style-type: none"> • Proposal relies on the use of serving sizes for disqualifying and other criteria but does not differentiate between food groups. This is of serious concern from a public health perspective.

**Proposal P293 Nutrition, Health and Related Claims
Summary of submissions to the Draft Assessment Report**

14. WEIGHT LOSS & MAINTENANCE CLAIMS

Submitter	Group	Comments
Dairy Farmers Group	Industry - Australia	<ul style="list-style-type: none"> • The restriction of this claim to only foods meeting the requirement for ‘low joule foods’ is seen as excessive and restrictive on innovation and future new products. • At a limit of 80kJ per 100mL even skim milk (148kJ per 100mL) would fail to qualify for its benefits towards a weight loss/maintenance diet. • Recommend this clause should refer to ‘reduced joule’ rather than ‘low joule’ and hence foods would need to comply with the conditions for making both a reduced joule claim and a low fat claim.
Community and Public Health, Canterbury District Health Board	Public Health – New Zealand	<ul style="list-style-type: none"> • ‘Weight loss or maintenance’ in table to clause 12 should be changed to ‘weight maintenance’. The food item itself is unlikely to contribute to weight loss.
Australian Fruit Juice Association (AFJA)	Industry - Australia	<ul style="list-style-type: none"> • Disagree with the proposed criteria as it will encourage poor food choices by consumers. • Questions why introduce the ‘low joule’ criteria. • Foods/beverages which will comply include such products as diet jam, diet soft drinks, diet cordials which are all nutrient poor.
Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry – Australia	<ul style="list-style-type: none"> • Understand that weight management is a sensitive area due to historically there being numerous products on the market making false, misleading and exaggerated claims. However, do not agree that the restrictions proposed will prevent this from occurring. • Submits this should be managed through effective monitoring of claims to ensure they are substantiated and not misleading. • Discriminating against whole foods based on selective properties does not make nutritional sense and will unfairly impact the dairy industry. • Strongly opposed to the qualifying criteria where foods must be low calorie/joule/energy to make, as it actually excludes skimmed milk and many other dairy foods. • This infers that dairy products such as skimmed milk are not suitable when dealing with weight management. However, scientific evidence is emerging supporting the role in dairy and weight management (refer to Attachment 2 to submission - Science Supporting the Dairy-Weight Management Connection, Dairy Management Incorporated,

Submitter	Group	Comments
Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry - Australia	<p>2005).</p> <ul style="list-style-type: none"> • This demonstrates that there are continually new advancements in research and development regarding existing or novel foods and their health benefits in the weight management area. If credible scientific evidence exists that a food can provide weight management benefits, the industry should be free to make claims in a truthful manner. The public is also entitled to be educated on this health concern, especially as weight problems are a serious health issue of increasing pertinence. • The issue of satiety needs to be considered alongside energy levels. Proteins and available carbohydrates have similar energy value, but differing effects on satiety, which directly relates to overeating and weight maintenance. Support the ability to make balanced satiety and fat burning type claims encouraging a weight controlled diet. • The proposed insertion of “combined with regular exercise” is considered as restrictive for marketing health benefits while being unnecessary and ineffective for consumers (see more detail under general level health claim – wording conditions). • See also attachment 4 to submission – Science supporting the dairy weight management connection
National Heart Foundation of Australia National Heart Foundation of New Zealand	Public Health – Australia Public Health - New Zealand	<ul style="list-style-type: none"> • Definition in Division 1 excludes ‘overweight’ so general level health claims will be permitted which reference overweight. Would be useful to have guidance on what would be classified as a weight maintenance claim versus a statement that references overweight without specifically making a claim linking the food with weight maintenance. • Recommends that for weight management the focus should be on the energy density of food and kilo joule intake, rather than on the reduction in fat intake alone. Fat is not the only determinant of energy density.
Parmalat Australia Ltd	Industry, Australia	<ul style="list-style-type: none"> • Opposes restrictions that will be imposed on a number of dairy products that currently constitute an important part of a weight management program through requiring food to meet the qualifying criteria of low calorie/joule/energy. • Recommends that the requirement for qualifying criteria of ‘low calorie/joule/energy’ for weight management claims be deleted. Other conditions applicable to weight management claims would seem to provide sufficient information to the consumer to provide an informed choice for those on weight management programs.
Department of Human Services Victoria	Government – Australia	<ul style="list-style-type: none"> • Suggests that weight management claims must have a recommended number of serves per day to assist consumers understanding that weight management should be understood in the context of a whole diet. • A proactive education campaign should accompany the introduction of the Standard to address weight management claims to prevent consumers from making inappropriate food choices. • Is also concerned with the distinction between overweight and obesity in the draft Standard. Overweight is normally defined as a biomarker for obesity, therefore recommends that where a food uses the word ‘obesity’ or ‘overweight’, the claim is considered to be a high level claim. All other weight management claims would be considered as general level claims.

Submitter	Group	Comments
Queensland Health	Government – Australia	<ul style="list-style-type: none"> • Should not be permitted given that some core foods such as fruit will not meet the low energy criteria. • Such claims likely to perpetuate the misconception that special foods are required to lose/maintain weight.
South Australia Department of Health	Government - Australia	<ul style="list-style-type: none"> • Should not be permitted as no one food can reasonably be expected to contribute to weight loss. • Considers that reduced or low energy content claims are okay where there is no reference to weight management. • If weight loss claims are permitted, proposes that they be considered as high level claims where reference to overweight (biomarker) or obesity (serious disease) is made and would need to substantiate the specific link between consumption and weight loss. Anticipates that a suitable level of evidence may be difficult to achieve. • Suggests that the Canadian model may be acceptable, which allows representation of foods for use in achieving a ‘healthy body weight’. • Notes that under the proposed disqualifying criteria, many fruits would not be able to make a weight management claim, which supports the recommendation that fruits and vegetables should be exempt from disqualifying criteria.
New Zealand Institute for Crop & Food Research Ltd	Academic and Other - New Zealand	<ul style="list-style-type: none"> • Support the view that weight management claims should be investigated in the same way as other diet-disease relationships. • In relation to a general level claim, support the criteria (5.5.7) and note that it is not sufficient to claim ‘low energy’ content alone to justify a weight management claim, as the evidence is weak. Other criteria, such as the need for regular exercise, are also required in support of the claim.
Obesity Action Coalition	Public Health – New Zealand	<ul style="list-style-type: none"> • Should be a prohibition on foods claiming to have weight reducing qualities or to be ‘slimming’ since no food can assist with weight reduction. Such a claim is misleading. Weight control is attributable to multiple factors. • Believes all claims regarding overweight or obesity should be treated as high level claims. Overweight should be the biomarker for obesity which should be classified as a serious disease.
Australian Consumers’ Association	Consumers - Australia	<ul style="list-style-type: none"> • Oppose the use of weight management or ‘slimming’ claims. • Even though the example given on page 58 of the DAR places the claim in the context of the total diet, it is inappropriate to make a weight management claim in relation to a specific product. It is the overall diet and lifestyle that is vital to weight management. Allowing weight management claims could potentially overstate the role of individual foods in weight management. • While not in support of the use of weight management claims, would like to add that the term ‘kilojoules’ would be better understood by consumers. Energy has a broader connotation and can apply to a person’s overall wellbeing.
Australian Nut Industry Council	Industry – Australia	<ul style="list-style-type: none"> • Does not support the conditions that allow only ‘diet’ foods to make general level claims about weight loss or weight maintenance. Many consumers would be familiar with “diet” foods containing artificial sweeteners and may mistake all ‘diet’ foods for foods containing artificial sweeteners. • Foods high in protein and fibre offer benefits from delayed digestion which has implications for managing hunger and reducing total food intake and hence kilojoules consumed. Therefore, nutritious foods other than ‘diet’ foods

Submitter	Group	Comments
Australian Nut Industry Council	Industry - Australia	<p>(such as nuts which contain protein and fibre) are suitable for balanced weight loss or for maintaining weight.</p> <ul style="list-style-type: none"> • Weight loss/maintenance only on ‘diet’ products may mislead consumers in believing they need to eat such foods to lose weight. • There are several studies that indicate nuts can be included in kilo joule controlled weight loss diets without promoting weight gain ^{1, 2}. • Believes claims about weight loss should be permitted for “whole foods” in particular fruit and vegetables, including nuts. • Recommends the conditions for making weight maintenance claims be changed to enable foods to make such claims in the context of a balanced diet and a healthy lifestyle that includes exercise. <p>¹ Wien MA, Sabate JM, Ikle DN, Cole SE, Kandeel FR. Almonds vs complex carbohydrates in a weight reduction program. International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity 2003;27(11):1365-72.</p> <p>² Fraser GE, Bennett HW, Jaceldo KB, Sabate J. Effect on body weight of a free 76 Kilojoule (320 calorie) daily supplement of almonds for six months. Journal of the American College of Nutrition 2002;21(3):275-83.</p>
Nestle Australia Limited and Nestle New Zealand Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> • It seems unrealistic that only foods that meet the requirements for a ‘low joule’ claim will be permitted to carry weight management claims, as foods that are considered relevant in weight management would be prohibited from making such a claim. • There will not be many foods that will be able to claim they are helpful with weight management (diet soft drink, diet cordials, diet jellies, diet jams and water). • Consumption of only low joule foods is not appropriate dietary advice for weight management and would be deficient in many essential nutrients. • Foods such as diet yoghurt would not meet the criteria. • Foods with low GI and foods that are high in protein can play a part in weight management. Section 5.5.4 mentions that ‘significant attention has been paid to GI as a result of its connection with weight control’. • Where substantiated, these claims should be permitted and should not be based on such a restrictive energy level.
New Zealand Food and Grocery Council (FGC)	Industry – New Zealand	<ul style="list-style-type: none"> • Recognise controversy but submit that such claims have a valuable role to play in providing useful information to consumers. • Such claims will have increasing importance as manufacturers implement initiatives to address the obesity problem. • The robust regulatory system that is being proposed and effective enforcement should address the concerns that are frequently raised in respect of weight management claims. • Disagree with the qualifying criterion of ‘low calorie/dual energy’. This will preclude many products that have a

Submitter	Group	Comments
New Zealand Food and Grocery Council (FGC)	Industry – New Zealand	useful role to play in weight management from making weight management claims. It will severely limit the range of products that can make the claim resulting in poorer health outcomes.
Go Grains Health and Nutrition Limited supported by George Western Foods Limited/AB Food and Beverages	Industry - Australia	<ul style="list-style-type: none"> • Do not agree that weight loss and weight management claims should be restricted to those foods that comply with the conditions for making a low joule claim. • Many grain-based foods, including bread, can contribute to a healthy balanced diet suitable for weight loss/maintenance but do not meet the ‘low joule’ criteria. • Oats and other wholegrain and high fibre foods provide satiety benefits and high fibre benefits relevant to weight management. It may therefore be misleading to consumers to see weight claims exclusively on ‘diet’ products.
George Western Foods Limited and AB Food and Beverages	Industry - Australia	<ul style="list-style-type: none"> • The draft proposal's suggestion that weight management claims should only be made in relation to foods that are low joule is unscientific. • Foods can assist weight management through other means, such as satiety. • Many grain based foods, including bread, can contribute to a healthy balanced diet suitable for weight loss/maintenance but do not meet the ‘low joule’ criteria. • To restrict the claim to low joule foods only places incorrect emphasis on individual foods and insufficient emphasis on the total diet and food intake. • The low joule requirement should be omitted.
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • National Foods submits that weight management and weight loss claims offers the food industry the opportunity to support government initiatives in tackling the public health issue of rising obesity. They provide information to consumers to enable informed choice and assist with positive dietary changes. • Weight management and weight loss claims offer incentives to food industry to pursue R&D innovation to achieve the Healthy Weight 2008 strategy outcomes and to communicate these benefits to interested consumers. • National Foods raises great concerns with the proposed weight management and weight loss criteria, and the negative implications it may have on consumers attempting to manage their weight. • The proposed criteria would permit only a select number of foods, namely empty calorie, nutrient-poor foods such as diet soft drinks, diet jams and water, from making weight management or weight loss claims. Fruits and vegetables, low fat dairy foods, whole meal breads and cereals, and lean meats, would fail to meet the criteria. • In recognising the need for some qualifying criteria, National Foods proposes two options: Option 1: <ul style="list-style-type: none"> – Weight management claims: all foods that align with National Nutrition Policies and Guidelines be allowed to make weight management claims. This includes core foods such as fruits, vegetables, wholegrain breads and cereals, lean meats and alternatives, and reduced and low fat dairy foods. – Weight loss claims: a revised energy criterion is considered.

Submitter	Group	Comments
National Foods Ltd	Industry, Australia	<p>Option 2:</p> <ul style="list-style-type: none"> – weight management claims: the energy criterion for ‘reduced’ is adopted, i.e. ‘25% energy reduction compared to the reference food’ – weight loss claims: the energy criterion for ‘low’ is adopted, i.e. <70KJ/100ml for a liquid, <180KJ/100g for a food <ul style="list-style-type: none"> • Provides data to illustrate this. • National Foods recommends the qualifying criteria for weight management and weight loss claims be revised, and aligned with the claimed benefit. National Foods recommends that all foods that align with National Nutrition Policies and Guidelines should be able to make substantiated weight management claims.
Adecron Food Tech Consulting	Industry – New Zealand	<ul style="list-style-type: none"> • The weight management claims regime is too restrictive with permissions only for low Joule/energy products. Artificially sweetened healthy non-fat dairy products would not be permitted although they have good dietary protein/mineral contributions, minimal fat/saturated fat and low levels of naturally present lactose. • The regime only seems to allow for those nutritionally ‘empty’ artificially sweetened, coloured lolly waters that are not a ‘food group’ that gives satiety and nutrition. • More realistic if the promotion of weight sensible eating includes a second tier disqualifier, with more stringent requirements to give real food guidance for dieters. For example, maybe relating to ratio’s and/or levels of %DI values and/or energy density. • Maybe here use of the old/current reference quantities and prescribed values as used in the vitamin/mineral regime could work for food categories, but then what about protein, saturated fats, sugars and energy? Perhaps a system like the Pick the Tick? • Diet cola is not a food that dieters should have to rely on – this is the wrong track to take and requires more thought.
Horticulture Australia Ltd (supported by Horticulture Australia Council and SPC Ardmona)	Industry - Australia	<ul style="list-style-type: none"> • Does not support only allowing ‘low energy’ foods to make general level claims about weight loss or weight maintenance. Some common fruit and all nuts would not qualify as low energy foods under the proposed criteria. • The proposed approach disadvantages nutritious foods that can contribute to weight maintenance as part of a kilo joule controlled diet. For example, nuts contain fibre and protein and therefore promote satiety, assist in weight maintenance and promote good nutrition. • Recommends that weight management claims not be permitted. If permitted, they should provide guidelines on how many serves/day of that food category are permitted (as in Australian Guide to Healthy Eating) in the context of a balanced diet and healthy lifestyle that includes exercise.
Murray Goulburn Co-operative Co Ltd	Industry – Australia	<ul style="list-style-type: none"> • Recommends that weight maintenance and management claims must be useful, truthful and not misleading and should not be limited to low joule foods. The following reasons were provided: <ul style="list-style-type: none"> – A low joule claim can only be made on a very narrow range of foods and drinks. People aiming to lose weight

Submitter	Group	Comments
Murray Goulburn Co-operative Co Ltd	Industry - Australia	<p>or to manage their weight need a wide variety of foods in the context of an overall appropriate energy intake and physical activity. Information on packaging or associated material of any food can legitimately provide useful advice on weight maintenance and/or management by placing the food in an appropriate regime.</p> <ul style="list-style-type: none"> – In the context of increasing overweight and obesity in Australia and New Zealand, FSANZ should be encouraging useful, truthful and not misleading information to assist individuals make eating and physical activity choices. – The evidence base for the CSIRO Total Wellbeing Diet indicates the wide range of foods which can be combined to assist in healthy weight loss and maintenance. – FSANZ should ensure that the new Standard does not encourage overuse of low kilojoule foods and drinks to the detriment of nutritional status.
New Zealand Dietetics Association (NZDA)	Public Health – New Zealand	<ul style="list-style-type: none"> • Weight loss, slimming and other similar terms should not be used as a benefit. No single food or beverage can successfully do this.
Campbell Arnott's Asia Pacific	Industry- Australia	<ul style="list-style-type: none"> • Should be amended to remove reference to only low joule foods • Prevents a range of other core foods from making claims such as cereals, fruit, vegetables, meat and dairy products. • Additional statement that the specific health effect be considered in context of the whole diet and regular exercise.
Glycaemic Index Ltd (GIL) Dietitians Association of Australia (DAA)	Public Health - Australia	<ul style="list-style-type: none"> • Does not support the provision of any claims about weight loss. • No single food can safely facilitate weight loss, and by only allowing foods that meet the definition for low joule, consumers will be misled into thinking they need to eat a range of non-core foods that in reality they could successfully manage without. • The criteria for low joule foods prevent most of the core foods that are the important part of a weight loss diet from making such claims. • If there is majority support for this claim then recommends that foods from the core food group categories (a) to (d) as defined in Clause 1 of the draft standard are also able to make weight management claims provided they meet the category specific disqualifying criteria. • Low joule foods and beverages eligible to make weight loss related claims should also meet their category- specific disqualifying criteria for saturated fat and sodium
Tomox Pty Limited	Public Health - Australia	<ul style="list-style-type: none"> • Proposed criteria for weight management claims raises the profile of 'diet' products, which have no nutritional benefit other than promoting the benefits of sensible eating. • Even skim milk (148kJ per 100ml) would not be able to qualify for weight loss claim. • Preferable to allow products that meet "diet" criteria (or reduced joule and low fat) to make weight loss or maintenance claims.

