FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Supporting document 1

Summary of submissions to the March 2009 Consultation Paper – preferred options

P293 – Nutrition, Health & Related Claims

Executive summary

FSANZ released a consultation paper in March 2009 seeking stakeholder views on two options for the regulation of general level health claims.

Option 1 was based on industry self-substantiation as recommended in the Final Assessment Report, but with minor amendments. The amendments included more explicit guidance for industry on the data requirements for food-health relationships that would meet a 'convincing' level of evidence.

Option 2 (presented as the preferred option) proposed pre-approval of food-health relationships which could be used as the basis for general level health claims and provided a list of 105 such relationships in Schedule 2 of the revised draft Standard. A food business would need to make an application to FSANZ for the inclusion of a new food-health relationship in the new Standard prior to using a health claim based on that relationship.

Submitter responses were categorised as follows:

- *Option 1* – 13 submitters (18%) supported either with or without variations
- *Option 2* – 28 submitters (39%) supported either with or without variations; four submitters (6%) opposed Option 2 but did not mention if they supported Option 1
- *No preference for 1 or 2* – 17 submitters (24%) opposed both options; five submitters (7%) opposed Option 2 but did not state a preference for Option 1; and eight submitters (11%) did not specify either way.

That is, in effect, out of 71 responses only 7 submitters (10%) fully supported Option 1 and 26 submitters (37%) fully supported Option 2 (see Table 1).

Table 1: Stakeholder group preferences

Sector	Option 1	Option 1 with variations	Option 2	Option 2 with variations	Other [a]	Total
Public Health [b]	-	-	9	-	1	**10**
Government	-	-	6	-	1	**7**
Food Industry	7	6	5	2	25	**45**
Consumer	-	-	3	-	-	**3**
Other [c]	-	-	3	-	3	**6**
Total	**7**	**6**	**26**	**2**	**30**	**71**

a. Includes submitters who either opposed one or both options, and/or did not specify a preference. Some submitters proposed variations on options 1 or 2 or new options.
b. Includes nutritionists/dietitians, public health and non-government organisations
c. Includes organisations associated with therapeutic products and their regulation, research institutions and partnerships

Most jurisdictions and public health stakeholders supported Option 2. Reasons given for their support included:

- the prevention of misleading claims and provision of better information to consumers
- claim relationships would only be approved where there is sufficient evidence
- FSANZ would provide an independent assessment of claim relationships
- it would result in a reduced resource burden for enforcement agencies and a reduced risk of inconsistent enforcement
- it could be implemented immediately within the existing legislative framework
- the cost of assembling evidence for an application for a supplier should be no different to that for self-substantiation.

Food industry submitters were generally more supportive of Option 1, as it was seen to allow more flexibility, competition and innovation. Food labels would not require significant changes and thus Option 1 was considered less disruptive to industry. The comment was made that industry self-substantiation has been successfully operating and is already subject to consumer and other fair trading laws.

For those 35 submitters (49%) who suggested a new option (including a variation of one of the two options proposed), their suggestions were often not well explained. Some food industry submitters supported Option 1 only if amendments were made. The following variations were suggested:

- re-examine the level of evidence required for substantiation, as 'convincing' is too high
- provide further guidance on substantiation Methods 3 and 4. A high level of confidence is needed before embarking on potentially costly development and substantiation processes
- remove the nutrient profiling scoring criterion from Option 1 as it restricts the use of credible information
- modify substantiation Methods 1-4 so that they are more definitive for enforcement (e.g. under Method 2, actual general level health claims that are approved by international regulatory bodies could be listed in the Standard).

In addition to the above, submitters also made the following suggestions to assist jurisdictions with enforcement relating to general level health claims:

- combine options 1 and 2 (i.e. adopt Option 2 with Methods 3 and/or 4). Under this variation, FSANZ would prescribe general level health claims in the Standard and industry would substantiate any further claims
- develop a guideline for general level health claims
- create one enforcement agency to prevent inconsistent verdicts between jurisdictions. FSANZ was seen as the most suitable body to apply or manage enforcement
- use fair trading provisions to alleviate the jurisdictions' concerns.

In the Consultation Paper, FSANZ sought comment on whether Method 4 should remain in Option 1. A number of manufacturers confirmed that they wanted Method 4 included.

Some industry submitters, who did not support Option 2, made suggestions for improving this model in the event that it is finally adopted. The following were recommended:

- consult industry bodies on emerging claims of interest at a pre-competitive level, so that efforts are focused on new claims, without undue burden to industry
- include Method 4 (or a self-substantiation or GRAS type system) to encourage innovation
- remove the nutrient profiling scoring criterion
- include more general level health claim relationships
- make whole foods a priority for extending Schedule 2
- align the level of evidence that supports health claims for food with the level required for therapeutic goods
- amend the level of evidence for substantiation so that it aligns with the degree of promise and the sixth policy principle in the Policy Guideline.

Fifteen submitters (21%) specifically proposed a co-regulatory approach with a non-regulatory component particularly for general level health claims, either with or without some requirement for third party assessment of suitable claims. Co-regulation was seen as the balance between protecting public health, preventing misleading conduct and facilitating trade. It was argued that a co-regulatory system can facilitate responses in a timely manner when change is required and such a system favours minimum effective regulation for low risk claims and full regulation for high risk claims. Some submitters were of the view that FSANZ should consider a third party certification or verification model even if it requires legislative reform. Reasons were that it could assist jurisdictions with enforcement, help industry develop systematic reviews and provide both industry and consumers with confidence in the system via certifications.

FSANZ also received comments that both options were unenforceable and inconsistent with the Policy Guideline.

A summary of submitter comments relevant to the options for the regulation of general level health claims.is provided in Table 2.

Table 2: Preferences for Option 1 or Option 2 (as presented in Section 8) of the March 2009 consultation paper

Submitter	Comments
Consumers	
Alison Wallace	• Prefers Option 2. • Would provide better information for consumers, and result in fewer un-validated claims. • Claims would only be permitted if there is sufficient evidence and independent scrutiny • Huge burden for industry to collate information; may not have expertise to critique information, which may result in wrong conclusions being made.
CHOICE	• Supports Option 2. • Option 2 would be consistent with all three primary objectives in the FSANZ Act. • Addresses Minsters' concerns about the enforceability of the Standard and manufacturers marketing foods in ways that contradict public health messages or misleads consumers. • Option 2 will also enhance consumer confidence because claims would be pre-approved by an independent food regulator. • FSANZ is best placed to pre-approve GLHCs. A pre-approval system would also provide clear guidance about the claims that can legally be made. • Notes that many manufacturers don't have access to the necessary resources and expertise to undertake substantiation of GLHCs. • Opposes Option 1 as it would still rely on food manufacturers to establish a convincing level of evidence for their claim. Individual enforcement agencies would still bear the burden of assessing this evidence to substantiate the claims. Would also place an unreasonable burden on those States with a bigger food manufacturing sector. • Commends FSANZ for the significant improvement in the rigour that will underpin the new health claims standard. The latest changes, combined with the proposed NPSC, instil greater confidence that the right balance is achieved between allowing claims to market products, and protecting the health and interests of Australian consumers.
Consumer NZ	• Supports Option 2. • Option 2 would be consistent with all three primary objectives in the FSANZ Act and the new approach will improve enforceability of the Standard. • FSANZ is best placed to pre-approve health claims as it has the authority and expertise. This will also give clearer guidance to industry and improve consumer confidence. • Have been opposed to nutrition and health claims on foods but note considerable improvements to the Standard over the last few years which will go some way to ensuring consumers are protected from misleading and unsubstantiated claims.
Food Industry	
Adecron Ltd	• Supports Option 2 • Unclear why the GLHC application procedure cannot be a confidential procedure. • Would be easier to provide advice with regard to label claims, when they are pre-approved in a list.
AFGC	• Opposes both options. • Propose further work be delayed until after the independent Review on Food Labelling Law and Policy. • Option 2 is too restrictive; Schedule 2-only claims would restrict expansion of product ranges and discourage innovation. • Legislation usually lags behind R&D; significant costs involved to expand range of GLHC. • Concerned about how Option 2 affects substantiation; FSANZ states the level of evidence is not predetermined to be 'convincing' as it will be determined case-by-case and 'other factors' can be taken into account. While such an approach is vaguely reassuring, it leaves open the question of whether it is consistent with the position of making 'sound, scientifically supported' decisions.

Submitter	Comments
	• Providing a paid application raises the questions of confidential data. Applications for GLHC or NCC would be open to public scrutiny. Market advantage would then be eroded and there would inevitably be a 'free-rider' effect for other manufacturers.
Australian Beverages Council Ltd (ABC) (supported by the Australasian Bottled Water Institute (ABWI))	• Opposes both options. • Option 2 would provide less flexibility in bringing new GLHCs to market. • Pre-approval (9 months application process) would take much longer than self substantiation and is too long when waiting for products to be launched. • No protection of confidentiality/exclusivity or first-to-market advantage. Application costs and justification (without the confidentiality of HLHC applications) could be inhibitory for industry. • Permitted Schedule 2 claims do not provide adequate expansion and encouragement of innovation by industry. • The level of scientific data, not being prescribed as 'convincing' but determined on a case-by-case level could run the risk of evidence or authoritative sources being questioned, disputed and challenged during the consultation process. • Other internationally recognised sources in addition to the EU Official Register of Health Claims should also be recognised as acceptable authoritative sources e.g. a number of nutrition and health claim frameworks and regulations in operation in other developed countries. • Option 1 is slightly less inhibitory, as it would allow more flexibility in terms of speed and cost of applications and access for market entry. However, it is still undesirable because of the burden it would place on jurisdictions and enforcement agencies and the complexity of evaluating whether a food actually meets the requirements of GLHC. • Potential for inconsistent enforcement across jurisdictions.
Australian Nut Industry Council and Nuts for Life	• Prefers Option 1with Method 4 (systematic review) retained. • This Option would allow GLHCs to be substantiated in a timely manner; provides ability to develop own systematic reviews to substantiate GLHCs without the need for prior approval. • Process is similar to the Therapeutic Goods Administration's system for claims on complementary medicines. • Opposes Option 2. • Option 2 is too restrictive because: – ANIC/Nuts for Life will not be able to register claims already in the market place prior to gazettal by any of the proposed methods other than Method 4. – There is no approved nut heart health claim in the UK JHCI which can be automatically added to Schedule 2 – There is no pre-approved nut heart health claim developed by FSANZ, although there is a 2003 US FDA approved qualified health claim for nuts and heart disease – There are no nut health relationships filed with the Cochrane Database despite there being more than 100 published papers on nut health relationships on nuts health benefits. • Seek clarification as to why scientific findings must be current and produced within the last five years. Previous discussions with FSANZ have indicated that the entire body of evidence should be submitted to substantiate claims. Much of the epidemiology research on nuts occurred from 1994 and hence would be excluded from a submission. Suggest that the entire body of evidence be submitted and assessed. • Could support Option 2 if FSANZ could prioritise reviewing whole food health claims prior to, and during, the transition phase. This would ensure whole food such as nuts, which are recommended by public health authorities, can be adequately promoted for the health of all Australians. • The main benefit of Option 2 is that the level of evidence is no longer prescribed by FSANZ allowing greater flexibility in the decision making process. Common sense and science rather than just a prescribed *convincing* level of evidence will be required to substantiate claims. Suspect that with the volume of research for nuts and heart health now available, we may have a convincing level of evidence already.