Submitter	Group	Comments
Cancer Society of New Zealand Inc	Public Health – New Zealand	<ul style="list-style-type: none"> Any diet or slimming claims should have to state the importance of physical activity.
The Cancer Council of Australia	Public Health - Australia	
Health Outcomes Team, Auckland Regional Public Health Service (ARPHS)	Public Health – New Zealand	<ul style="list-style-type: none"> Weight loss and slimming claims should not be allowed as no single food or beverage can do this. By only allowing foods that comply with the conditions for a low joule claim, there is potential to mislead consumers into believing they require specialised foods in order to achieve weight loss.
Dairy Australia	Industry-Australia	<ul style="list-style-type: none"> Some excellent foods for dieters will be ineligible to make weight management claims. Skim milk will not be able to make a claim, nor will any foods listed in the Proximate Composition of Australian Dairy Foods (1999), and low fat, low fat and reduced varieties of milk and yoghurt. Weight management claims are too narrowly defined using the low joule criteria proposed. Believes that consumers will be misled by the absence of weight management claims on skim milk as for years it has been regarded as suitable to include in a healthy weight loss diet. Consumers may be misled into thinking that no type of milk is suitable for inclusion in a weight-reducing diet. Should also be alignment between the Standard, weight management claims and products permitted to carry the ‘Weight Watchers’ logo. Suggests that only water and foods from the Australian Guide to Healthy Eating core/main food groups be permitted to carry weight management claims. Also only the lower energy foods within the core main foods should be required to carry weight management claims, for example fresh fruit but not dried fruit or fruit juice.
Fonterra Co-Operative Group Limited	Industry – New Zealand	
Kellogg (Aust.) Pty Ltd	Industry-Australia	<ul style="list-style-type: none"> Supports communication of substantiated weight management claims, including that all claims should be made in the context of the total appropriate diet. Criteria and conditions that have been applied to weight management claims are impractical. The provision that the food must meet the qualifying criteria of a ‘low joule’ food means that virtually no food or drink will qualify Primarily diet soft drinks would be able to make such a claim Foods outlined in the Australian Guide to Healthy Eating should be able to carry weight management claims subject to the claim being contextualised as part of a varied and health diet and regular exercise regime. An additional solution could be that %DI for energy be declared prominently along with a message about the importance of a varied and healthy diet and physical activity in managing weight. This would increase the relevance of the information in the nutrition information panel and help consumers make informed choices.

Submitter	Group	Comments
Coles Myer Ltd	Industry, Australia	<ul style="list-style-type: none"> Strongly supports the permission for and regulation of weight management claims in accordance with the Claims Classification Framework.
<p>Australian Food and Grocery Council</p> <p>(Supported by Nestle Australia Ltd and Nestle NZ Ltd, Unilever Australasia, George Western Foods Limited/AB Food and Beverages, Simplot Australia Pty Ltd)</p>	Industry, Australia	<ul style="list-style-type: none"> Rejects FSANZ proposal to restrict weight management claims to foods meeting the low joule criteria. Rejects FSANZ proposal that the generic disqualifying criteria apply to weight management claims (see GLHC – disqualifying criteria). Rejects FSANZ proposal for %DI energy labelling requirement for foods making weight management claims. Reiterates information provided in IAR submission on slimming claims. To restrict weight maintenance claims to foods that are low joule is harmful to public health and safety, restricts informed choice, and is misleading to the consumer. Consumers choosing only low joule foods for weight maintenance purposes, risk sustained weight loss and poor health outcomes. Recommends that reduced and low energy foods be permitted to make substantiated weight management claims. Notes that any food, providing the information is truthful and not misleading, which can be substantiated in an appropriate context for weight maintenance or management should be permitted to make such claims.
Sanitarium Health Food Company	Industry – Trans-Tasman	<ul style="list-style-type: none"> Does not support the proposed weight loss and weight management claims criteria. Many grain-based foods can contribute to a healthy balanced diet suitable for weight loss and maintenance but do not meet the low joule criteria. Research supports that wholegrains, along with their fibre content, can aid in weight maintenance. There are several factors that may explain the influence of wholegrains on body weight regulation such as promoting satiety (7, 8). The high volume, low-energy density of wholegrain foods can delay the feelings of hunger after a meal and therefore lower levels of kilojoules are consumed during the day (9, 10). In addition, staple foods such as fruits and vegetables that do not meet the low joule criteria, should not be excluded from being able to be promoted as suitable foods for those watching their weight. Recommends removing the requirement to meet the ‘low joule’ food criteria for these types of claims. <p>7 Jacobs DR Jr, Meyer KA, Kushi LH & Folsom AR. Wholegrain intake may reduce the risk of ischemic heart disease death in postmenopausal women: the Iowa Women’s Health Study. American Journal of Clinical Nutrition 68, 248-257.</p> <p>8 Pauline Koh-Banerjee, Eric B. Rimm. Whole grain consumption and weight gain: a review of the epidemiological evidence, potential mechanisms and opportunities for future research. Proceeding of the Nutrition Society (2003), 62, 25-29.</p> <p>9 Slavin, J. Whole grains and human health. Nutrition Research Reviews (2004), 17, 99-110.</p> <p>10 James W. Anderson. Whole grains protect against atherosclerotic cardiovascular disease. Proceedings of the Nutrition Society (2003), 62, 135-142.</p>

Submitter	Group	Comments
Meat and Livestock Australia	Industry - Australia	<ul style="list-style-type: none"> • FSANZ proposes certain criteria and conditions apply to weight management claims that are regulated as general level claims. E.g. the food would need to meet qualifying criteria for a "low calorie" claim. Do not support this particular qualifying criterion, as food is not necessarily 'low calorie' to assist with weight management. For example, low fat protein foods which are not necessarily 'low calorie' will aide satiety (Halton et al, 2004; Crovetti et al, 1997; Poppitt et al, 1998) and have been shown to reduce food intake (Porrini et al, 1997; Weigle et al, 2005; Barkeling et al, 1990) and support weight loss (Nicklos-Richardson et al, 2005; McAuley et al 2005). • A meta-analysis of 50 papers, conducted by Halton et al (2004) evaluated the effect of protein on satiety. The researchers concluded that in the short-term, evidence supports that meals higher in protein tend to increase satiety compared to meals lower in protein, also adding that the evidence shows that higher protein intakes cause a decrease in energy intake at a subsequent meal. <p>References</p> <ul style="list-style-type: none"> • Barkeling B et al (1990) 'Effects of a high protein meal (meat) and a high carbohydrate meal (vegetarian) on satiety measured by automated computerised monitoring of subsequent food intake, motivation to eat and food preferences.' International Journal of Obesity 14: 743-51 • Crovetti R et al (1997) 'The influence of thermic effect of food on satiety' EJCN 52: 482-88. • Halton TL et al (2004) 'The effects of high protein diets on thermogenesis, satiety and weight loss: a critical review' Journal of American College of Nutrition 23(5): 373-85 • McAuley, KA, Smith KJ, Taylor RW, McLay RT, Williams SM, Mann JI (2006). Long-term effects of popular dietary approaches on weight loss and features of insulin resistance. Int J Obes; 30(2): 342-9 • Nickols-Richardson SM et al (2005) 'Perceived hunger is lower and weight loss is greater in overweight premenopausal women consuming a low carbohydrate /high protein vs. high carbohydrate/low protein diet' JADA; 105(9): 1433-7 • Porrini M et al (1997) 'Weight, protein, fat, and timing of preloads affect food intake.' Physiol Behav 62: 563-70 • Weigle DS et al. (2005) A high protein diet induces sustained reductions in appetite, ad libitum caloric intake, and body weight despite compensatory changes in diurnal plasma leptin and ghrelin concentrations.' American Journal of Clinical Nutrition 82: 41-8
National Centre of Excellence in Functional Foods	Academic & Other - Australia	<ul style="list-style-type: none"> • While it is valid to make weight loss claims on foods that comply with the conditions for making low joule claims, it is not necessary to limit weight loss claims to only these foods. It is also important to consider how consumers perceive food attributes in relation to their desire to manage weight. • Recommend foods that contain properties that have a scientifically substantiated influence on appetite control should also be able to make claims related to weight loss or weight maintenance.

**Proposal P293 Nutrition, Health and Related Claims
Summary of submissions to the Draft Assessment Report**

**15. HIGH LEVEL CLAIMS
– EXCLUSIVITY OF CLAIMS
– FURTHER REVIEW AND APPROVAL PROCESS**

EXCLUSIVITY OF CLAIMS

Submitter	Group	Comments
Cadbury Schweppes Pty Ltd	Industry - Trans Tasman	<ul style="list-style-type: none"> Do not believe the proposal will provide industry with much scope for innovation unless the high level claims approval process has a greater degree of commercial confidentiality. Manufacturers will be very reluctant to apply for new high level claims permissions if the process is fully open to public scrutiny and there is no guarantee to exclusive rights to the claims for a defined period. Only where patents are in place will a manufacturer have any exclusivity.
Coalition for a Healthy Australian Food Supply (CHAFS)	Public Health - Australia	<ul style="list-style-type: none"> If the reason for permitting health claims is to benefit public health, CHAFS believes that the more widely the health claim was used, the better. The desire for exclusivity shows that health claims are basically a marketing tool to increase consumption. The FSANZ summary in section 11.3 appears to support the view point that public health benefits could be stifled by exclusivity, which CHAFS agrees with. Suggest that where an application is assessed, participation in the assessment process should include public health and consumer representatives who have no conflict of interest. Such participation should entail a fee being paid for the time of the public health or consumer group representatives. Representations on any assessment panel should be open and transparent.
Australian Consumers' Association	Consumers – Australia	<ul style="list-style-type: none"> Does not support the Food Regulation Standing Committee proposal to remove the requirement for public consultation on applications seeking pre-approval of high-level claims and is concerned about the Food Regulation Ministerial Council endorsing these changes to the FSANZ Act. It is important FSANZ retains an open consultation process that protects consumers and not only commercial interests. An open and transparent process that allows all public health and consumer stakeholders to have input assists in ensuring that FSANZ delivers on its primary objectives. Concerned about transparency in the selection of an expert panel (that will consider applications seeking pre-market approval of high-level health claim) and potential conflicts of interests of panel members.

Submitter	Group	Comments
Australian Consumers' Association	Consumers - Australia	<ul style="list-style-type: none"> Disagrees with the justification provided in the Food Regulation Standing Committee working group discussion papers that health claims are not an issue of public health safety, but only an issue of consumer choice. Health claims are an issue of public health as they have the potential to encourage over consumption of unhealthy foods and under consumption of healthier food choices.
Campbell Arnott's Asia Pacific	Industry-Australia	<ul style="list-style-type: none"> Endorses the proposed approach to management of high level claims, providing the proposed amendments to the FSANZ Act to protect innovation are in place prior to gazettal of the Standard. Essential that submissions on new high level claims be treated in commercial confidence to avoid the 'free rider' effect.
Community and Public Health, Canterbury District Health Board	Public Health – New Zealand	<ul style="list-style-type: none"> Support that claims are made or approved in relation to that food as opposed to a brand.
Consumers' Institute of New Zealand	Consumer – New Zealand	<ul style="list-style-type: none"> Concerned about allowing the proposal for the protection a companys' commercially valuable information with the Food Regulation Ministerial Council recommended changes to the FSANZ Act. This will allow the food industry to seek pre-market approval of high level claims with no public consultation.
Horticulture Australia Ltd (supported by Horticulture Australia Council and SPC Ardmona)	Industry - Australia	<ul style="list-style-type: none"> Does not believe that the provisions to support exclusivity of claims is in the best interests of achieving public health benefits as it could inadvertently lead to a situation where a company could move to restrict or block claims on a particular product. The fact that any claim is treated as confidential until approved provides a unique opportunity to place the product in the marketplace and the benefits of this alone should be sufficient to justify undertaking the application process.
Meat and Livestock Australia	Industry - Australia	<ul style="list-style-type: none"> Favours the options to gain exclusive rights to claims for individual or 'bundles' of ingredients/components protected by trademarks, patents etc. Recommends exclusivity of claims is extended to a particular food (e.g. red meat or specific product formulation or bundle of nutrients) rather than a class of food (e.g. meat, protein). Does not support the proposal to make claims available for general use after approval, as it is likely an organisation will have made a considerable investment to substantiate a claim. This investment could include resources to fund research as well as the preparation of documents to substantiate a claim. Recommends FSANZ make high level claims, company specific, at least for a set period of time (e.g. 2 years) to enable some return on investment. Is unclear if, and when the changes to the FSANZ Act will be approved. When implemented would mean it would be possible to keep high level claim applications confidential until the claim is approved.
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> As per page 90 of the Draft Assessment Report, the MC has endorsed a proposal for managing new applications for high level health claims, to provide a period of confidentiality. Public consultation will be forfeited in favour of an Expert Committee. Applications will also receive 'advice' from food regulatory agencies in all jurisdictions.

Submitter	Group	Comments
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • National Foods requests further clarification of this process, and in particular: <ul style="list-style-type: none"> – What qualifies as ‘advice’ from food regulatory agencies in all jurisdictions? – How is the Expert Committee recruited? – What is the minimum number of Committee members? – What is the process if there is a conflict of opinion(s)? – What is the application assessment timeframe? – What is the process if an application is ‘not accepted’ (and ‘not rejected’) – either in its entirety, or in parts?
New Zealand Food and Grocery Council (FGC)	Industry – New Zealand	<ul style="list-style-type: none"> • Supports and encourages the early enactment of the proposed amendment to the FSANZ Act, whereby it will be possible to keep Applications of High-Level Claims confidential until approval, thus giving first to market advantage. • It would be extremely helpful to have this amendment in place before gazettal of the Standard.
NSW Department of Health	Government - Australia	<ul style="list-style-type: none"> • Under the proposed changes to FSANZ assessment and approval processes, pre-market assessment and approval of high level claims will be undertaken by FSANZ with no public consultation. Instead, a closed process would apply using an expert panel to assist FSANZ in determining whether the proposed claim is substantiated, and otherwise meets the requirements of the Standard. • Recommendation B1 includes a requirement for a consumer representative on the panel and for the criteria for selection and membership of the panel to be publicly available. Is concerned that these provisions of B1 are effectively implemented to ensure transparency in the selection of the expert panels and to avoid potential conflicts of interest of panel members.
Nutrition Australia	Public Health - Australia	<ul style="list-style-type: none"> • Believes that FSANZ has well represented the dilemma posed by this issue. • In the event of changes too the FSANZ Act to allow exclusivity, recommend, that where an application is assessed, participation in the assessment process should include public health and consumer representatives who have no conflict of interest. • Such participation should entail a fee being paid for the time and expenses incurred by the public health or consumer group representatives as is the case for TGA assessments. Representations on any assessment panel should be open and transparent. • Disagree with the justification provided in the FRSC working group discussion papers on changes to the FSANZ Act that health claims are not an issue of public health safety, but only an issue of consumer choice. • Health claims are an issue of public health safety as they have the potential to contribute to over consumption of unhealthy foods and under consumption of healthier food choices.