Submitter	Comments
	• Options 1 and 2 will be costly as we will have to commission a substantiation document during the transition period.
Axiome Pty Ltd on behalf of Danisco Australia Pty Ltd	• No Option preference specified. • Option 2 would have serious consequences for innovation of new food ingredients and foods, due to likely very significant regulatory assessment costs and delays, removal of the incentive to develop and utilise proprietary information specific to beneficial health effects for their ingredients and foods, and the creation of an overly complicated, inhibitive and prescriptive regulatory environment. • Danisco contracted NCEFF to evaluate one of their food ingredients for potential GLHCs in anticipation of the introduction of Standard 1.2.7 and the substantiation approach proposed at Preliminary Final Assessment. It was intended to provide NCEFF food industry clients with supportive evidence (Danisco's proprietary information) for any GLHC that resulted from the NCEFF evaluation, so that foods incorporating this ingredient could be developed and marketed on the basis of conferring a health benefit. More than 20 clinical studies and reports concerning the physiological effects of the ingredient were provided to NCEFF and from their review a number of "convincing" and "probable" GLHC'S were determined. The cost for completion of this work was substantial and under the revised approach, this opportunity will be lost. • If preapproved during the transition period, GLHCs would be available for use with foods incorporating the same ingredient from a competitive manufacturer, thereby losing any commercial benefit to Danisco and their clients. • For GLHC's developed after the transition period, the time required for processing an application will result in delays to market or significant additional costs if the application was expedited. Commercial advantage would then be lost. • Diminished incentive to develop and seek approval of GLHC's for ingredients or foods unless the products in question are protected by patent or other licensing type arrangement. • The original approach for industry self-substantiation has been successfully operating, and subject to consumer and other fair trading laws, many health type claims are currently made about foods, that would in future be classified as GLHC's under Standard 1.2.7. • The proposal to include/update pre-approved GLHC's for general food industry use in the Standard is supported with some amendments suggested. • Essential that the use of GLHC's is not limited by overly prescriptive and regulatory requirements. This is consistent with the Ministerial Council guidelines in respect to relaxing restrictions on use of health claims with foods, and the general aims of the Code for less prescriptive regulation.
Bayer Australia Pty Ltd	• Supports Option 2. • Provides a more level playing field as it would be more prescriptive in the types of claims allowed and would be more easily monitored by regulatory authorities. However, the claims proposed under Option 2 are too broad. • Schedule 2 allows foods that qualify to make even stronger GLHCs than therapeutic goods, although the food may have substantially less evidence for efficacy. Could lead to confusion among consumers. • Permitting food to make GLHC for non-serious and serious health conditions with often much less evidence to support the claims discourages the therapeutic goods industry from constantly innovating and conducting research in to health benefit relationships with overlapping food/therapeutic good ingredients e.g. vitamins • Schedule 2 may encourage more foods to have GLHCs just because they meet minimum requirements. This could add to more consumer confusion. • Based on Schedule 2, the food industry would be allowed to refer to serious health conditions in advertising/packaging; unlike therapeutic goods. This seems unfair. Propose that food industry have the same restrictions apply to them in the type of GLHC allowed in Schedule 2. • Opposes Option 1 because it would provide an opportunity for varying opinions as to the degree of evidence required to make GLHC, so would be open to interpretation and this freedom may be taken advantage of by unscrupulous parties.
Beneo- Orafti Group	• Opposes both options.

Submitter	Comments
	• Option 2 provides no confidentiality for the applicant and therefore erodes any potential competitive advantage. High applications costs without confidentiality/ownership would dissuade manufacturers from making applications. • No incentive for innovation and investment in nutrition research. • Regarding proposal that data requirements for applications are included in the Application Handbook: – *the findings need to reflect a consensus within the scientific community* - consider this is unrealistic and likely to be unachievable, especially in relation to areas of emerging science. – *findings are current and produced within the last 5 years* –likely to take more than 5 years to undertake the necessary studies and assemble a body of data to support a new claim. This is unrealistic and impractical and a disincentive to innovation and investment in research.
Boehringer Ingelheim	• Supports Option 1. • Would be the least disruptive in relation to product labelling, provided that food companies hold the evidence for the nutrition content claims or GLHCs. • Extends requirements for nutrition claims. • Still provides consumers access to the best quality food products, more information about the food. • Legislates that companies hold the evidence for every single nutrition content claim, which is not the requirement of Option 2. • Provides fair system for companies to provide enforcement agencies with a 'convincing level' of evidence. • Opposes Option 2 • Option 2 would require significant product changes, result in an unfair market place for those products for which evidence is held by their companies (as Option 2 no longer requires companies to hold evidence for scheduled claims) • Does not necessarily protect consumers from deceptive or misleading conduct, as enforcers will still be responsible for seeking out non-compliant companies.
Brewers Association of Australia and New Zealand	• Supports Option 2 • Understands that Option 2 would permit brewers to continue to make energy and carbohydrate claims, and to provide literature on the medical benefits of moderate alcohol consumption on consumer websites.
Cadbury Pty Ltd	• Supports Option 1. • Although Option 1 does not provide an ideal process for claim substantiation, it is preferred over Option 2 has critical issues that impose a time and cost burden & would limit innovation and reformulation. • Concerns about Option 2 are: – Lack of confidentiality – The time required to process an application – The required level of evidence is not prescribed – Cost barrier – No prescribed wording – Ongoing maintenance of a schedule of pre-approved claims
Calorie Control Council	• Opposes both Options. • Opposes proposed criteria for GLHC relationships. There is no confidentiality through the application process, which would infringe on the potential for competitive advantage. High application costs are also a deterrent. As a result proposed approach stymies GLHCs as a commercially viable option for product placement. • Supports the co-regulatory approach for nutrition content claims and GLHCs as proposed by AFGC.\
Campbell Arnott's Asia	• Supports Option 1, but only with the following amendments:

Submitter	Comments
Pacific	– Remove the NPSC requirement from GLHCs, as applying the NPSC inadequately considers the diversity of foods and further restricts the use of credible information for consumers. – Supportive of science-based substantiation from recognised authoritative sources; recommends guidelines be developed for acceptability of such sources. • Opposes Option 2 because: – Whole of diet criteria to single foods should not be applied to GLHCs, as it fails to take into consideration micronutrients and renders many foods ineligible to carry GLHCs. – Confidentiality issues will impact innovation negatively i.e. no first-to-market advantage. – Costly and lengthy process of pre-approval – Enforcement issue not resolved with pre-approved GLHCs. Acknowledge that it is not feasible to develop prescribed wording, but notes that this will result in an uncertain enforcement environment due to the potential for inconsistent interpretations across jurisdictions.
Chamber of Commerce and Industry of Western Australia	• Opposes Option 2, but no mention of supporting Option 1. • Would support GLHCs in a Guideline outside the Standard. • Option 2 has the potential to stifle innovation due to the length of time required to vary a Standard. The potential result in following this approach is that industry will be denied protection of intellectual property during the application process and first to market advantage.
Coles Supermarkets	• Supports Option 2, with following amendments: – Schedule 2 should include a thorough list of GLHCs. • GLHC requirements may be too rigid and could stifle innovation. • Notes the costs and time associated with making an application. • Queries why GLHCs do not have the same level of exclusivity as HLHCs and asks if company data in new applications could be treated as confidential. • Queries what words in Schedule 2 can be varied so the claim can be more consumer friendly. • Queries who will enforce these claims, noting that a consistent enforcement approach is needed.
Confectionery Manufacturers of Australasia Ltd (CMA)	• Opposes both options. • Both options fail to meet the needs of stakeholder groups. • Option 2 would slow innovation, increase bureaucracy, provide no appreciable enforcement improvement and relegate Australia and New Zealand to second class in food science developments globally. • The pre-approval phase of Option 2 will slow market delivery of new products. Food industry would have to wear higher costs and slower product development return on investment, jobs as manufacturing becomes a commodity and is shipped offshore. Consumers would be no better informed and face higher food prices and less choice.
CSR Ltd	• Supports Option 2. • Adoption of GLHC will simplify the introduction of new products into the market. • New food products will significantly improve health outcomes, which is consistent with Ministerial Council policy principles. • Option 2 will help consumers understand that GLHCs are underpinned by relevant clinical research.
Dairy Australia	• Opposes both options in their current form. • Option 1 may result in inconsistent enforcement and be a significant burden on industry with regard to seeking clarification of acceptability prior to use of a GLHC. • Concerned about the proposal to remove Method 4 – Systematic Review. This method is the most appropriate method to substantiate new food-health relationships. Communication of health benefits to consumers is a strong research driver. • Recommends that Method 4 be retained in Option 1, or similar model if such an option were to be pursued, with clearer guidance as to

Submitter	Comments
	what constitutes a 'consistently agreed' or 'weight of evidence' relationship when using this method, as per 'Substantiation Requirements' within the Policy Guideline. • Any variation on the proposed Option 1 model should retain the intent and principles of the Claims Classification Criteria and Substantiation Requirements, within the Policy Guideline. • Option 2 as it has been presented poses a number of problematic issues. It does not appear to be consistent with the Policy Guideline on Nutrition, Health and Related Claims with respect to some of the policy principles. • The approach to pre-approve GLHC may impede fair trading, both domestically and internationally. Claims that may have been approved via costly research and application on specific product related criteria may be picked up by other products that contain that component but not in the same context. Consequently, the claim may not be valid but it would be difficult for any enforcement agency to manage as the manufacturer would not be required to provide evidence of the substantiation. If GLHC are not approved on a similar level of substantiation as other major international exporting countries, Australian products may be placed at an export market disadvantage in regions that require imported products to comply with exporting regulation. • Innovation in new food products leading to healthier products may be restricted. Innovation and ongoing research will be restricted if the financial viability is made more doubtful through increased costs related to a pre-approval process, extended time to market whilst seeking approval, potential confidentiality issues, and the inability to clearly communicate the benefit of the innovation to the public. • All claims will be pre-approved and listed in the Standard, for both HLHC and GLHC, rather than substantiated and classified on the basis of the 'degree of promise to the consumer'. Application of health and food relationships is not seen as an area of sufficient value to pursue. • All relationships between foods, components and sources of substantiation should be treated equally, for instance if one core food group can be approved for GLHC on the basis that the Dietary Guidelines/NRV documents provide a scientific basis for establishing a link between the food group and disease or biomarkers then all food groups should also be given approval for GLHC on this basis. • GLHC should be consistent with dietary guideline advice and substantiating documents as well as NRV background documents.
Fonterra Co-operative Group Ltd	• Opposes both options. • Considers that neither Option 1 nor Option 2 adheres to certain policy principles in the Policy Guideline. • Also considers that FSANZ has not given due regard to some of the principles outlined in the FSANZ Act.