Submitter	Group	Comments
Public Health Association of Australia	Public Health - Australia	<ul style="list-style-type: none"> • Have concerns about the proposed legislative changes to the FSANZ Act 1991 whereby the food industry could seek pre-market approval of high level health claims with no public consultation. Instead, an expert panel will consider applications for these claims. • Believes it is important that there are open and transparent consultation processes for the assessment and approval of health claims applications to protect public health and consumer interests and not solely commercial interests. • Disagrees with the justification provided in the FRSC working group discussion papers that health claims are not a public health and safety issue, but only an issue of consumer choice, as they have the potential to distort consumption patterns. • The proposed system will reduce transparency and will become vulnerable to conflict of interest concerns e.g. in the selection of experts. • Recommends that public health and consumer representatives, who have no conflict of interest, participate in the assessment process and should entail payment of a fee for time and expenses incurred.
Queensland Health	Government – Australia	<ul style="list-style-type: none"> • Exclusivity of claims would be difficult and should not be allowed.
Rosemary Stanton	Public Health - Australia	<ul style="list-style-type: none"> • If the reason for permitting health claims is to benefit public health, one would assume that the more widely the health claim was used, the better. The desire for exclusivity shows that health claims are basically a marketing tool to increase consumption. • The FSANZ summary in section 11.3 appears to support the view point that public health benefits could be stifled by exclusivity, which is commendable. • Suggest that where an application is assessed, participation in the assessment process should include public health and consumer representatives who have no conflict of interest. Such participation should entail a fee being paid for the time of the public health or consumer group representatives. Representations on any assessment panel should be open and transparent.
South Australia Department of Health	Government – Australia	<ul style="list-style-type: none"> • Is concerned about the issue of bioavailability when a high level claim is used in relation to other food matrices containing the nominated nutrient but without pre-approved substantiation e.g. the bioavailability of phytosterols changes dramatically (5-16%) in different food matrices. • Recommends that more work be done to ensure that the use of a pre-approved high level claim is only acceptable in the same food matrix and only where the manufacturer holds evidence of effect.
Tarac Technologies	Industry, Australia	<ul style="list-style-type: none"> • For innovative ingredient companies the lack of Intellectual Property (IP) protection and exclusivity after claim approval is granted is a major disincentive to develop products and conduct research to support a high level claim. • It is stated in section 11.3.3 that exclusivity could be protected via a trademark; however, it is not clear how this will operate. It is unclear if it possible to have a high level health claim approved for an ingredient brand as opposed to a generic ingredient.

Submitter	Group	Comments
Unilever Australasia	Industry – Trans Tasman	<ul style="list-style-type: none"> Fully supports the approach proposed for the management of High Level Health Claims, in conjunction with the proposed changes to the FSANZ Act to protect innovation in this area enabling us to help educate consumers by informing them of the benefits of including our products in their diet.
Fonterra Brands Australia (P&B)	Industry - Australia	<ul style="list-style-type: none"> Proposed amendments to the FSANZ Act to protect innovation need to be in place before gazettal of this standard.

FURTHER REVIEWS AND APPROVAL PROCESS

Submitter	Group	Comments
Adecron Food Tech Consulting	Industry – New Zealand	<ul style="list-style-type: none"> The suggested 5-10 year review period is too long, and should instead be every 2-4 years. The high level health claim substantiation process must be speedy if it is to work. Current timeframe of two years (personal estimate) to amend the Code is too long, particularly if this is in addition to the substantiation process. Unclear whether or not the two processes (substantiation & applications) can run concurrently or if they are the same. Likely that some people will ‘jump the gun’ out of frustration. Considers that it is just as well that the most common/likely claims have been pre-approved. Figures 2.1 and 3.1 (Attachment 8) provide a useful overview.
Australian Nut Industry Council	Industry - Australia	<ul style="list-style-type: none"> Recommends an additional claim in relation to nuts and reduction of the risk of heart disease be considered. Supports the introduction of a high level health claim for fruit and vegetables and reduced risk of coronary heart disease and strongly believes that nuts should be included in this claim given FSANZ includes nuts in the definition of fruits and vegetables in Standard 2.3.1. There is a clear dose response relationship between increased nut consumption and reduced risk of coronary heart disease. Epidemiological evidence suggests frequent nut consumption significantly reduces the risk of developing coronary heart disease in men and women and significantly reduces mortality from coronary heart disease. The degree of risk reduction for coronary heart disease with minor dietary changes to include nuts is significant, with research showing 30-50% risk reduction from regular consumption of nuts 2-5 times per week ¹⁻⁵. Many clinical studies support the epidemiological evidence by indicating how nuts reduces heart disease risk through effect on biomarkers such as reducing LDL cholesterol and improving endothelial function ⁶⁻¹¹. A nut health claim would increase nut consumption and provide an education message. This is in line with public health recommendations by the National Heart Foundation and the National Health and Medical Research Council to include nuts regularly in the diet for cholesterol management and for general healthy eating.

Submitter	Group	Comments
Australian Nut Industry Council	Industry - Australia	<p>References</p> <ol style="list-style-type: none"> 1. Kushi, L. H. et al. Dietary antioxidant vitamins and death from coronary heart disease in postmenopausal women. <i>N Engl J Med</i> 334, 1156-62 (1996). 2. Hu, F. B. et al. Frequent nut consumption and risk of coronary heart disease in women: prospective cohort study. <i>BMJ</i> 317, 1341-5 (1998). 3. Albert, C. M., Gaziano, J. M., Willett, W. C. & Manson, J. E. Nut consumption and decreased risk of sudden cardiac death in the Physicians' Health Study. <i>Arch Intern Med</i> 162, 1382-7 (2002). 4. Brown, L., Rosner, B. A., Willett, W. C. & Sacks, F. Nut consumption and risk of recurrent coronary heart disease. <i>FASEB J</i> 13, A538 (1999). 5. Fraser, G. E., Sabate, J., Beeson, W. L. & Strahan, T. M. A possible protective effect of nut consumption on risk of coronary heart disease. The Adventist Health Study. <i>Arch Intern Med</i> 152, 1416-24 (1992). 6. Mukuddem-Petersen J, Oosthuizen W, Jerling JC. A systematic review of the effects of nuts on blood lipid profiles in humans. <i>J Nutr.</i> 2005 Sep;135(9):2082-9. 7. Hiraoka-Yamamoto J, Ikeda K, Negishi H, Mori M, Hirose A, Sawada S, Onobayashi Y, Kitamori K, Kitano S, Tashiro M, Miki T, Yamori Y. Serum lipid effects of a monounsaturated (palmitoleic) Fatty Acid-rich diet based on macadamia nuts in healthy, young Japanese women. <i>Clin Exp Pharmacol Physiol.</i> 2004 Dec;31 Suppl 2:S37-8. 8. Garg ML, Blake RJ, Wills RB. Macadamia nut consumption lowers plasma total and LDL cholesterol levels in hypercholesterolemic men. <i>J Nutr.</i> 2003 Apr;133(4):1060-3. 9. Tapsell LC, Gillen LJ, Patch CS, Batterham M, Owen A, Bare M, Kennedy M. Including walnuts in a low-fat/modified-fat diet improves HDL cholesterol-tototal cholesterol ratios in patients with type 2 diabetes. <i>Diabetes Care.</i> 2004 Dec; 27(12):2777-83. 10. Jenkins DJ, Kendall CW, Marchie A, Parker TL, Connelly PW, Qian W, Haight JS, Faulkner D, Vidgen E, Lapsley KG, Spiller GA. Dose response of almonds on coronary heart disease risk factors: blood lipids, oxidized low-density lipoproteins, lipoprotein(a), homocysteine, and pulmonary nitric oxide: a randomized, controlled, crossover trial. <i>Circulation.</i> 2002 Sep 10;106(11):1327-32. 11. Ros E, Nunez I, Perez-Heras A, Serra M, Gilabert R, Casals E, Deulofeu R. A walnut diet improves endothelial function in hypercholesterolemic subjects: a randomized crossover trial. <i>Circulation.</i> 2004 Apr 6;109(13):1609-14.

Submitter	Group	Comments
Australian Nut Industry Council	Industry - Australia	<ul style="list-style-type: none"> • A nut health claim is consistent with recommendations regarding nut consumption by key health authorities, including the Australian Guide to Healthy Eating, the Dietary Guidelines for Australians, National Heart Foundation of Australia¹, American Heart Association, World Health Organisation, National Cholesterol Education Programme Expert Panel, Heart and Stroke Foundation of Canada and the Food and Drug Administration¹⁻⁸. • Suggests FSANZ develop the claim in relation to nuts and reduction of the risk of heart disease as the fruit, vegetable and nut industry do not have the margins to pay for claims development and fast tracking of approval processes. If this is not possible, recommends FSANZ assist the industry by fast tracking these claims at no extra cost due to the public health benefit. <p>References</p> <ol style="list-style-type: none"> 1. Smith, A., Kellett, E. & Schmerlaib, Y. <i>The Australian Guide to Healthy Eating</i> (Commonwealth of Australia, 1998). 2. National Health and Medical Research Council. <i>Food for Health – Dietary Guidelines for Australian Adults</i> (Commonwealth Department of Health and Ageing, Canberra, 2003) 3. 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). 4. Krauss, R. M. et al. AHA Dietary Guidelines: revision 2000: A statement for healthcare professionals from the Nutrition Committee of the American Heart Association. <i>Circulation</i> 102, 2284-99 (2000). 5. World Health Organisation. <i>Diet, Nutrition and the Prevention of Chronic Diseases</i> (World Health Organisation, Geneva, 2003). 6. Third Report of the National Cholesterol Education Programme (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. <i>Circulation</i> 106, 3143-421(2002). 7. Heart and Stroke Foundation of Canada. Healthy eating - blood cholesterol. (2001). 8. U.S. Food and Drug Administration. Accessed: 25/11/04 at http://vm.cfsan.fda.gov/~dms/qhcnuts2.html (Maryland, 2003).
Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry – Australia	<ul style="list-style-type: none"> • Submits that the cost for a paid application is high (the highest fee of up to \$150 000), and may inhibit industry from applying for claim approval. This cost does not take into account the cost of dossier preparation and review by the company. • Believes that the approval process for high-level claims as defined in Attachment 8 should be conducted within a shorter timeframe – possibly 6 months in comparison to the stipulated 12 months. This would facilitate more effective product launches and align more with timelines overseas. • Supports that there be a FSANZ appointed panel of external experts (preferably publicly noted) who can consider a review performed by a selected expert in the field of the claims. A “convincing” answer would advance the claim to the next step.

Submitter	Group	Comments
Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry - Australia	<ul style="list-style-type: none"> • Submits that the expert panel should be separate to FSANZ and should be paid by industry directly (although it could be used by FSANZ as well if required). This would then also allow industry not to submit to FSANZ in case the application is not successful and increase transparency on costs and timing. • FSANZ has noted it would then model the dietary consequences of its addition to the chosen food vehicle for “adverse consequences” in high consumers and vulnerable groups, decide on any risk management steps and make a recommendation. More information on how this modelling is performed and the considerations it involves is required. • Submits this process should be confidential to the submitter and that public consultation is not required. This will lead to increased incentive for innovation and may encourage an evidence based determination rather than clouding the issue through lobbying by self-interest groups.
Horticulture New Zealand	Industry - NZ	<ul style="list-style-type: none"> • Government should produce a set of guidelines of acceptable wording with the aim of making fruit and vegetables preferred food choices. • The guidelines should include a number of pre-approved general level claims plus as many high level claims as can be substantiated. The national Fruit and Vegetable Alliance (FAVA) should be invited to prepare such a list for ratification.
Meat and Livestock Australia	Industry - Australia	<ul style="list-style-type: none"> • Does not agree that the pre-market assessment of high level claims should involve two rounds of public consultation, as this is likely to jeopardise commercial confidentiality. The process is likely to be time-consuming and therefore slow down innovation. • Recommends that the pre-market assessment be conducted by FSANZ in conjunction with an independent panel of experts. This would ensure the details of the submission remain confidential to competitors and that a group who is sufficiently qualified to judge the quality of the submission will conduct the assessment. • Recommends that food manufacturers/marketers should have the opportunity to liaise with FSANZ (or key members of the Expert Panel) prior to research being conducted and/or a submission being prepared for high level claims for guidance e.g. it would be beneficial for members of the Expert Panel to assess the draft research proposal to ensure the study design meets the necessary standards (e.g. appropriate population, and control, biomarkers/end-points, statistical analysis, dosage, intervention time versus anticipated claim). • Would like to know how long it will take from the time an application is submitted until the claim is able to be used in market (assuming a submission is successful first time). • Would like to know how much it would cost to get an application assessed for pre-market approval.
New Zealand Food Safety Authority (NZFSA)	Government – New Zealand	<ul style="list-style-type: none"> • Request confirmation that the review of evidence for the proposed high level claim around wholegrain and CHD is consistent with the new definition of wholegrain in the Code.
Public Health Association of Australia	Public Health – Australia	<ul style="list-style-type: none"> • Is concerned that no high level claims for pre-approval involve fresh foods e.g. fruit and vegetable consumption is positively associated with reduced risk of cancer.

Submitter	Group	Comments
Public Health Association of Australia	Public Health - Australia	<ul style="list-style-type: none"> • Considers this should be a priority, given that fruit and vegetable growers are unlikely to have the funds to mount a submission. • This is an area where FSANZ could assist the campaigns by Governments to increase consumption of vegetable and fruit.
Queensland Health	Government – Australia	<ul style="list-style-type: none"> • Has serious concerns that no pre-approved high level claims will be available for fruit and vegetables, particularly given their significant role in health, and the high priority placed on these claims by public health organisations, industry and government during the consultation process for prioritising work on pre-approved high level claims. • Cannot comprehend that one of the reasons for this is that FSANZ was unsure of the inclusion of cancer in the definition of a serious disease. • Claims for fruit and vegetables (for all chronic diseases) must be considered as a matter of priority. • A process for reviewing the evidence for approved high levels is required at periodic intervals (e.g. 5 years) or as new evidence becomes available. This should also be accompanied by a clear process for withdrawing a claim should the evidence no longer substantiate the claim.
The Cancer Society of Australia	Public Health – Australia	<ul style="list-style-type: none"> • It is pleasing to note that none of the pre-approved health claims relate to cancer. Do not believe health claims should be permitted in relation to cancer as the current level of scientific evidence for such association is weak. • The relationship between diet and cancer is complex and the only food category for which a beneficial claim might be made is for fruit and vegetables but even with this there is controversy. It is generally agreed that the cancer preventing benefits of fruit and vegetables may be indirectly mediated through their benefits in maintaining a healthy body weight. • If claims relating to health and cancer were to be received then request FSANZ to include representation from The Cancer Council on any expert assessment panels as they are well placed to advise FSANZ on the evidence relating to nutritional issues and cancer. .

Submitter	Group	Comments
The Omega-3 Centre	Industry – Australia	<ul style="list-style-type: none"> • Support FSANZ’s decision to consider a high level health claim relating to Omega-3 fatty acids and cardiovascular disease. • Attached the Executive Summary of P293 IAR submission, which included the rationale for high level health claims for Omega-3 fatty acids. • Foods permitted to use the high level Omega-3 health claim should comply with the conditions for a good source of Omega-3s in the Table to Clause 11. Oppose arbitrary disqualifying criteria and the need for any other conditions of use. • A minimum amount of 60mg EPA and DHA represents almost 50% of the calculated mean Adequate Intake for adults expected to be included in the new Nutrient Reference Values document [Baghurst K (Chair of the Working Party for Revision of the Australian/New Zealand Nutrient Reference Values). Key foods for meeting Nutrient Reference Values presented at International Life Sciences Institute & the National Centre of Excellence in Functional Food Symposium Carbohydrates, fats, protein – what’s the optimal mix, 20 June 2005 Baghurst, 2005]. It also represents 12% of the calculated mean Suggested Target for ‘reduced risk of chronic disease’ [Baghurst K same reference as above]. This means that eight serves of a variety of foods containing 60mg/serve can provide sufficient long chain Omega-3 to reach the Suggested Target. • Table to Clause 6 should include the additional claim: Substantiated diet-disease relationship: Omega-3 fatty acids EPA and DHA and cardiovascular disease; Conditions: (a) the food complies with the conditions under Clause 11 of the Standard for a nutrition content claim in relation to a good source of Omega-3 fatty acids. Claim Statements: <ul style="list-style-type: none"> – the property of the food is Omega-3 fatty acids EPA and DHA; and – the specific health effect is reduced risk of cardiovascular disease, may help reduce blood triglycerides, plasma triglycerides or plasma triglyceride levels, blood pressure, susceptibility of the heart to arrhythmia, thrombogenesis, inflammation, blood vessel rigidity; and – the population group is the general population; and – the context is a healthy diet with a variety of foods low in saturated and trans fatty acids. • Point (d) of the claim statement relates to the recommended modified conditions for a low in saturated fat nutrient content claim.
Kellogg (Aust.) Pty Ltd	Industry- Australia	<ul style="list-style-type: none"> • Supports the pre-approval of high level health claims. • Request that FSANZ consider how they will continue to expand the list of pre-approved high level health claims to ensure timely inclusion into the Standard e.g. will the current review of Omega-3 Fatty Acids and coronary heart disease be completed in time for gazettal of the standard • Two rounds of public consultation may slow innovation and provision of information to consumers.