Submitter	Comments
	• Primary concerns are around the use of Method 4 which are relevant to both options, and the requirement for a level of convincing evidence in order to substantiate a claim that falls outside the scope of Methods 1 to 3. Method 4 is particularly key to sustaining and encouraging industry food innovation. • Method 4 is also vital to the suite of claims that currently exist on our products. • Undertakes considerable validation work to substantiate claims and to ensure that there is no risk to legislative challenge in relation to misleading and deceptive conduct. Also has an internal nutrition policy that underpins our work to develop innovative nutritionally sound products. • Current claims may not meet the level of substantiation required as provided in Attachment 7 of the Consultation Paper. There is a degree of ambiguity and interpretation in regards to what makes a 'substantial' number of studies and where an association moves from 'moderate to consistent'. For example, if from a total of 16 papers, 15 papers show a positive effect of an ingredient on a health outcome, and one paper shows no effect, queries where the level of evidence then falls. • The requirement to have a convincing level of evidence has already been illustrated as difficult to achieve during the consideration of the HLHCs. However requiring the same level of confidence under Method 4 for a GLHC is not aligned with the Policy Guideline and furthermore contradicts this. • Understands the enforcement and legal issues that have arisen at Final Assessment Report which are associated with the decision to change the level of evidence required from 'probable' to 'convincing'. Under the new proposed Option 2, the onus is taken from the enforcement agencies and the advantage is that the anticipated legislative difficulties are removed. However, if Option 2 is adopted, requests some consideration and amendment around the level of substantiation required for Method 4. • Under Method 4, conducting research may also be more difficult to gain approval and funds for due to this ambiguity. May also impact adversely on general scientific research undertaken by public institutions (Universities, CSIRO, etc) and science expenditure. Public institutions are often contracted by the food sector to conduct research. Research projects may be commercial in nature resulting in intellectual property (specific bio active ingredients), while they may also be for the broader public good (e.g. wider investigation of the effects of dairy on health at a pre competitive level). A potential impact on the requirements of Method 4 is a shrinking of the critical mass of the Australian food science and nutrition science capability. The proposed substantiation requirements for GLHC are potentially adding 3-5 years onto new product development times which will lead companies to shy away from this type of research and reduce their investment in making the food supply more nutritious.
Fonterra Co-operative Group Ltd	• The level of substantiation being proposed is not so different from the current health claims situation in the European Community (EC). Indication from industry in the EC is that the level of uncertainty is substantial enough for reconsideration of research priorities and withdrawal of applications to make a claim. • Comments specific to Option 1: notwithstanding the previous comments, is of the opinion that Method 4 is important to enable continued innovation and general research in the area of health and diet/food relationships.
Food and Beverage Importers Association (FBIA)	• Opposes both options. • For Option 1, while maintaining self-substantiation as an option, its effectiveness would be significantly weakened by the foreshadowed removal of Method 4. Method 4 is important for continued innovation and general research into health and diet/food relationships. • Option 2 strays from the principles set out in the Policy Guideline and is unnecessarily restrictive. The necessity to apply to FSANZ for the addition of a new claim will not encourage innovation. The application process itself is lengthy.
Foster's Group	• Opposes both options. • Foster's shares the broad concerns raised by the AFGC in their submission on P293 that the proposed changes will produce a Standard with a high degree of complexity for consumers, industry and enforcement agencies. In our view it is questionable whether the proposed changes would place the food industry in a better position than exists under the current law.

Submitter	Comments
Frucor Beverages Ltd	• Supports Option 1. • Opposes Option 2 because there is no confidentiality or security of application information. Given the transparent nature of all applications, disclosure of market sensitive information to competitors is a major concern. This would substantially diminish any competitive advantage of 'first to market' for any new innovation. • The regulatory burden would result in delays for achieving 'speed to market'. • It is not apparent how the pre-approved GLHCs will be monitored and reviewed, as no time frame or system is identified. It is not made clear as to the make-up of any labelling review panel and the level of expertise that would be required to determine whether new and existing GLHC's will be approved.
George Weston Foods Ltd and on behalf of AB Food and Beverages (GWF)	• Supports Option 1 with variations. • Believe it will provide a credible, safe and useful system for stakeholders to use and manage health claims. An effective health claims regulation will help support industry funded nutrition research and innovation. • Option 2 requires applications to be made on an ongoing basis for additional claims to be added to this Standard. Notes that Schedule 2 contains claims that we would already hold substantiation for. • Understands that enforcement agencies have expressed concerns regarding Option 1, however Option 2 still requires enforcement agencies to monitor claims and ensure compliance to this Standard. Fair Trading legislation also provides protection against false and misleading claims. • Option 2 also shifts the burden for assessment of scientific evidence to FSANZ, which will significantly increase the workload for FSANZ. Unclear how FSANZ can supply the resources necessary to fulfil this task. • The current draft Standard reduces the incentive for industry to be involved in nutrition research and innovation.
Go Grains Health & Nutrition Ltd	• Supports Option 1 • Option 1 allows the food industry to substantiate GLHC relationships and brings claims to the market in a timelier manner than Option 2. It also gives industry first to market advantage for GLHC's, which is not provided by Option 2. The more explicit guidance given to industry on the data requirements for GLHC relationships should help ensure the types of claims being made by the food industry are scientifically valid and sounds. • Opposes Option 2 because it would stifle innovation due to lack of confidentiality protection or first to market benefit, delay in getting products to market and potentially imposes additional costs on industry if are required to assemble evidence and pay FSANZ to expedite process.
Goodman Fielder Ltd	• Opposes both options • Agree that Option 1 is unlikely to be supported by enforcement agency it is therefore not a viable scenario. • Option 2 remains restrictive towards innovation, includes the requirement for nutrient profile scoring, and will add costs through enforcement agencies. • Concerned that industry will be required to make paid applications to include function claims for new innovations or with developments in scientific research. • Notes the risk that other manufacturers may take advantage of this work and copy relatively quickly.
Heinz Australia and Heinz Wattie's (Heinz)	• Opposes both options. • For Option 2, FSANZ should provide additional GLHC's in Schedule 2 (that can be substantiated) prior to gazettal of the Standard. A significant number of GLHC's currently in the marketplace could be considered by FSANZ and added to Schedule 2, saving FSANZ and industry significant time and money by providing a Standard that is scientifically based and giving consumers clear public health messages. For example, wholegrains, antioxidants and probiotics. • Notes that FSANZ has indicated applications or proposals could be considered (with one round of public comment) within nine months, but