Submitter	Group	Comments
<p>Cancer Society of New Zealand Inc</p> <p>Public Health Dietitians</p> <p>The Cancer Council of Australia</p>	<p>Public Health – New Zealand</p> <p>Public Health – New Zealand</p> <p>Public Health - Australia</p>	<ul style="list-style-type: none"> • Concerns regarding recommended changes to the FSANZ Food Act which will allow for the protection of commercially valuable information but will diminish community consultation required by FSANZ. • Important that there are open consultation processes that protect consumers, not commercial interests. • Potentially no public consultation will occur for high level claims. This is in conflict with FSANZ’s objectives. • Disagree with the justification that health claims are not an issue of public health safety but only of consumer choice; as they have the potential to contribute to the over consumption of healthier foods and the under consumption of unhealthier food choices. • Suggests there must be a transparent process in selecting panel members to review food industry submissions. Panel members will need to declare any conflicts of interest and be listed for public viewing (submitted by The Cancer Council of Australia only).
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • Partly concurs with FSANZ recommendation to a review period every five to 10 years for approved health claims to ensure they are based on the best available scientific evidence. • Believes a review of the scientific substantiation for a health claim should occur every five years or as new scientific evidence becomes available.
Beer Wine and Spirits Council of New Zealand (BWSC)	Industry – New Zealand	<ul style="list-style-type: none"> • This process requires such an extraordinary level of proof for any health benefit that it negates any major opportunity for the community to understand product specific claims • This approval system is based upon the Canadian system where it is considered a failure and is unused by industry for product specific claims, because the burden of proof, the clumsiness and the prolonged nature of the process make it uneconomic for industry. • While the proposed changes allow a measure of confidentiality, it will not significantly change a flawed system. To prefer a ‘pharmaceutical’, level of proof with double blind clinical trials, is inappropriate when measuring the effects of long term eating patterns. This is a medicine model not a food model. • Not accepting the current probable level of proof is a missed opportunity for improved consumer knowledge and health • Does not apply risk/benefit analysis but rather is safety for the people running the system and a lost opportunity, the cost of which will be borne by the community. • Very few claims will get thought the high level claim system which will be a failure of the system and lost opportunity. • Recommends a review of the high level health claims process from a pharmaceutical level of proof to the “probably correct level of proof”. • The consequences of a food health claim later being disproved with further scientific work are much less the equivalent to the consequences for a pharmaceutical health claim; which allows the establishment of a more appropriate mechanism and level of proof to establish a health benefit from the long term consumption of a food.

Submitter	Group	Comments
Coalition for a Healthy Australian Food Supply (CHAFS)	Public Health - Australia	<ul style="list-style-type: none"> • Concerned that no high level claims for pre-approval involve fresh foods such as fruits and vegetables, even though the need to increase consumption of vegetables and fruit has been identified, such as through SIGNAL programmes. • This should be a priority considering individual growers are unlikely to have funds to mount subsequent submissions • A health claim standard should be assisting State, Territory and Commonwealth governments to increase consumption of fruit and vegetables by Australians and New Zealanders.
Campbell Arnott's Asia Pacific	Industry-Australia	<ul style="list-style-type: none"> • Recommends same criteria be used as they recommended for content claims - 'good source' containing 7.5g (dry weight) wholegrains and 'source' claims containing minimum 3g. • Supports the continued assessment of pre-approved high level claims for omega-3 fatty acids, EPA and DHA and a reduction in cardiovascular disease. • Include an additional claim in the Table to Clause 6, related to long chain Omega 3 fatty acids EPA, DHA and the reduced risk of cardiovascular disease and beneficial effects on associated biomarkers including platelet aggregation/thrombogenesis; with the following conditions: <ul style="list-style-type: none"> (a) the food complies with the conditions under clause 11 of this Standard for a nutrition content claim in relation to a good source of omega-3 fatty acids <p>Claim statement</p> <ul style="list-style-type: none"> (a) the property of the food is; Omega-3 fatty acids EPA and DHA; and (b) the specific health effect is; May help reduce the risk of cardiovascular disease, may help reduce blood triglycerides, plasma triglycerides or plasma triglyceride levels, blood pressure, susceptibility of the heart to arrhythmia, thrombogenesis, inflammation, blood vessel rigidity; and (c) the population group is; the general population; and (d) d) the context is; a healthy diet with a variety of foods low in saturated fatty acids.
Cancer Society of New Zealand Inc	Public Health – New Zealand	<ul style="list-style-type: none"> • The relationship between diet and cancer is complex and the only food category for which a beneficial claim might be made is for fruit and vegetables but even with this there is controversy. It is generally agreed that the cancer preventing benefits of fruit and vegetables may be indirectly mediated through their benefits in maintaining a healthy body weight. • If claims relating to health and cancer were to be received then request FSANZ to include representation from the Cancer Society of New Zealand on any expert assessment panels. • Organisations like the Cancer Society of NZ should be able to encourage fruit and vegetable consumption at the point of sale.
Coles Myer Ltd	Industry – Australia	<ul style="list-style-type: none"> • Strongly supports further reviews of diet-health relationships as the basis for proposed approved high level claims for: <ul style="list-style-type: none"> – Omega 3 and Coronary Heart Disease (CHD)

Submitter	Group	Comments
Coles Myer Ltd	Industry - Australia	<ul style="list-style-type: none"> – Wholegrain and bran intake and CHD; and – Fruits, vegetables and heart disease. • Lists various government initiatives in public health promoting consumption of fruit and vegetables. • Strongly supports the review of a diet-health relationship for fruits; vegetables and heart disease should also be instigated as a priority and not delayed pending resource availability. • CML welcomes opportunity to discuss with FSANZ potential ways in which it can contribute to this review.
Fonterra Brands Australia (P&B)	Industry - Australia	<ul style="list-style-type: none"> • Further clarification is required on the resourcing of high level claims approval by FSANZ. • It may be more appropriate to have an independent expert panel responsible for reviewing health claims, which can be approached by FSANZ or food companies for claims assessment.
Horticulture Australia Ltd (supported by Horticulture Australia Council and SPC Ardmona)	Industry - Australia	<ul style="list-style-type: none"> • Is disappointed that the high level claim relating to fruit and vegetable intake has not been progressed fully and no timetable has been provided. • The high level claim relating to fruit and vegetable intake and heart disease should be progressed as a matter of priority. Evidence is also strong for the protective effects of fruit and vegetables in other serious conditions such as stroke, diabetes and cataracts as well as the protective effects of nuts in cardiovascular disease. Substantiation of high level claims in these areas should also be considered a high priority. • The ability to use high level claims in relation to fruit and vegetables would assist in promoting the objectives of the National Go for 2&5 campaign, of reducing a range of chronic diseases. It would also seek to assure whole food producers that there was no bias in the advancement of high level claims. • Believes that preference should be given to the development of high level claims by whole foods. • Considers that FSANZ should reconsider the approach whereby an organisation may pay a fee to expedite an application for a new high level claim. • This approach may give a perception of bias in favour of larger commercial interests who are prepared to expedite the application process. Also, fruit, vegetable and nut industries do not largely have the profit margins required to pay for the claim development and approval process. • The granting of high level claims for a particular brand of food combined with exclusivity of claims could lead to a situation where there are a large number of applications for products of a similar nature. This is against the interests of providing the public with sufficient information to make informed choices and also poses a potential impact on FSANZ's resources.
Janet Weber (Massey University)	Academic and other – New Zealand	<ul style="list-style-type: none"> • The request for additional high level claims to be approved is to come from industry. But if we believe that health claims have a benefit then responsibility also lies with the public sector needs to propose new claims so that those claims which may not easily result in a clear marketing advantage are also brought to the attention of consumers.
Murray Goulburn Co-operative Co Ltd	Industry - Australia	<ul style="list-style-type: none"> • Supports the Dairy Australia submission that whole milk should be permitted to make a high level health claim related to blood pressure.

Submitter	Group	Comments
Nestle Australia Limited and Nestle New Zealand Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> • Public consultation will be required on the three reviews still to be completed. Nestle look forward to providing comment on these. • Note that the Dietary Guidelines for Australian Adults and the Dietary Guidelines for Children and Adolescents in Australia both report that foods that contain at least 51% wholegrain can be described as wholegrain foods. Without pre-empting what the conditions for a pre-approved claim will be, if the minimum level for a health claim is 51% whole grain, then in a 30g serve of breakfast cereal the amount present for a high level claim would need to be at least 15.3g, only 0.3g higher than the level necessary for a good source claim as proposed by FSANZ. • Where pre-approval of health claims is required, this should be limited to validation of the science surrounding the claim with the exact wording of the claim determined by the manufacturers, who in the development of the claim are able to research the type of claim that has meaning and is relevant to the consumer.
Food Products Association (FPA)	Industry-International	<ul style="list-style-type: none"> • Pre-approval submissions may disadvantage smaller companies who do not have the resources to prepare submission substantiations in the Australian and New Zealand markets • Supports use of identified High Level Claims but notes that the US FDA has recognised 12 Health Claims substantiated by significant scientific agreement and three substantiated by authoritative statements by the US government or the National Academy of Sciences (www.cfsan.fda.gov). • Encourages FSANZ to move forward expeditiously to expand the list of pre-approved high level claims to all those for which substantiation by significant scientific agreement has been identified in the US and other nations and authoritative bodies such as the National Academy of Sciences.
5 + A Day United Fresh	Industry-NZ	<ul style="list-style-type: none"> • Fruit and vegetable industry needs to promote the health benefits of fruit and vegetables as these benefits become substantiated by sound science • If certain sectors of the fruit industry are unable to make high level health claims for their products then this will be an impediment to funding current and future research in health and nutrition. Without this there is no reason for industry to fund much needed nutrition research. • Responsible reporting of research linking increased consumption of fruit and vegetables with increased protection against diseases needs to be allowed, such as protection against heart disease and obesity. • FSANZ should ensure substantiation of as many pre-approved high level claims (and general level health claims) for fruit and vegetables be adopted
Rosemary Stanton	Public Health - Australia	<ul style="list-style-type: none"> • Concerned that no pre-approval for high level claims involve fresh foods such as fruit and vegetables. • As Departments of Health in Australia and New Zealand have already identified a need to increase consumption of fruits and vegetables, this would seem the obvious place to start with pre-approved claims. • Much of the evidence has already been gathered by SIGNAL.

Submitter	Group	Comments
Brismark/Brisbane Markets Limited (BML)	Industry-Australia	<ul style="list-style-type: none"> • Pre-approved nutrient function statement doesn't include fruit and vegetables; when it comes to making high level claims the six listed statements have little to do with fruit and vegetables. The benefits of eating fresh fruit and vegetables are already justified globally. • Current process to do this is inequitable. Manufacturers have a product while as a commodity, no one 'owns' fruit and vegetables. • It is suggested that at least one high-level claim must be made available for fruit and vegetables before the Standard is implemented. It would be preferable if the claim 'on hold' (fruit and vegetables and heart disease) was repositioned at the head of the substantiation queue without the need for a hefty application fee. • The disparate and decentralised horticulture industry lacks the ownership motivation or funding to afford its own high-level health claim research
Sanitarium Health Food Company	Industry – Trans-Tasman	<ul style="list-style-type: none"> • Is pleased to see a number of pre-approved health claims in the draft Standard. However, there are other health claims that were short listed for being included in the draft Standard that could be included via the streamlined assessment approach. • Recommends resources be allocated to assess other well-substantiated high level health claims, such as soy protein and heart disease / cholesterol, and soluble fibre and heart disease (both of which claims have already been approved by the FDA), to be included as pre-approved health claims.
Meat and Livestock Australia	Industry - Australia	<ul style="list-style-type: none"> • Believes there needs to be scope for the approval of new biomarkers as the science evolves.
Nutrition Australia	Public Health - Australia	<ul style="list-style-type: none"> • Concerned that there are no high level health claims for pre-approval involving fresh foods such as fruits and vegetables. • Increased consumption of fruits and vegetable is a major health promotion objective for all jurisdictions. • This is an example where regulations should underpin public health nutrition objectives.

**Proposal P293 Nutrition, Health and Related Claims
Summary of submissions to the Draft Assessment Report**

16. HIGH LEVEL CLAIMS CRITERIA

GENERAL

Submitter	Group	Comments
Public Health Association of Australia	Public Health - Australia	<ul style="list-style-type: none"> • Within the scope of Option 3, urges FSANZ to conduct a public health risk and benefit analysis of including provision for mandating high level claims from the perspective of ‘disease claims’. In this context a high level claim would refer to the relationship between a food, or an ingredient in a food, as a contributing causal factor for a disease outcome e.g. a claim that describes the relationship between a high sugar food and dental caries.
Queensland Health	Government – Australia	<ul style="list-style-type: none"> • The logic behind why certain disqualifying criteria will not apply to pre-approved high level claims is not clear.
Jenny Robertson Consulting Services (Jenny Robertson & Dan Southee)	Industry, Australia	<ul style="list-style-type: none"> • In general, accepts the approach for high level claims.
New Zealand Food and Grocery Council (FGC)	Industry – New Zealand	<ul style="list-style-type: none"> • Supportive of the approach being taken in respect of High-Level Claims. • The fact that six diet-health relationships have been substantiated and that two further reviews is welcome. • Meeting the stringent and highly prescriptive requirements to obtain approval of a health claim is demanding and requires substantial resources. The ability to have a number of high level claims available for use at the time the Standard comes into effect is helpful.
Queensland Health	Government – Australia	<ul style="list-style-type: none"> • Food compositional criteria should be per standard serve size, or per 100 g, not manufacturers’ serve size.
New Zealand Institute for Crop & Food Research Ltd	Academic and Other - New Zealand	<ul style="list-style-type: none"> • The required elements of high level claims appear to be unnecessarily wordy and unclear. If companies find it difficult to fit this claims on their label, then they may choose a general nutrient claim on their label.

SATURATED FATTY ACIDS/TRANS FATTY ACIDS AND LDL CHOLESTEROL

Submitter	Group	Comments
The Omega-3 Centre	Industry - Australia	<ul style="list-style-type: none"> • Modifications suggested to the nutrition content claim for ‘low in saturated fats’ (below) would apply to HLC claims for SFA & LDL Cholesterol in the Table to clause 6. <ul style="list-style-type: none"> – the food contains <ul style="list-style-type: none"> (i) as a proportion of the total fatty acids content, no more than 28% saturated fatty acids and trans fatty acids; or (ii) no more saturated fatty acids and trans fatty acids than 0.75 g per 100 g for liquid food; or (iii) no more saturated fatty acids and trans fatty acids than 1.5 g per 100 g for solid food.
Campbell Arnott’s Asia Pacific	Industry- Australia	<ul style="list-style-type: none"> • Conditions should be modified to: • the food contains: as a proportion of the total fatty acids content , no more than 28% saturated fatty acids and trans fatty acids; or no more saturated fatty acids and trans fatty acids than 0.75g per 100g for liquid food; or no more saturated fatty acids and trans fatty acids than 1.5g per 100g for solid food.
Adecron Food Tech Consulting	Industry – New Zealand	<ul style="list-style-type: none"> • It might be an overstatement when a HLC about SFA and LDL cholesterol is made and yet the scientific report summary states that proof is ‘probable’ but not ‘conclusive.’ • The underlying factors that cause arterial damage are still unknown; therefore it is highly likely that several of the now approved statements will need adjusting in the future.
Unilever Australasia	Industry – Trans Tasman	<ul style="list-style-type: none"> • The final major concern in this area is how the qualifying criteria for a ‘Low saturated fat’ claim have been used as the disqualifying criteria for the one High Level Health Claim for fat that has been reviewed for introduction with this standard. • To permit this claim only on foods that are intrinsically low in total fat, and therefore low in saturated fat, is not contributing to the education of consumers or helping them to choose products that give them the essential nutrients they require from fat while ensuring that the less healthy fats are minimised. • We therefore also urge consideration of amended criteria for this High Level Claim in conjunction with a re-consideration of the qualifying criteria for the ‘Low saturated fat’ claim.
John Birkbeck (Massey University)	Academic – New Zealand	<ul style="list-style-type: none"> • Claims about saturates and trans-unsaturates refer to <i>elevated</i> levels of LDL cholesterol.
National Heart Foundation of Australia National Heart Foundation of New Zealand	Public Health – Australia Public Health - New Zealand	<ul style="list-style-type: none"> • Two aspects of the draft Standard fail to support Heart Foundation’s efforts in fatty acids and cardiovascular health: <ul style="list-style-type: none"> – <u>Conditions for ‘low saturated fatty acid’ and ‘low saturated and trans fatty acid’ claims</u>: proposed conditions limit these claims to low fat foods which means that only low fat foods, and not those with higher levels of unsaturated fats such as oils, dressings, nuts, margarines would be able to make an approved high level health claim relating ‘type of fat’ to blood cholesterol levels. These foods would likely make ‘low in trans fat’ claims – which may be true but it would take the emphasis away from the more important issue of reducing saturated fats and increasing polyunsaturated fats in the diet.

Submitter	Group	Comments
National Heart Foundation of Australia	Public Health – Australia	<ul style="list-style-type: none"> – The required claim statements for the high level health claims on saturated fat – by not referencing the importance of increasing unsaturated fats as the preferred replacement for saturated fats in the diet, these claim statements are not fully consistent with the Heart Foundation’s recommendations on dietary fat intake.
National Heart Foundation of New Zealand	Public Health - New Zealand	<ul style="list-style-type: none"> • Recommends that the requirements for the claim relating to saturated fatty acids and LDL cholesterol be extended to include the statement that the extent of LDL cholesterol reduction is great when saturated fatty acids are replaced with unsaturated fatty acids. Suggests that part (c) of the claim statement is not required (‘the population group is the general population’).
Murray Goulburn Co-operative Co Ltd	Industry - Australia	<ul style="list-style-type: none"> • Supports the Dairy Australia submission that the approved high level claim for saturated and trans fatty acids and LDL cholesterol should take account of the currently accepted definition of trans fatty acids.
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • National Foods raises concerns with the proposed qualifying and disqualifying criteria and the impact this has on preventing certain core foods, such as dairy foods, from making substantiated high level health claims relating to saturated fat and LDL cholesterol. • The proposed qualifying criterion prohibits certain dairy foods from making this high level health claim, namely regular fat dairy foods. The qualifying criteria fails to consider the beneficial impact of raising HDL cholesterol or the totality of the scientific evidence of dairy foods on LDL cholesterol and heart disease. This again signifies the impact of considering individual nutrients instead of the nutritional value of the whole food. • National Foods recommends that the substantiation for saturated fat (and trans-fats) and LDL cholesterol high level health claims be reviewed and the totality of the evidence considered. National Foods recommends that dairy foods be permitted to make these high level health claims, if scientifically substantiated. • If the high level health claim for saturated fat (and trans-fat) and LDL cholesterol is still permitted, for labelling and education purposes, trans fats should be defined as those from industrial sources only. It is incorrect to broadly extrapolate the data and definition to all forms of trans-fatty acids.
Dairy Australia	Industry-Australia	<ul style="list-style-type: none"> • Skim milk but no other types of milk or cheese or yogurt will be able to make this claim.
Fonterra Co-Operative Group Limited	Industry – New Zealand	<ul style="list-style-type: none"> • A recent ten-country consensus states that the total LDL and Cholesterol are not the most important measures of cardiovascular risk and that Apo B should be included (Barter PJ. et al., (2006) Apo B versus cholesterol in estimating cardiovascular risk and in guiding therapy: report of the thirty-person/ten country panel. Journal of Internal Medicine 259, 247-58.) • Greater emphasis should be placed on the effect of foods on actual disease. • In short term studies Apo B should be used as a marker of risk rather than just relying on LDL-cholesterol levels.
Rosemary Stanton	Public Health – Australia	<ul style="list-style-type: none"> • Concerned that FSANZ is assuming that trans fats are likely to be present at low levels of intake in Australia and New Zealand.

Submitter	Group	Comments
Rosemary Stanton	Public Health - Australia	<ul style="list-style-type: none"> • There are no current reports available to gauge intake but the Australian Consumers' Association found high levels in many foods, with up to 23% (see www.choice.com.au). • A recent check at a supermarket revealed 8 margarines, including big selling home brand products, labelled as 'unsaturated' but containing up to 8% trans fatty acids.

SODIUM AND BLOOD PRESSURE

Submitter	Group	Comments
John Birkbeck (Massey University)	Academic – New Zealand	<ul style="list-style-type: none"> • There is convincing evidence for those with high blood pressure, but he is less sure about normotensives.
National Heart Foundation of Australia	Public Health – Australia	<ul style="list-style-type: none"> • Supports inclusion of this high level claim in the Standard. • Recommends the requirement for the claim statements be extended to include the statement that 'high blood pressure is a condition associated with many factors including overweight, excessive alcohol consumption, inadequate intake of dietary potassium and inactivity.'
National Heart Foundation of New Zealand	Public Health - New Zealand	<ul style="list-style-type: none"> • Suggests that part (c) of the claim statement is not required ('the population group is the general population').
Department of Human Services Victoria	Government – Australia	<ul style="list-style-type: none"> • Considers that the evidence used by FSANZ for this claim is not strong enough to support widespread use and that experts remain divided about the potential benefits to public health of implementing programmes to decrease sodium intake. • Questioned whether the results obtained by the expert review on salt and hypertension commissioned by FSANZ (Samman 2005) were clinically significant. • Notes that salt sensitivity only occurs in 5-16% of the population, a salt reduced diet only produces reductions in blood pressure of <1- <5mmHg and studies with salt restrictions showed significant concomitant increases in total and LDL cholesterol and triglycerides (of 4.6-5.9%). • Refers to the National Heart Foundation lipid position paper which states that "changes in blood cholesterol in the order of 5-6% translate to changes in cardiovascular disease risk of 10%" and that this increase is unacceptable.
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • The proposed disqualifying criteria for a high level health claim for sodium and hypertension as per Attachment 5 of the Draft Assessment Report (page 64), prevents regular milk from claiming its hypertensive benefits because it fails to meet the saturated fat criteria. The same is true for low- and regular-fat yogurts that exceed the proposed disqualifying criteria for sugar. Provides extensive evidence supporting this issue. • National Foods dismisses the need for disqualifying criteria. On the basis of available scientific evidence, high level health claims for sodium and blood pressure should be permitted on foods scientifically justified, including milk and dairy foods.

Submitter	Group	Comments
Dairy Australia Fonterra Co-Operative Group Limited	Industry-Australia Industry – New Zealand	<ul style="list-style-type: none"> • Whole milk cannot carry this claim due to the saturated fat content. • Whole milk is lower in sodium than reduced and low fat varieties so it may be confusing if reduced-fat and skim milk could make this claim but whole milk could not. • Rather than considering single nutrients in isolation, it is more relevant to examine the effects of the whole food. • Research indicates that it is inconsistent with scientific evidence to bar whole milk from carrying this blood pressure reduction claim. • Submission cites studies and provides more information and references to justify this (pages 24 – 26). • Sodium is not the only nutrient to affect blood pressure, potassium, magnesium and calcium also have a beneficial effect. • Recommends that if the saturated fat disqualifying criteria is kept for this claim, some food categories should be exempt – if there is good scientific evidence that the saturated fat present does not cause an increase in blood pressure or risk of cardiovascular disease (perhaps due to the effects of other beneficial nutrients contained in the food).

CALCIUM, VITAMIN D AND OESTEOPOROSIS/CALCIUM AND ENHANCED BONE DENSITY

Submitter	Group	Comments
Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry – Australia	<ul style="list-style-type: none"> • Prescription for over 65 year olds only is too narrow. • The age bracket should be lowered, as while more prevalent in older women, its aetiology begins much earlier than age 65. • The claim seems to be based more on evidence from fracture data (rates are obviously more prevalent in older age groups) without accounting for indicators of fracture risk such as bone mineral density. • A meta-analysis of 12 cohort studies showed that low bone mineral density (BMD) is indicative of fracture risk. (Johnell O, Kanis JA, Oden A, Johansson H, De Laet C, Delmas P, Eisman JA, Fujiwara S, Kroger H, Mellstrom D, Meunier PJ, Melton LJ 3rd, O'Neill T, Pols H, Reeve J, Silman A, Tenenhouse A. Predictive value of BMD for hip and other fractures. J Bone Miner Res. 2005 Jul; 20(7):1185-94. Epub 2005 Mar 7.) • This is also supported by evidence from Taylor et al (2004). (Taylor BC, Schreiner PJ, Stone KL, Fink HA, Cummings SR, Nevitt MC, Bowman PJ, Ensrud KE. Long-term prediction of incident hip fracture risk in elderly white women: study of osteoporotic fractures. J Am Geriatr Soc. 2004 Sep;52(9):1479-86). • Believe there is supporting clinical evidence to suggest the diet-disease relationship occurs much younger. In a randomized, double-blind, placebo-controlled trial, Bonjour et al (1997) showed that a daily supplement of 850 mg calcium for 48 weeks increased bone mineral content and bone size in 8-year old girls, with a trend for a greater progression in standing height (Bonjour J.P, Carrie A.L. et al. (1997). Calcium-enriched foods and bone mass

Submitter	Group	Comments
Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry - Australia	<p>growth in prepubertal girls: a randomized, double-blind, placebo-controlled trial. J Clin Invest., 1287-1294.).</p> <ul style="list-style-type: none"> • In a follow-up study undertaken more than three years after the girls received calcium supplementation, the effects of increased bone mineral mass had been maintained in the supplemented group (Bonjour J.P., Chevalley T. et al. (2001). Gain in bone mineral mass in prepubertal girls 3-5 years after discontinuation of calcium supplementation: a follow-up study. Lancet, 358, 1208-1212.). • In another large-scale randomised controlled trial, milk powder supplementation of Chinese school children resulted in significant increases in bone mineral density. The study concluded that supplementing the diet of Chinese children with milk powder was effective in enhancing bone accretion (Lau 2004 (full reference not provided)). • Osteoporosis and bone ‘health’ is a very pertinent issue for all ages and these studies highlight the long-term benefit of optimal calcium intake. They demonstrate the importance of maximising peak bone mass in early years because post-menopausal or age-related bone loss increases the risk of osteoporosis and fragility fractures. • It is therefore government responsibility to highlight the significance of these facts through relevant claims aimed at an age where preventative measures and actions can occur.
Goodman Fielder NZ Ltd	Industry – New Zealand	<ul style="list-style-type: none"> • Supports appearance of these claims appearing in the list of pre-approved high level health claims. Pleased to be able to utilise the new permissions and contributing to public health by strengthening consumer understanding of the relationship between dietary calcium and bone health/disease.
Parmalat Australia Ltd	Industry - Australia	<ul style="list-style-type: none"> • Concerned about the inclusion of qualifying criteria of no less than 300mg calcium/serve. As whole milk contains an average of 285mg calcium per serve, most whole milks will be excluded from making this claim. • Supports the substantiating framework for enabling manufacturers to incorporate high level health claims in labels in advertising. Welcomes inclusion of a pre-approved HLC for calcium, Vitamin D and Osteoporosis/Bone Mineral Density. • Recommends that for high level health claims relating to calcium, vitamin D and Osteoporosis that : <ul style="list-style-type: none"> – Qualifying criteria for calcium be reduced from 300 mg to 200mg, consistent with that of a similar claim for enhanced bone density. – Requirement that claim currently including the words ‘ reduce the risk of osteoporosis in women or men aged 65 years and older’, be removed or reworded to ensure it is not interpreted as applying solely to a population group 65 years or older.
Queensland Health	Government – Australia	<ul style="list-style-type: none"> • Pre-approved high level claims for osteoporosis should also be required to indicate that osteoporosis is a multifactorial disease and factors such as exercise, smoking, caffeine and phosphorus consumption also have an important role.
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • National Foods raises strong concerns with limiting the calcium and osteoporosis high level health claims to foods that have >300mg calcium per serve. Questions how this qualifying criteria was derived, considering the calcium and bone mineral density high level claim requires only >200mg calcium per serve.

Submitter	Group	Comments
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> Such criterion limits regular milk from making this calcium and osteoporosis claims, and yet a fortified water or sports drink may qualify. For example, Pura regular milk contains 295mg calcium per 250ml serve. Again, this signifies the impact of considering individual nutrients instead of whole foods. National Foods recommends that the high level health claim for calcium and osteoporosis be extended to the general population and that the qualifying criteria be matched to the calcium nutrition content claim being made (i.e. 200mg calcium per serve for a 'good source' claim).
Dairy Australia Fonterra Co-Operative Group Limited	Industry-Australia Industry – New Zealand	<ul style="list-style-type: none"> Prevents whole milk and some types of cheese from making this claim, because it contains 285mg calcium per 250ml serve. Can result in increased consumer confusion Claim is aimed at an older age group or men and women many who are frail and where whole milk is suitable. Inconsistent with the protection of public health that whole milk cannot make this claim. Whole milk should not be excluded from making this claim. Suggest the qualifying criteria are altered to no less than 200mg pr serve so that whole milk can carry this claim. Some types of cheese that appear similar will not be able to carry the same claim due to differing calcium contents. This is confusing for the consumer. All types of hard and semi-hard cheese are permitted to use this claim. Qualifying criteria for this claim be no less than 200mg per serve.
John Birkbeck (Massey University)	Academic – New Zealand	<ul style="list-style-type: none"> Why are sections 6.3.2.1 and 6.3.2.2 separated? They cover the same subject and one must always consider vitamin D status when making claims about calcium and osteoporosis.
Glycaemic Index Ltd (GIL) Dietitians Association of Australia (DAA)	Public Health - Australia	<ul style="list-style-type: none"> Foods with high level calcium claims should meet the 'conditions for general level claims other than a nutrition content claim' to be consistent with the other high level claims and therefore not provide unfair market advantage.
Dairy Australia Fonterra Co-Operative Group Limited	Industry-Australia Industry – New Zealand	<ul style="list-style-type: none"> Are pleased that the qualifying criteria are set at 200mg per serve rather than 300mg, meaning that all types of milk and yogurt and most hard and semi-hard cheeses will be eligible. p7 and 8 of Attachment 10 (to the Draft Assessment Report) outline important new evidence published since the Canadian review into calcium and bone health Need to consider the benefits of calcium intake after cessation of intake in context e.g. no expectation that eating a high fibre diet for a year will prevent constipation for life Increase in bone density of 1% sounds small but should not be dismissed and is noteworthy in terms of its economic impact. (note that sodium has a small effect on blood pressure reduction but this does not cause the effect to be dismissed). Recognition should be given to research of Professor Goulding (2004) showing that milk avoiders have a two-and-a-half time's greater than average fracture risk

Submitter	Group	Comments
Dairy Australia Fonterra Co-Operative Group Limited	Industry-Australia Industry – New Zealand	<ul style="list-style-type: none"> • There was inappropriately heavy emphasis on the Lanou review. Lanou et al (2005) is cited in Appendix 10, page 8 but does not comply with the standards set out for systematic reviews and is not free of commercial interests. • Recommends that greater attention is given to other reviews such as ‘Bone Health and Osteoporosis: A Report to the Surgeon General’ (2004) and ‘Nutrition and Your Health: Dietary Guidelines for Americans’ (2005). These are suitable reviews by authoritative bodies as stated on page 5 of Attachment 8. Detailed information is provided in the submission on these reviews. • Further information is provided in submission regarding the points above. • Recommends that a high level claim be permitted on all milk, yoghurt and cheese indicating that the intake of milk products is especially important to bone health during childhood and adolescence as it is protective against osteoporosis later in life. This will complement the claims already approved.