Submitter	Comments
	considers that it would be extremely difficult for FSANZ to simultaneously manage the influx of applications/proposals in a nine month timeframe. • Rejects Option 2 as a feasible option as it is overly prescriptive, not providing enough flexibility to enable innovation in the industry with speed to market. • Option 1 relies on the manufacturer to hold the substantiation documentation (self-substantiation), and to work from prescribed resources. Manufacturers would be asked to provide evidence for the claim to enforcement agencies. Heinz believes this is unnecessarily suppressing innovation and burdening the enforcement agencies. • Rejects Option 1 as it will be difficult for industry to maintain all substantiation documentation to convince different enforcement agencies, it is possible the enforcement agencies may draw different conclusions without adequate guidance from the Code. This will place restrictions on innovation and speed to market.
Horticulture Australia Limited (HAL)	• Supports Option 1 with variations. • Notes need for any system to support the consumption of a wide range of fresh natural foods as outlined in the Australian Dietary Guidelines, meet FSANZ objectives and also be in support of existing public health policy directions in terms of promoting healthy dietary intake. • Option 1 provides the necessary flexibility for industry, while at the same time maintaining a high level of evidence. • Support the inclusion of Method 4, as it has been shown to be particularly relevant in determining the role of dietary patterns on emerging health issues over time and the ongoing identification of the foods, nutrients or inter-relationships between foods that may lead to health benefits. • Supports a process under which GLHCs can be determined by taking into account not only scientific evidence but also all other relevant factors. • Option 2 may deliver more certainty, but industry more strongly supports the need for a framework of self substantiation. • A disadvantage of Option 2 is that any applications do not have the protection of confidentiality or first-to-market advantage. If this Option is pursued HAL supports the suggestion made in the document that this aspect could be changed with future legislative amendment. Such an amendment would add consistency to the process adopted for both GLHCs and HLHCs. • However, if Option 2 is implemented, it will provide industry with greater surety as to the permissible health claims for individual products. The approach that establishes permitted claims and provides the opportunity for new claims to be presented, tested and either approved or rejected is seen as providing clarity and will enable industry to more effectively know its position when applying health claims in the marketing of specific products.
International Chewing Gum Association (ICGA)	• Opposes both options. • Notes that it appears enforcement agencies won't support Option 1. • Option 2 would impose greater costs on industry and regulators. Manufacturers will need to file regulatory petitions with FSANZ with more formal filing requirements. This will also increase the time needed to bring new products and new GLHCs onto the market. • Option 2 will also require FSANZ to create and staff a central office to conduct scientific review of all GLHC, requiring a not-insignificant amount of FSANZ resources. • Fear that Option 2 may reduce industry's incentive to innovate, reducing the range of 'better for you' products, because of lack of confidentiality or first to market advantage.
Kellogg's (Aust.) Pty Ltd (Kellogg)	• Opposes both options. • Considers that FSANZ should defer any further work on P293 until the outcomes of the Comprehensive Review of Food Labelling and Policy are known. • Neither Option 1 nor Option 2, as proposed addresses key issues raised by the ANZFRMC on 20 June 2008, meet the requirements of the Policy Guideline, or meet the objectives for developing or varying a food standard, which is defined by Section 10 of the FSANZ Act.