FOLIC ACID AND NEURAL TUBE DEFECT

Submitter	Group	Comments
John Birkbeck (Massey University)	Academic – New Zealand	<ul style="list-style-type: none"> • The lack of use of the folate claim currently permitted is related to the extremely limited extent to the claim which clearly can be considered to apply to only a tiny minority of the population. Wider claims of health benefits of folate need consideration. • Why specify pate and soft cheese, when pregnant women are advised not to eat them anyway?
New Zealand Food Safety Authority (NZFSA)	Government – New Zealand	<ul style="list-style-type: none"> • Requests that FSANZ reconsiders the way the terms ‘folate’ and ‘folic acid’ are referred to in the Food Standards Code. • The use of folic acid and folate interchangeably (table to clause 6) is misleading when it is now generally accepted that they are not equivalent due to the differences in bioavailability and absorption characteristics of naturally occurring folates and synthetic folic acid. 65 µg folic acid does not equate to 65 µg folate. • The term ‘dietary folate equivalents’ is also mentioned. • Standard 1.2.8 requires the nutrition information panel to declare folate. • As it is folic acid that the pre-approved high level health claim has been substantiated for, NZFSA believes that this term needs to be used in the proposed new standard, not folate. • Recommends FSANZ review the use of these terms throughout the Code to ensure consistency. This review should occur as part of the work on the adoption of the new NRVs in to the Code. The proposed new Standard should not perpetuate confusion.

Submitter	Group	Comments
Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B) Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry – Australia Industry – New Zealand Industry - Australia	HLC – general <ul style="list-style-type: none"> • The diet-disease relationships substantiated for high-level health claims appear very prescriptive. The objectives of encouraging industry and educating the public to address the prevalent health concern may be limited by the strong and lengthy wording. • A major issue under the folate promotional programme was the difficulty in marketing the fortified foods due to the prescribed health claim being a very negative message to appear on a food product, which was not well received by consumers, possibly even having a deterrent effect on purchase decisions. Possibly a significant reason that the existing programme was not overly successful. • Comprehensive public health campaigns using positive messages and more flexible wording through a variety of communication mediums need to be developed to encourage industry incentive and promote public consumption. Believe FSANZ should support the activities of food manufacturers to market claims effectively as they increase consumer awareness and trust. • Therefore prefer less rigidity with the language and phrasing of the prescribed claims, without being considered too generic or broad. For example, messages such as ‘folate supports healthy brain development in babies’ should be permitted as the relevant science to support the claim has been performed, making the claim accurate while being more marketable and better understood by consumers.
Heinz Australia/Heinz Wattie’s New Zealand	Industry – Trans Tasman	<ul style="list-style-type: none"> • Recommends the exclusion of products regulated from Standard 2.9.3 from making this claim, is deleted. • Notes that drinks such as Complian and Complian Positiv are formulated to meet the needs of pregnant women and contain added folate. In order to add folate and other nutrients into a powdered drink base, they must be made under Standard 2.9.3. • The Standard gives unfair advantage to supplements made under therapeutic goods or dietary supplements which are not prohibited from making these claims.
Therapeutic Goods Administration	Therapeutic – Australia & Trans Tasman	<ul style="list-style-type: none"> • The provisions that will permit folic acid and neural tube defect claims to be made for foods, do not have a requirement for the claim to be made within a dietary context of a ‘healthy diet’ or a ‘variety of foods’ as required for all other high level claims specified in the Table. This could allow therapeutic type claims relating to folic acid and neural tube defects to be made in relation to foods. The requirement in the Policy Guideline that claims in relation to food can only be made in the context of the appropriate total diet is paramount to differentiating between foods and medicines. • The folic acid neural tube defect claim could be placed in a dietary context with an extra condition that there is a statement accompanying the claim that it is important to maintain a varied diet.
Kellogg (Aust.) Pty Ltd	Industry-Australia	<ul style="list-style-type: none"> • Does not support disqualifying nutrients for High Level Health Claims; disqualifying criteria should only be applied if there is scientific evidence to support their inclusion based on the claim being made. Existing legislation already prohibits misleading claims.

Submitter	Group	Comments
Kellogg (Aust.) Pty Ltd	Industry-Australia	<ul style="list-style-type: none"> Note that all food products are required to carry a nutrition information panel which provides full information about nutrients and ingredients etc. The suggested inclusion of a %Daily Intake information may do more than disqualifying criteria to provide consumers with information about foods which contribute to their overall intake
Food Products Association (FPA)	Industry-International	<ul style="list-style-type: none"> Appreciates the flexibility in claim statements proposed and believes that clauses identified for these statements are appropriate Questions the product exclusion for claims made about folic acid and relationship to neural tube defects. Reiterates the need for FSANZ to move forward to approve additional claims related to disease risk reduction applicable to as wide a variety of foods and beverages as possible.
<p>Australian Food and Grocery Council</p> <p>(Supported by Nestle Australia Ltd and Nestle NZ Ltd, Unilever Australasia, George Western Foods Limited/AB Food and Beverages, Simplot Australia Pty Ltd)</p>	Industry, Australia	<ul style="list-style-type: none"> Notes that the folate health claim is a life stage claim (women of child bearing age) and should be considered in a consistent manner with other general level and high level claims as proposed by FSANZ for all life stage claims.

**Proposal P293 Nutrition, Health and Related Claims
Summary of submissions to the Draft Assessment Report**

17. SUBSTANTIATION

Submitter	Group	Comments
Complementary Health Care Council of Australia	Industry-Australia	<ul style="list-style-type: none"> • Does not support the rationale for not prescribing analytical methods (pg 26). • Supports the prescription of analytical methods to ensure consistency and minimise confusion and misinterpretation by the food industry and regulators, and to minimise misleading consumers. • Considers this issue to be critical and must be addressed if claims are to be substantiated and to assist enforcement agencies. Raises the real possibility that more than one method of analysis maybe used for an ingredient by different laboratories leading to obvious differences in results, may be misleading especially in comparative claims. • Notes that the issue of substantiation of a claim over shelf life including bioavailability of a product component has not been addressed. • Strongly suggests that specific, robust, validated, transferable analytical techniques are essential to verification that the nominated amount of the active substance in the food is bio-available over the shelf life. • Particularly relevant if the active substance is derived from a pre-processed concentrate or the active substance is an additive. • The nutrient must be present at the time of ingestion at a known content and must be bio-available. • Without clear guidance on these issues it is difficult to see how FSANZ will be able to meet the stated criteria of ensuring the levels of the property of the food about which the claim is made is sufficient to confer the claimed benefit (pg 18). • Strongly emphasises the importance of the substantiation of claims
Food Technology Association of Western Australia (FTAWA) Environmental Health Association Australia	Industry - Australia Government-Australia	<ul style="list-style-type: none"> • Further work is required on the substantiation process so that the standard is easily understandable • Materials for substantiation of general level claims must be easily accessible particularly for small business with limited resources. • Further clarification is required on resources for approval of high level claims. • Appropriate to have an independent expert panel that can review and assess health claims • Confidentiality is important and timeframes to suit new product development timelines (short).

Submitter	Group	Comments
Australian Competition and Consumer Commission (ACCC)	Government-Australia	<ul style="list-style-type: none"> • All substantiation must be evidence based and commensurate with the level of the claim, and consistent with regulatory guidance. It is understood that this will be expanded upon in the user guide. • Concerned that general level claims have the potential to lack transparency to consumers given that consumers cannot request the substantiating evidence. • The information should be sufficiently transparent and readily accessible. A lack of transparency and accessibility to corporate information may result in consumer dissatisfaction and/or complaints. • Irrespective of the amount of truth in a claim, if it is presented in a way that creates a misleading impression in the consumer’s mind, it may well be considered misleading under the Trade Practices Act.
Cancer Society of New Zealand Inc The Cancer Council of Australia	Public Health – New Zealand Public Health - Australia	<ul style="list-style-type: none"> • Supports the comprehensive substantiation framework developed by FSANZ. • Attachment 8, section 2.3.3, instead of the WHO reference, the correct reference is the World Cancer Research Fund; International Agency for Research on Cancer should be added to the list of internationally recognised scientific bodies’, Attachment 8, p 25. • The term ‘reasonable certainty’ (Attachment 8, page 4) should be further clarified with the definition for convincing evidence (pg 22).
Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry - Australia	<ul style="list-style-type: none"> • Note that different interpretations of evidence may result in different positions as to the efficacious level of a food property that is the subject of a claim. • Do not see these as an issue, as differences are unlikely to be large. Based on individual research, reasonable discrepancies concerning a stated dosage amount are to be expected even between standard test methods. • There are often maximum and minimum limits between which are a range of values, and many other factors can determine the final value. • In developing a substantiation framework or guidelines, FSANZ should review examples outlined in other countries. Existing frameworks should be explored where it is the quality “gold standard” of the trials rather than the quantity that is considered. • The degree of risk of the claim should reflect the amount of verification the submitter must provide – general level claims should not have the same threshold as stronger health claims.
Dairy Australia Fonterra Co-Operative Group Limited	Industry-Australia Industry – New Zealand	<p>General level health claims</p> <ul style="list-style-type: none"> • What happens when authoritative, generally accepted information is conflicting, for example a US peak organisation comes out with a more recent position paper than one from an Australian organisation? • Lack of clarity around substantiation of general level health claims • Scientific consensus does change but it can take organisations a few years to catch up, e.g. soy and heart health. • Information should be provided to companies about what to do in this situation.

Submitter	Group	Comments
Dairy Australia Fonterra Co-Operative Group Limited	Industry-Australia Industry – New Zealand	<ul style="list-style-type: none"> • Notes that the website suggested in attachment 8 (NHMRC) no longer works and a search of the NHMRC website for the position papers was unsuccessful. <p>Nutrient function statements</p> <ul style="list-style-type: none"> • Absence of a pre-approved nutrient function statement for vitamin A should be rectified. • Important for companies to communicate these benefits • Low vitamin A intake is a problem in Australia (statistics provided page 22 of submission). • Concern for pregnant women should be treated in the same way as Listeria and pregnancy where the relevant foods are eligible to make a claim, as information regarding excessive intakes of vitamin A in pregnancy is widely disseminated. • The claim for calcium is ‘Calcium is necessary for normal structure of bones and teeth’ is very dull, and unlikely to encourage consumers to select calcium-rich foods carrying this statement. • Suggests a more compelling statement, such as ‘Calcium is critically important to bone health’ (from Chapter 6, page 2 of the Surgeon General’s Report on Bone Health and Osteoporosis, US Department of Health and Human Services 2004).
John Birkbeck (Massey University)	Academic – New Zealand	<ul style="list-style-type: none"> • Substantiating material should be required to be submitted, not just held by a supplier. • All such claims (low level) should be lodged with FSANZ, albeit they need not routinely be screened for compliance, however of random check of say 5% to discern whether unreasonable claims are being made without sufficient substantiation. • A non complying claim could lie dormant for years unless challenged by a competitor, etc. • Food composition tables - the margin of error is typically quite large, sometimes very much so. They should not normally be allowed as source of nutrient values but are designed for population studies where such variation is covered by the sample size (pg 66).
Kellogg (Aust.) Pty Ltd	Industry-Australia	<ul style="list-style-type: none"> • Commends the work that has been done to develop the framework and the type of evidence required to support communication of both general and high level claims is well documented in the Draft Assessment Report. • Believes it is important that FSANZ work with industry in developing and finalising the user guide documents and would welcome an opportunity to be involved
New Zealand Food and Grocery Council (FGC)	Industry – New Zealand	<ul style="list-style-type: none"> • Agrees with the approach that while nutrition content claims and general level claims must be scientifically substantiated they will not require pre-market assessment and approval. <p>High level claims</p> <ul style="list-style-type: none"> • Support the establishment of a robust substantiation framework as proposed in Attachment 8. • Note concern that high level of proof that will be required in respect of a health claim may preclude Applications.

Submitter	Group	Comments
<p>New Zealand Food Safety Authority (NZFSA) New Zealand Food Safety Authority (NZFSA)</p>	<p>Government – New Zealand Government – New Zealand</p>	<ul style="list-style-type: none"> • Voluntary claims raise consumer expectations of that product and there should be a corresponding step up in regulation regarding the respective ‘property of the food’. • Questions whether the use of an average value for properties of a food provides a sufficient level of substantiation to match consumer expectation. This was not considered in the draft assessment report. • Where the property of the food that is the subject of a claim is added as a fortificant, they believe that the manufacturing process should be such that defined tolerance limits of variation should be defined and able to be adhered to. • From an enforcement perspective the use of average values is problematic and defined tolerance limits would rectify this. • The use of an ‘average’ for the amount of the biologically active substance with no specified tolerance limits makes it difficult to ascertain compliance. • Will suppliers will be required to hold a complete substantiation dossier if they make a general level health claim relating to maternal ‘folate’ intake, or can they reference the FSANZ pre-approved high level claim substantiation? <p>Nutrient function statements</p> <ul style="list-style-type: none"> • Requests clarification with respect to the use of nutrition function statements from the Joint Health Claims Initiative list that have not been chosen for inclusion on the ‘model list’ of nutrient function claims. • Specifically, if a claim that is specific rather than general, appears in the Joint Health Claims Initiative list of substantiated nutrient functions but does not appear on the model list for nutrient function statements under Standard 1.2.7, can that claim be used and considered substantiated subject to verification that the claim is relevant to the Australian/New Zealand populations? • If not, NZFSA request justification as to why certain claims are on the model list for the proposed new standard while other claims have not been included. For example for iodine, the statement “iodine is necessary for the normal production of thyroid hormones” has been chosen to be on the model list while “iodine is necessary for normal neurological development” and “iodine is necessary for normal energy metabolism” are not included.

Submitter	Group	Comments
New Zealand Institute for Crop & Food Research Ltd	Academic and Other - New Zealand	<ul style="list-style-type: none"> • Prefer that nutrition analysis be made mandatory for nutrient claims and that all values on which a nutrient claim is based need to be obtained directly from analysis of the food in question. Recognise though that this may not be practical in all circumstances. At least, would like current guide clarified on this point and if a claim is made more computational rigor is needed. Actual nutrient measurements are required for consumer confidence. It is misleading and deceptive under fair trading laws if claims are based on a particular composition but analysed amounts are very different. • Support the development of user guidance documents, in particular to assist with the accurate determination and maintenance of nutritional data used by manufacturers. • Regarding non-compliance due to inaccurate food composition data. Under a substantiation framework the source of the data used to calculate nutrition label values is increasingly the prerogative of the manufacturer, and guidance or guidelines should be clear. • The NZFSA study looking at Fortification Overages in the Food Supply (1) clearly indicates that overages contribute a large uncontrolled variance in the values reported on labels. Support the statement made in this report that “consideration may be given to defining a tolerance around the label claim that incorporates these uncertainties”. Would like to extend this to the adoption of similar recommendations to those currently used by the US FDA (2). • To evaluate the accuracy of ALL label values, various classes have been determined by the FDA, i.e. <ul style="list-style-type: none"> – Class I nutrients must be present at 100% or more of the value declared on the label; – Class II nutrients must be present at 80% or more of the value declared on the label; and – Class III must be 120% or less. When checked for compliance the values are expressed as a ratio/error by this calculation: (laboratory value / label value) x 100 = % <p>¹ Thomson, B Fortification Overages of the Food Supply Folate and Iron, Environmental Science and Research Ltd, September 2005</p> <p>² FDA Nutrition Labelling Manual (1998) – A Guide for Developing and Using Data Bases, see http://www.cfsan.fda.gov/~dms/nutrguid.html</p>
Rae Frampton	Consumer – New Zealand	<ul style="list-style-type: none"> • Supports the approach that claims must be substantiated with scientific evidence and assessed by FSANZ.
Coles Myer Ltd (CML)	Industry, Australia	<ul style="list-style-type: none"> • They make every effort to ensure compliance of private label range of food products with legislation and industry codes of practice. • Division 2, Subclause 5 (1) (a) of draft Standard 1.2.7 requires that the supplier of the food has records substantiating the (conditions for general level) claim. They would require clarification of the definition of ‘supplier’ in the substantiation framework as there is currently no definition of this term in the draft standard. Coles is the ‘brand owner’ of the brand names on Coles Housebrand food products but does not manufacture a single product itself. Is the responsibility for holding the evidence for substantiation the responsibility of CML or the manufacturer?

Submitter	Group	Comments
Coles Myer Ltd	Industry, Australia	<ul style="list-style-type: none"> • CML welcomes the opportunity to be involved in further discussions on the issues of substantiation. <p>Nutrient function claims</p> <ul style="list-style-type: none"> • Clause 5(1)(a) states it is a nutrient content claim condition that the supplier must have records substantiating the claim. “Supplier” is defined in Standard 1.1.1 to mean “the packer, manufacturer, vendor or importer of the food in question”. Request that condition 5(1)(a) be clarified to confirm that is not the obligation of a retailer such as Coles Meyer Ltd to undertake this record keeping function.
Health World Ltd	Industry-Australia	<ul style="list-style-type: none"> • Believes that FSANZ should also accept traditional types of data as well as scientific data. • Traditional evidence is accepted by the Therapeutic Goods Administration for use in complimentary medicines. These foods have been used by cultures for hundred of years. • Chinese, Indian and Indigenous foods are increasingly being used as the demographics of society changes. • These foods are acknowledged by people to have known nutrition purposes e.g. garlic, cinnamon, tomatoes, soy and mushroom. • Substantiation of claims should follow a specific set of requirements, which should be made available through the Standard or in an annex to the Standard. • Questions of transparency need to be reviewed. • Questions which need answering include: will the sponsor be able to submit further information/data to substantiate claims; is there a cost associated with submission of a high level claim; what timeframe is allocated for completion of the review; how will FSANZ take action against initial claims which are later deemed unsuitable due to conflicting evidence and will the manufacturer be penalised? <p>High level claims</p> <ul style="list-style-type: none"> • Ensuring good manufacturing practices and using high quality materials is the only way the consumer can be assured that the high level nutrition claim can be attained and that health and safety is not compromised. • Quality of the raw materials should be assured that that they comply with minimum standards. These standards must be underpinned to a pharmacopeia or similar reference. • If a biomarker is part of the claim then each batch of finished product must be analysed for that marker. • Manufacturing processes should have a high standard. Each batch of food produced must have auditable quality and production records that traces the finished product back to the raw materials used. These records must be made available on request.
Jenny Robertson Consulting Services (Jenny Robertson & Dan Southee)	Industry, Australia	<ul style="list-style-type: none"> • COAG principles have been reflected in the Ministerial policy advice to FSANZ, particularly in the requirements for a rigorous scientific substantiation of high risk claims, generic claims where evidence is clear and minimum regulation where risk assessment indicates the protection of public health and safety.

Submitter	Group	Comments
National Centre of Excellence in Functional Foods	Academic & Other – Australia	<ul style="list-style-type: none"> • Supports the proposed general processes for substantiation of claims, however would like to reiterate the points made known to FSANZ in August 2005. NCEFF has undertaken systematic reviews of 37 potential health claims for products, involving the detailed evaluation of 251 individual published studies. Through this process two key areas have been identified as problematic. <ol style="list-style-type: none"> 1. Classifying the totality of evidence 2. The level of evidence required to substantiate a potential claim • Have also considered the processes of review <p>Classifying the totality of evidence</p> <ul style="list-style-type: none"> • In section 2.4.1 of the proposed substantiation framework in P293 Initial Assessment Report, there are 11 factors suggested for consideration in assessing the totality of evidence and in section 2.4.2, four categories of evidence are defined, based on the WHO classification. When NCEFF analysts tried to apply this, they found no clear relationship between these two sections. The definitions allow a considerable degree of subjectivity in the final classification. Significant difficulties were encountered in differentiating between the definitions of Probable and Possible evidence in practice. Considers this implies the need for a more clearly defined process that enables the classification to be undertaken in amore objective reproducible fashion. • Considers it would be helpful if the definitions in the substantiation document related directly to the factors identified in section 2.4.1 and could incorporate a more explicit method for classification. For example, it could be based on the following key criteria: 1. Higher quality supportive studies exist. 2. There is consistency of findings across study types. 3. A biologically plausible mechanism is available. 4. Dose-responses have been determined 5. The studies show that beneficial effects have population health significance. • While a claim with Convincing evidence would be expected to have all criteria satisfied, there could be some differentiation for a Probable level claim (e.g. criteria 3 and 4 above). For a Possible level claim, perhaps only the first criteria need to be satisfied. These issues would benefit from strong scientific debate, but would serve as a start. The guidelines to accompany the process description could also include worked examples to assist companies to ensure their evaluations are acceptable and are as objective as possible. <p>Levels of evidence</p> <ul style="list-style-type: none"> • In the Initial Assessment Report draft framework for substantiating health claims it is stated that approval of high level claims “is likely to require convincing scientific evidence” (pg 171). The use of the term ‘likely to require’ in this statement, suggests that there may be times when Probable scientific evidence will be appropriate. I using the draft framework for substantiating general level claims, NCEFF analysts found that it is often difficult to obtain Convincing evidence for a claim. While obviously Convincing evidence is preferred, analysts found that Probable evidence is usually the highest level of evidence obtained for general level claims.
National Centre of Excellence in Functional Foods	Academic & Other - Australia	

Submitter	Group	Comments
National Centre of Excellence in Functional Foods	Academic & Other – Australia	<ul style="list-style-type: none"> • It would be useful if examples could be given of when Probable evidence could be considered adequate for the substantiation of some general level claims. When the evidence may be bordering on Possible or Probable, it could be considered to incorporate into the process an evaluation of the potential risk that the claim carries. For example, the following two claims: ‘soluble fibre for promoting healthy bacteria in bowel’ and ‘soluble fibre is important for decreasing cholesterol absorption’ could be considered as lower and higher risk general-level claims respectively. The risk associated with such general level claims could relate to the risk of serious behaviour change which has the potential to adversely affect an individual’s overall health or management of a health condition. • If the claim is considered ‘lower-risk’ then when the evidence distinguishing between Possible or Probable is not clear, the choice to classify the claim as ‘Probable’ is relatively safe, particularly if it is supporting dietary patterns consistent with general dietary guidelines. However, should the claim be considered ‘higher-risk’ and there is a greater element of uncertainty, then the safer choice would be to classify the evidence as ‘Possible’. • Recommends guidelines providing explanation or inclusion of a list of nutrient/health outcome relationships, which may form the basis of claims considered ‘lower-risk’ and ‘higher-risk’, and some examples, may be a useful tool to assist in the application of the substantiation process. <p>Review processes</p> <ul style="list-style-type: none"> • The process by which the review of claims is conducted falls within a set of practices that have been developed in other areas involving scientific review and critique, such as the assessment of grant applications through the ARC and NHMRC. Important features include transparency in processes, assurance of appropriate expertise, accountability and systems for dealing with declarations of conflict of interest. • Recommend FSANZ consider the processes followed for the development of the review infrastructure and processes with reference to existing bodies under government auspices, such as the ARC and NHMRC. Consideration could also be given to the current processes for addressing reviewer bias published by the World Cancer Foundation. • As outlined in first submission to the Initial Assessment Report, the standard should not be ‘anti-innovative’. The standard needs to accommodate advances in science, and thereby food innovation, to the general benefit of society. • Will be evaluating processes and reviewing data from NCEFF reports to gain a better understanding of the types of evidence available in the food and nutrition field and how this might be applied in an evidence-based practice sense, in this case to nutrition marketing. • Would be happy to share findings with FSANZ when available to assist in the development of guidelines to Standard 1.2.7 and finalisation of the claim substantiation framework. • Would be willing to work with FSANZ to provide worked examples of the evidence classification process for general level claims.

Submitter	Group	Comments
National Centre of Excellence in Functional Foods	Academic & Other - Australia	<p>General level health claims</p> <ul style="list-style-type: none"> • Page 30 of Attachment 8 – Substantiation Framework of the Draft Assessment Report states “When interpreting information contained in dietary guidelines, it is important to bear in mind that the guidelines apply to the total diet and not to a single food within a diet. Where the dietary guidelines documents indicate that evidence for a relationship is weak, this suggests that the relationship is not substantiated to a consistently agreed level.” • It would be useful if the term ‘evidence for a relationship is weak’ could be quantified. In the Dietary Guidelines for Australian Adults, the strength of evidence relating to diet-health relationships is described in terms of a scale comprised of six levels of evidence (I, II, III-1, III-2, III-3, IV) as determined by the NHMRC. Weak evidence could perhaps be considered to be any level of evidence less than level II. • Refers to the Dietitians Association of Australia, in conjunction with the New Zealand Dietetic Association publishing and regularly maintaining a list of text books and as stated in Attachment 8 would be appropriate for use in substantiating general level claims. • Using current textbooks used in University Dietetics courses can vary considerably in terms of the quality of information used to substantiate the information contained in the text. For example, when references were checked on information in a textbook which appeared to substantiate a general-level claim, the studies referenced were conducted in animal models. Other textbooks may contain statements which support a general-level claim however the text is not referenced with scientific papers which may not be suitable of substantiating a general level claim. • Questions whether one textbook is sufficient or should the substantiating information be sited in several textbooks. Considers that when the information of the textbook is not referenced with scientific papers more than one textbook should be required. • If textbooks are to be permitted there will need to be a careful quality assurance process to ensure that the Dietetic Associations reference suitable books and that there is agreement from the associations that they would comply with such a process. • Suggests that the following statement in reference to the Draft Substantiation Framework under 4.4.2 of Attachment 8 of the DAR be moved to section 4.3.4 which refers to the current scientific texts for substantiating general level claims, to ensure the point is not missed. “...a search of the scientific literature published since the texts were released should be carried out to ensure no major new evidence has emerged that would modify the conclusions reached in these documents.”
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • Recommends that all foods should be able to describe their substantiated claimed benefits in relation to the whole food itself, or the ingredients or nutrients contained therein. <p>High level claims</p> <ul style="list-style-type: none"> • In principle, accepts the approach for high level health claims but raises concerns with limited application and scientific substantiation.

Submitter	Group	Comments
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> • Supports the implementation of high level health claims based on robust, credible scientific evidence in order to facilitate a climate of acceptance amongst the consumer and enable innovation for the manufacturer. • Supports the inclusion of information for high level health claims - the pre-requisites, wording conditions and claims criteria. Supports the development of a comprehensive users-guide to facilitate understanding and implementation of the high level claims substantiation process, including a list of pre-approved high level health claims. We highly recommend including a flow chart, summarising the three substantiation steps and related sub-steps. • National Foods recommends the restriction on only three biomarkers being suitable for high level claims be removed, and the wording amended to recognise that any biomarker that meets the conditions and criteria as stated on page 34, Attachment 8, be permitted for use in any application for approval of a biomarker high level health claim. • National Foods raises strong concerns with the substantiation process undertaken for four (noting there are subsets for bone and heart disease), of the seven pre-approved high level health claims. We state that the above Policy Principle and Claims Classification Criteria have not been aptly followed. • The current pre-approved high level health claims are restrictive on their applicability and have not considered all of the available scientific evidence. • As only four of the seven reviews for high level health claims have been completed, National Foods asks for clarification when the substantiation for the remaining three will be available for public comment, namely: <ul style="list-style-type: none"> – 1. omega-3 (long-chain) and coronary heart disease – 2. fruits and vegetables and coronary heart disease – 3. wholegrains and coronary heart disease. • National Foods believes FSANZ has failed to appropriately substantiate high level health claim for calcium and osteoporosis, putting great emphasis on a review paper by Lanou et al (2005). This paper by the Physicians Committee for Responsible Medicine concluded that there was scant evidence to support increasing dairy products to promote child and adolescents bone mineralisation. Despite its negative conclusion, certain studies did support a small beneficial effect of dairy and calcium on bone health. • Provides extensive studies relating to this issue. <p>Nutrient function statements</p> <ul style="list-style-type: none"> • FSANZ, as per Attachments 8 and 10, have proposed a list of pre-approved general level health claims for inclusion in a user-guide. The list is indicative, rather than exhaustive. Wording conditions and criteria must be followed – however wording is for the ‘nutrient function statement’ only (not the entire general level health claim). • The proposed list excludes fat, saturated fat, trans-fatty acid, sodium, vitamin A, fluoride, chloride and potassium. • National Foods applauds FSANZ for this initiative as it facilitates consistency of communication messages to

Submitter	Group	Comments
National Foods Ltd	Industry, Australia	<p>consumers, and eases the substantiation process for industry and enforcement agencies.</p> <ul style="list-style-type: none"> • National Foods recommends the list for pre-approved general health claims be expanded – consulting further with the Canadian Food Inspection Agency and JHCI lists – to maximise consistency of communication messages and implementation by industry. • National Foods believes FSANZ has wrongly limited the nutrients permitted for pre-approved general level health claims, and recommends a review of the list to include fat and vitamin A, as a minimum. • Also asks for a commitment from FSANZ in continuing to undertake new reviews for general level claims for pre-approval, to ensure the list (available in a users-guide) is reflective of the weight of scientific evidence.
Seafood Services Australia	Industry – Australia	<ul style="list-style-type: none"> • Is concerned about the potential cost impost for substantiation of new health claims (both general & high level claims). • For primary food producers it will be difficult for individual businesses to invest in and capture the benefits of such substantiation due to the general nature of their products – this is particularly the case for high level claims. • Manufacturers involved in new product development (with appropriate IP protection) do have the ability to capture direct benefits from their investment in substantiation of claims – although this is more likely for large companies and not small to medium enterprises (SMEs) that comprise the majority of Australia’s food manufacturing industry. • The apparent overly cautious approach to accepting overseas evidence will contribute to the potential costs and will be difficult to bear by the Australian food industry. Many food companies operate globally and develop packaging and advertising for a product line for use in all markets. Inconsistent application of health claims would add additional costs not only to the manufacturer/producer/distributor but also to consumers. <p>General level health claims</p> <ul style="list-style-type: none"> • Requires clarification on whether the information for substantiation needs to be held by individual companies or whether such information can be gathered and held in a central location (e.g. industry association) accessible by individual businesses and enforcement agencies as needed. • Questions why reviews undertaken by overseas authorities can only be used in substantiation of general level claims if those reviews are conducted to the same standard as FSANZ proposes for substantiation of high level claims – this appears to be inconsistent. <p>High level claims</p> <ul style="list-style-type: none"> • The cost of undertaking work required for high level claim substantiation has potential for adverse public health outcomes if relevant diet based disease management and prevention information is not made readily available. • Given the potential cost impost, consideration should be given to including substantiation of high level claims high in the National Research Priorities for government investment, and on a whole of government basis such that unnecessary duplication does not occur.

Submitter	Group	Comments
Department of Human Services Victoria	Government – Australia	<ul style="list-style-type: none"> • Recommends that Australian Standards and/or internationally recognised analytical methods to analyse foods for compliance with qualifying and disqualifying criteria be included in the guidelines to the Standard. • This will facilitate certainty and consistency for manufacturers and regulators. • Failure to do so will result in legal argument about which test methods are acceptable and the use of different methods, providing different results. This will be problematic for enforcement. • The issues of analytical error, batch error and seasonal variations have made enforcement of NIPs difficult. • Suggests that a maximum tolerance from the defined disqualifying criteria be mandated or included in the guidelines. <p>High level claims</p> <ul style="list-style-type: none"> • Consider that the evidence should be reassessed at a minimum every 5 years to ensure consumer safety and relevance of these claims. • Recommends adding the following to the substantiation process for future high level claims: <ul style="list-style-type: none"> – Evidence based on human studies only. – Animal model studies and in vitro studies may be provided as supporting knowledge base only. – Trials should not demonstrate a negative nutritional and health impact. – Preference for double blind randomised controlled trials.
Community and Public Health, Canterbury District Health Board	Public Health – New Zealand	<ul style="list-style-type: none"> • Acknowledge that substantiation for general level claims is comprehensive. • Believe that substantiation of general level claims which are not nutrition content claims needs to be assessed by a technical body and not by the enforcement body. Alternatively, the general level claim needs to be pre-approved. • For enforcement it needs to be very clear whether a claim is adequately substantiate or not, and enforcement bodies may have varying levels of resource or expertise to be able to make that assessment. The assessment also needs to be consistent and hence would be better undertaken by one body. • Pre-approval of claims would prevent non-compliances.
Food Products Association (FPA)	Industry- International	<p>General level health claims</p> <ul style="list-style-type: none"> • Endorses the view that manufacturers must ensure that all claims are truthful and substantiated by scientific evidence • General level claims in relation to the presence of a specific nutrient or the function of that nutrient in relationship to health should be permitted when that information is scientifically established <p>High level claims</p> <ul style="list-style-type: none"> • Canada recently implemented labelling amendments that recognise that diet-disease reduction relationships have been scientifically substantiated to support claims related to fruit and vegetables and some types of cancer. • Encourages FSANZ to take advantage of this evidence which would allow the pre-approval of additional claims without imposing redundant/unnecessary burdens on industry to provide and regulators to assess the evidence.