Submitter	Comments
	• Notes that the Ministerial Council has asked for a first review as the previous standard is not consistent with existing Policy Guidelines. • Option 2 significantly discourages innovation in the food supply and international trade. • Option 1 is not consistent as it requires a 'convincing level of evidence' for GLHC which have been deemed lower risk in the Policy document due to where they are on the continuum. Option 2 is also not consistent as FSANZ decides whether the application meets their substantiation requirements (which will not be prescribed) and whether the application also meets the 'all other relevant factors in order to meet our (FSANZ0 statutory objectives'. This puts unreasonable level of evidence and uncertainty on what have been essentially accepted as lower risk claims based on the ANZFRMC Policy Guidelines continuum of claims. • FSANZ has not demonstrated that claims currently made by industry promote irresponsible food consumption patterns and furthermore, there is no modelling provided to illustrate that the proposed Standard using either Option 1 or Option 2 for GLHC will protect against irresponsible food consumption patterns. • Option 2 places unreasonable cost burden on the food industry. The large majority of GLHCs currently made would be prohibited as they are not currently listed within Schedule 2. Kellogg estimates that around 75% of its own existing claims would be affected. This is unreasonable as FSANZ has not demonstrated harm to public health based on the current labelling requirements nor has a cost impact statement been developed for the proposed options. Furthermore significant cost would be incurred by industry to change packaging to remove all ineligible claims, change advertising, develop comprehensive dossiers for all GLHCs, and deal with whether a claim will be permitted in the future, • Would need to review of the impact of the current European requirement for all claims to be pre-approved as it has placed significant cost and resource strains on the industry as well as on the European Commission, the European Food Safety Authority and Member States' administrations. • Enforcement of Option 1 will still require substantial resources, which has not been diminished due to the move to the requirement for 'convincing' levels of evidence. • Option 2 has simply moved the difficulty to comply with in practical and resource terms from the enforcement agencies to FSANZ and industry, both of whom will require significant additional resources and funds to undertake. Food industry will continue to bear the cost and burden not only during the transition period but ongoing as it will need to apply for every new claim it wants to make. This needs to be factored into the cost benefit analysis by FSANZ. • Does not meet the Policy Guideline in other areas not highlighted by the Ministerial Council, namely • Policy Principle 7 – 'draw on the best elements of international regulatory systems for nutrient, health and related claims and be responsive to future trends and development'; • Policy Principle 8 – 'Provide for collaborative action among enforcement agencies, industry and consumers to optimise educational resources' and Desirable Feature 2 – 'enable better engagement of sectors other than government in providing nutritional advice and information'; and • Claims Classification Criteria statement – 'only high level claims will be pre-approved, with approved claims being listed in the standard'. The proposed Standard does not meet the objectives that FSANZ is required by its legislation to meet along with various principles that FSANZ must have regard to: Objective 1 – The protection of public health and safety, and Objective 2 – The provision of adequate information relating to food to enable consumers to make informed choices. Considers Objective 2 would not be met under Option 2 due to the onerous nature of pre-approval and the requirement for foods to meet the NPSC. • Policy Principle 2 – 'the desirability for an efficient and internationally competitive food industry' whereby the uncertainty as to whether a claim will be approved (e.g. FSANZ disagreeing with other countries' substantiation for a claim e.g. wholegrain and heart disease) and also under Option 2 the substantiation requirements are not described, means that the food industry will not be internationally competitive. FSANZ should consider developing reciprocity agreements with other countries so as to facilitate acceptance of claims that have already been approved by these jurisdictions

Submitter	Comments
	• Policy Principle 3 – 'The promotion of fair trading in food'. The proposed Standard does not promote fair trading in food, as by the very nature of having a pre-approval system; manufacturers need to bear all cost and risk with no recognition of confidentiality for applications.
Kraft Foods Limited	• No preference stated for either Option • It is difficult to have new claims added. Manufacturers would be unlikely to apply to have a claim added as they would have little opportunity for exclusivity over the use of the claim. Unpaid submissions would just go in the queue. • May limit innovation which doesn't assist players to remain internationally competitive. • Disadvantages of Option 1 are: – The amount of work for industry. This could be reduced if industry and jurisdictions agree to an acceptable list of claims for Methods 1 and 2 – The resources required by enforcement agencies will be proportional to the claims outside the agreed list. • Advantages of Option 2: – Would eases the burden for industry, with major benefit from small to medium enterprises – Would provide clearer definition of the acceptability of claims – There would be more certainty for jurisdictions. • Disadvantages of Option 2: – FSANZ proposes that factors other than just scientific basis of the claim would be taken into consideration. This means the claims would not necessarily scientifically valid but would be distorted by whatever political pressure is applied. FSANZ has a high level policy principle requirement to be scientifically accountable.
Martek Biosciences Corporation	• No preference stated for either Option. • FSANZ should consider critically examining the current GLHC situation in the marketplace and determining the existing level of misleading/unsubstantiated claims before concluding that a move toward an Agency-regulated process is justified. • The current claims situation in the EU is a likely harbinger of the results expected from the implementation of Option 2. It is obvious from the EU process that this form of regulation can become overwhelmed resulting in major agency resource expenditures and limited ability for industry to remain competitive in the international marketplace.

Submitter	Comments
National Foods	• Support Option 1 with variations. • Both options contradict the Policy, do not address concerns raised by the First Review request and do not meet P293's original objectives. Industry self-substantiation of GLHCs, as described by Option 1, is the only option that meets the Policy Guidelines. However, oppose the need for 'convincing' levels of evidence. GLHCs should require 'consistently agreed' or 'the weight of the evidence' to support them and a list of suggested GLHCs could be included in a 'guideline', as examples only. Method 4 should be maintained as a method of substantiation for GLHCs. • In their current form both options are restrictive and will not deliver to initial objectives of P293, in particular to 'enable industry to innovate, giving consumers a wide range of healthy food choices'. Nor will they enable food industry to provide new innovative healthy food choices that have the potential to protect and improve public health. • Notes there are numerous examples of innovative products in the market place which give consumers a wide range of healthy food choices and have the potential to benefit public health. E.g. Plant sterol enriched foods are an excellent example of a product that makes a GLHC claim about reducing cholesterol absorption, currently substantiated by a systematic review. • Specific Issues with Option 1: – It is unreasonable and too restrictive to require 'convincing evidence' to substantiate GLHCs. Recommend that GLHCs should require 'consistently agreed' or the 'weight of the evidence' to support such claims – Method 4 should be maintained as a method of substantiation. The Policy Guideline explains that the level of evidence should be commensurate with the 'level' of the claim. – FSANZ have conceded that it is not necessary to have 'convincing' levels of evidence for GLHCs and that the level of evidence should be commensurate with the 'level' of claim. In creating the pre-approved list FSANZ have included claims which they have previously stated are not supported by 'convincing' evidence. E.g. a GLHC in Schedule 2 for EPA and DHA and heart health. However, FSANZ had not permitted a HLHC from the same body of evidence as it was not 'convincing'. – Removal of Method 4 is extremely concerning as it will limit innovation, research and the potential for new science to be used to benefit consumer health. • Specific issues with Option 2: – Contradicts a number of aspects of the Policy Guidelines, as well as the objectives of P293 as set out by FSANZ. • FSANZ has not delivered options that meet the Policy Guidelines, nor has it evaluated these options against all of the legislative aims of the review.
National Starch Pty Ltd	• Supports Option 1 with variations. • The disadvantages identified for Option 2 in the Consultation Paper would be onerous for the food industry and as such respectfully submit that further consideration and refinement to a self-substantiation model is warranted. • Disadvantages identified with Option 2 include: – A lack of flexibility in bringing new GLHCs to market – Time taken to approve GLHCs (longer than six months) is likely to impact on speed to market advantages – Costs to industry are likely to be higher under this model – evidence collection as well as FSANZ application fees – Transparency in the application f new GLHCs may stifle innovation, as competitors will be aware of company/product intentions with respect to GLHCs. – Confidentiality is unlikely to be protected in the proposed new system.
Nestle Australia Ltd and Nestle New Zealand Ltd	• Supports Option 1 with variations. • Strongly object to Option 2 because: – Lack of confidentiality. – Lack of incentive to build an innovative food industry and cost to workforce.