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Health Outcomes Team, Auckland Regional Public Health Service	Public Health – New Zealand	<ul style="list-style-type: none"> The authoritative, generally accepted information sources that can be used need to be tightly specified to avoid arguments about the quality of the evidence.
Kraft Foods Ltd	Industry - Australia	<ul style="list-style-type: none"> Notes that nutrition and health claims must: be substantiated; make reference to a specific property of the food; and other than nutrition content claims, make reference to a specific health benefit. Notes that the draft Standard allows for exemption to this where the substantiation concludes it is not scientifically practical to identify a specific property, in which case a class of properties or the whole food may be referred to. This exemption is supported, as components such as vitamins can have impact on many different areas of the body, so to isolate one at a time might be confusing.
Meat and Livestock Australia	Industry – Australia	<p>General level health claims</p> <ul style="list-style-type: none"> Agrees in principle to FSANZ’s framework for substantiating general level claims. However, in circumstances where there is no pre-approved nutrient function statement, does not agree that a thorough systematic review is required to substantiate claims, given the low level of risk to the consumer. <p>High level claims</p> <ul style="list-style-type: none"> Supports FSANZ approving the proposed six generic high level claims. Rigorous proof would be required to substantiate high level claims. Believes this process would be extremely time-consuming and expensive. According to the NHMRC (FSANZ suggests following the NHMRC guidelines), a thorough systematic review will take on average 30 weeks to complete. Many food companies would have to employ personnel with the specific skills needed to conduct a thorough systematic review (i.e. skills in comprehensive literature searches and the ability to appraise scientific studies across a wide range of nutritional areas). Assuming high level claims would be generic, and not limited to the submitter, it is unlikely small food manufacturers/marketers would have the resources to prepare submissions for high level claims. It is also questionable whether consumers would understand the differences between high level and general level claims, thus general level claims are probably sufficient to inform consumers about the health benefits of a product. There appears to have only been two generic health claims approved by the JHCI-UK since 2002. Industry groups rather than individual food manufacturers/marketers i.e. Soya Protein Association and Omega-3 Health Claims Consortium generated both submissions. The proposed Substantiation Framework is based on the level of evidence required for the therapeutic management of specific diseases therefore it is questionable whether the same process is necessary and applicable for the substantiation of health claims. In relation to FSANZ’s proposed evidence for high level claims, believes in some circumstances it would not be realistic or necessary to provide evidence from a “substantial number of human studies” and seems unnecessary provided the evidence comes from a single high quality study.

Submitter	Group	Comments
Meat and Livestock Australia	Industry - Australia	<ul style="list-style-type: none"> • Recommends that FSANZ allow high level claims to be possible using evidence from at least one well-controlled experimental human study, in an appropriate population, using appropriate end-point(s), provided there is supporting evidence from other studies. e.g. substantiation of a claim about a specific product formulation would require at least one well-controlled experimental study, plus supporting evidence from other studies showing a causal diet-disease relationship between several components that make up the whole product. • Does not consider observational studies such as prospective cohort studies as a main source of evidence because these studies do not measure “cause and effect”. • Recommends that under certain circumstances manufacturers /marketers should have to prove the ingredient’s/component’s are effective in the associated product/food rather than just the ingredient/component e.g. the efficacy of iron and zinc on health will vary depending upon the make up of the food. A wholegrain food fortified with iron and zinc will not have the same effect on health as the same amount of iron and zinc occurring naturally in red meat. This needs to be considered when substantiating claims to avoid misleading the consumer. Alternatively higher qualifying criteria could be used for wholegrain foods making claims about iron and zinc.
Mrs Mac’s Pty Ltd	Industry- Australia	<ul style="list-style-type: none"> • Framework needs to require minimal resources for the substantiation of general level claims.
Nestle Australia Limited and Nestle New Zealand Limited	Industry – Trans Tasman	<p>General level health claims</p> <ul style="list-style-type: none"> • Although the draft assessment report (6.2.1) states that analysis is preferable, Nestle note that it is not always necessary to analyse the final product, because the nutrient level of raw materials might be well known with other control measure in place to ensure compliance of the claim, and there is permission to use nutrition tables. • The analysis of product can be used as a verification of compliance of the claim, with other validation methods used to test the claim itself. • Although the draft Assessment report states that evidence must be relevant to Australians and New Zealanders, Nestle consider that evidence from other parts of the world should be accepted, although it should be shown to be relevant to Australia and New Zealand. • Substantiation user guide should be developed in consultation with industry and subjected to consultation prior to development of the standard. As the proposed changes are significant, the user guide must be available at gazettal of the standard. <p>High level claims</p> <ul style="list-style-type: none"> • The Draft assessment report states, “high level claims will be subject to qualifying criteria based on the substantiating evidence....” Concern is that: <ul style="list-style-type: none"> – There is no quantitative definition to the term “substantiating evidence”. As it stands, any scientific publication may be construed as sufficient. – The grading of evidence has not been discussed in the Draft Assessment Report. In other words all scientific

Submitter	Group	Comments
Nestle Australia Limited and Nestle New Zealand Limited	Industry – Trans Tasman	<p>evidence provided for substantiating a claim need to be graded on the basis of the scientific work undertaken and the acceptance of the work within the scientific community.</p> <ul style="list-style-type: none"> – There must be clear criteria to establish the quality and degree of evidence needed. • Fully support the requirement for substantiation and is interested in playing an active role in developing a template for the preparation of a Scientific Substantiation Dossier including guidelines for providing and grading evidence.
Therapeutic Goods Administration	Therapeutic – Australia & Trans Tasman	<ul style="list-style-type: none"> • Recommends that the substantiation requirements for general level claims should be included with the requirements for high level claims in the Standard at the time of its introduction. • Considers that any other approach would lead to a protracted period of varying degrees of industry compliance, the likelihood of consumers being misled and imposing an unnecessary burden on enforcement agencies in the interim. • Notes TGA’s experience from 1999 with allowing guidelines for substantiating general level claims to be in a ‘guideline’ rather than underpinned by legislation. The transition phase of 4 years was too long in terms of encouraging industry compliance, leaving the guidelines unenforceable where non-compliant sponsors chose to challenge them.
NSW Food Authority	Government – Australia	<ul style="list-style-type: none"> • The term “supplier”, as defined in Standard 1.1.1, has the potential to create enforcement barriers. If the option exists for the supplier to be the manufacturer or packer, in the case of imported foods, the manufacturer or packer will be overseas and therefore beyond the powers of jurisdictions to demand the substantiation records. • Suggests that 5(1)(a) be amended to require that in the case of imported foods, the substantiation records be held by the importer of the food, which could result in records being held by multiple importers. This is unlike the TGA, which allows only one importer to import or sponsor a product. • It is not practical to require the retailer, as the vendor of the food to hold the substantiation records as this would result in records being held by multiple vendors. • Suggests that 5(1)(a) be amended to require that the records be held by the manufacturer, where the food is manufactured in Australia or New Zealand. In the case of contract packing (e.g. Woolworths brand), the records should be held by the vendor. Where the product is imported, the importer should hold the records (this would not include foods imported into Australia from New Zealand and vice versa). Jurisdictions engaged in enforcement could then rely on the “State of Origin” arrangements. • It is not clear who must be satisfied with substantiation and what appeal mechanisms are in place e.g. is it sufficient to satisfy the authorised officer, the Food Authority or a higher authority? • It may be necessary to make an extra provision which places an obligation on the supplier to make the records available, rather than just being in possession of the records. Notes, however that powers under the Model Food Act includes the power to demand records etc.

Submitter	Group	Comments
Queensland Health	Government – Australia	<p>General level health claims</p> <ul style="list-style-type: none"> • The issue of who (e.g. an authorised officer, Government agency) must be satisfied with substantiation and what appeal mechanisms are in place needs to be clarified. • An extra provision is required which places an obligation on the supplier to make the records available, rather than just being in possession of the records. <p>Nutrient function statements</p> <ul style="list-style-type: none"> • The pre-approved nutrient function claim with respect to Docosahexaenoic acid (DHA) should more clearly indicate that the benefit to brain, eye and nerve development is for foetal development, not adult development.
Tarac Technologies	Industry, Australia	<p>General level health claims</p> <ul style="list-style-type: none"> • There is no comment in the substantiation guideline about the level of evidence required; will the level of evidence required by the same for high level and general level claims that are based on the assessment of all available scientific evidence? • If the level of evidence is the same there will not be any differentiation between the requirement for a general and high level claim, even though the risk, as related to a function of the body or non-serious disease, is much lower. This is non-consistent with the foundation of a step approach to regulation. • Recommends a more consistent approach between the proposed regulation and the guideline may be that a minimum of “probable scientific evidence” according to WHO, is required to substantiate general level claims that relate to functions of the body and non-serious diseases. <p>High level claims</p> <ul style="list-style-type: none"> • The evaluation of the evidence to substantiate a high level claim, based on a comprehensive review of all available evidence, is well defined in section 2.3. • There is no comment in the substantiation guideline about the level of evidence required; will the level of evidence required by the same for high level and general level claims that are based on the assessment of all available scientific evidence? • If the level of evidence is the same there will not be any differentiation between the requirement for a general and high level claim, even though the risk, as related to a function of the body or non-serious disease, is much lower. This is non-consistent with the foundation of a step approach to regulation.
South Australia Department of Health	Government – Australia	<ul style="list-style-type: none"> • Recommends that commonly used general level claims e.g. claims in relation to calcium and iron, be set out in the Standard with pre-approved wording. This assists small business and makes enforcement easier.

Submitter	Group	Comments
Campbell Arnott's Asia Pacific	Industry-Australia	<ul style="list-style-type: none"> • The three biomarkers suitable for substantiating high level claims appears overly restrictive and does not take into account any emerging new evidence. This restriction should be removed. • Wording should be amended to recognise that any biomarker that meets the condition and criteria stated (page 34 of Attachment 8) should be permitted for use in any application for approval of a biomarker high level claim.
Chamber of Commerce and Industry of WA	Industry-Australia	<ul style="list-style-type: none"> • Process for high level claims requires two round of public consultation which exposed a company's intellectual property to competitors which in turn limits the company's opportunity to recover its research and development costs from the market • Industry prefers a risk based system that enables truthful and scientifically substantiated statements that may protect consumer health, to be on food.
Confectionery Manufacturers of Australasia Supported by CMA NSW Branch, Queensland Branch, SA Branch, Victoria Branch and Langdon Ingredients CMA NZ Branch International Confectionery Association	Industry – - Australia Industry – New Zealand Industry - international	<ul style="list-style-type: none"> • Queries the ability of enforcement agents to ensure compliance with the substantiation provisions for health claims. Will verification be conducted to ensure producers hold the required substantiation to support their claim and potential health benefit?
Food Technology Association of Victoria Inc.	Industry-Australia	<ul style="list-style-type: none"> • Concerns expressed about the level, sources and qualifications of the examiners of the substantiation supplied and required to support such a claim
New Zealand Nutrition Foundation	Public Health – New Zealand	<ul style="list-style-type: none"> • Diet-disease relationships rely on large, selected population-focused studies, the interpretation of complex and often tortured statistical analysis, a disease and/or biomarker focus, and any author/s bias. • It is easy to justify almost anything with a careful selection of papers. Meta-analysis improves scientific confidence. Gold standard double blind trials are rarely possible. • Are we putting too much emphasis on the evidence of disease prevention as a marker for a high level claim? • Notes the reviews are nutrient-health claims and arguable not diet-health claims. • Suggests that Nutrient Reference Values are used to define food/nutrient relationships.

Submitter	Group	Comments
Australian Food and Grocery Council (Supported by Nestle Australia Ltd and Nestle NZ Ltd, Unilever Australasia, George Western Foods Limited/AB Food and Beverages, Simplot Australia Pty Ltd)	Industry, Australia	<ul style="list-style-type: none"> • Supported by Kraft Foods in its endorsement of the proposed approach to the management of high level claims • FSANZ have proposed (Attachment 8 P34) that only 3 biomarkers are suitable for substantiating diet disease relationships for high level claims: serum cholesterol; bone mineral density and blood pressure. • This is unnecessarily restrictive. FSANZ have included a biomarker definition (see below) which would suggest that others are possible. However, no mechanism is suggested by which a new biomarker might be validated <ul style="list-style-type: none"> – A measurable biological parameter which, when present at an abnormal level in the human body, is predictive of the risk of a serious disease. • The AFGC recommends that the restriction on only 3 biomarkers being suitable for high level claims be removed and the wording amended to recognise that any biomarker that meets the conditions and criteria stated on P34 (Attachment 8) should be permitted for use in any application for approval of a Biomarker high level claim.
Parmalat Australia	Industry, Australia	<p>High level claims</p> <ul style="list-style-type: none"> • Supports the substantiating framework for enabling manufacturers to incorporate high level health claims in labels in advertising. Welcomes inclusion of a pre-approved HLC for calcium, Vitamin D and Osteoporosis/Bone Mineral Density. <p>Nutrient function statements</p> <ul style="list-style-type: none"> • Commends FSANZ in providing a number of pre-approved general level health claims that will reduce the resources needed by industry in gathering substantiating data.
Glycaemic Index Ltd (GIL)	Public Health - Australia	<ul style="list-style-type: none"> • Previous advice from ANZFA in 2001 was that glycaemic index claims were nutrition function claims, not nutrition content claims and should therefore be regulated as general level health claims • If the GI remains as nutrition content claims, and no disqualifying criteria are required for content claims, GIL will continue to be disadvantaged in the market place.
Adecron Food Tech Consulting	Industry – New Zealand	<ul style="list-style-type: none"> • Suggest entering the pre-approved general health claim statements into the regulations or in a more closely associated appendix. Not like in the proposal where it was hidden further away than the pre-approved higher level health claims.
Horticulture New Zealand	Industry - NZ	<ul style="list-style-type: none"> • Government should produce a set of guidelines of acceptable wording with the aim of making fruit and vegetables preferred food choices. • The guidelines should include a number of pre-approved general level claims plus as many high level claims as can be substantiated. The national Fruit and vegetable Alliance (FAVA) should be invited to prepare such a list for ratification.
Murray Goulburn Co-operative Co Ltd	Industry - Australia	<ul style="list-style-type: none"> • Supports the Dairy Australia submission on the inclusion of a pre-approved nutrient function statement for vitamin A.

Submitter	Group	Comments
<p>National Heart Foundation of Australia</p> <p>National Heart Foundation of New Zealand</p>	<p>Public Health – Australia</p> <p>Public Health - New Zealand</p>	<ul style="list-style-type: none"> • Heart Foundation believes it is an anomaly that general level function claims for vitamin A, saturated fat and sodium are excluded from the pre-approved list in Attachment 10, yet content claims for these are permitted subject to meeting the requirements of the Table to clause 11 and general level health claims permitted subject to the conditions in 5(2). The rationale given in Attachment 10 is that saturated fat and sodium are risk-increasing nutrients and because of safety concerns for vitamin A. However, a nutrient function claim may not necessarily be promoting the benefit of a nutrient – for example, manufacturers may claim that saturated fat will ‘clog arteries’ and sodium may ‘harden the arteries’ or ‘reduce arterial flexibility’ – the Heart Foundation suggests it would be preferable to have some pre-approved function claims for these nutrients rather than leaving them to manufacturer creativity. • On the other hand, if function claims for nutrients that are not in the pre-approved list (e.g. vitamin A, saturated fat and salt) are intended to be prohibited, then the standard should explicitly state that only the nutrients in the pre-approved nutrient function statement list can have general level claims (nutrient function or risk reduction of non-serious disease) made.
<p>Horticulture Australia Ltd (supported by Horticulture Australia Council and SPC Ardmona)</p>	<p>Industry - Australia</p>	<ul style="list-style-type: none"> • Mandating scientifically validated analytical methods for compliance with qualifying and disqualifying criteria will ensure consistency for both manufacturers and regulators.