Submitter	Comments
	– Cost to industry. Cost factors will arise from: o Cost of application: o Time for approval – Speed to market: o Retailer sell in o Media Buying o Packaging – No opportunity for Modification/comment/amendment of GLHC submitted for pre-assessment. – Regulations should not be more restrictive than necessary to achieve the intended objectives and the requirements under Option 2, pose unnecessary restrictions, in particular nutrient profiles, prohibition of certain claims and the need to formally apply for pre-approval of GLHC to be positively listed within the Standard proper to use rather than relying on the current practice of self substantiation without pre approval. Notes the experience within the EC of establishing claims or claim relationships. – Considers that innovation will be stifled by the restrictive nature of the Option 2 approach. This will discourage R & D investment, deny consumers within the community potentially beneficial products and information, and could halt the steady improvement of product renovation and nutrient intake. • Considers that the Standard should only include nutrition content claims and HLHCs. GLHCs should be indicated in a guideline document external to the Standard. An approach where industry can still perform systematic reviews and hold the substantiation evidence without being required to lodge an application and gain pre-approval will enable industry to be globally competitive and innovative. Strongly objects to Option 2 as it is considered that the impact on the industry would be significant and overly restrictive and not commensurate with the level of risk.
New Zealand Juice & Beverage (NZJBA)	• Supports Option 1. • Supports a legislative framework that will allow: – Innovation within the food industry – Supports worldwide trends – Meets consumer demands – Protects the interest of its members – The protection of consumer safety • Opposes Option 2 for the following reasons: – Once the claim/product is identified in the pre-approval process, there is no confidentiality in the information. – There is no system or timeframe identified to monitor/review the pre-approved GLHCs. There is also a lack of clarity on how labelling review panels are done and the level of expertise that would be required to determine whether new and existing GLHCs will be approved. – Considers that Option 2 would be very detrimental to speed to market and would considerably lower the competitive edge of the industry at a local and international level.
NuMega Ingredients	• Opposes Option 2, but no mention of supporting Option 1. • Oppose pre-approval of GLJCs because the process will: – be slow for new claims and will not be able to keep up with scientific evidence (e.g. The science supporting the roles of long chain omega-3 fatty acids is rapidly increasing due to huge interest in this area by researchers internationally). – slow down the opportunity to communicate claims of interest and relevance to consumers – broadcast a manufacturer's interest in the specific area to competitors as it is not confidential. This will reduce incentives for market

Submitter	Comments
	innovation. – place the load of substantiation on one applicant to the benefit of all manufacturers of similar products. • If Option 2 proceeds, then recommends: – Simplifying the process for adding to the list of claims – Shortening the time required to process new claims applications – Confidentiality during the application process, to ensure a first to market advantage to encourage innovation and consumer communications.
New Zealand Food and Grocery Council (NZFGC)	• Opposes Option 2, but no mention of supporting Option 1. • Generally supportive of the pre-approval of up to 90 GLHCs, however notes keeping this list updated, to reflect new research will be resource intensive. However strongly opposed to the system of pre-approved relationships. The proposed system completely unworkable because: – no confidentiality, therefore a loss of first to market benefit for companies who have made significant investment in the research leading to a new claim – has the ability to destroy innovation and therefore NZ industry – the application process is lengthy and adds considerably to the innovation development cycle – no certainty GLHC will be approved at end of cycle and there is no right of appeal if application fails – Industry will have to substantial costs with each approval; due to current economic crisis no additional costs can be absorbed. The extra costs would be passed to the consumer. – Costs will be duplicated if approval has already been sought from the EU/ other jurisdictions – As list of pre-approved claims grows, it must be maintained and updated which is a significant administrative burden that FSANZ will have to meet. – In NZ there is no justification for regulating GLHC in NZ as the Fair Trading Act prohibits misleading or deceptive conduct. If a company has funded reputable research, and the results are conclusive and supportive of the claim, then the idea that pre-approval is required over and above the legislation already in place is absurd. • In the event that FSANZ does implement the system of pre-approved relationships, recommends GLHC's be afforded the same level of confidentiality as HLHCs and the default timeframe for processing a GLHC should be reduced from 9 months to 3 months.
Omega-3 Centre	• Opposes both options. • Although the concept of pre-approved GLHCs is supported, there are a number of concerns that would need to be addressed in relation to Option 2. • Opposes the NPSC and the requirement that foods making GLHCs need to meet the NPSC. • Schedule 2 contains an incomplete GLHC list on omega-3s. • Option 2 will prevent industry from communicating new science effectively and quickly. Believes that Option 2 will not support a number of FSANZ key guiding principles for the regulation of GLHC, namely: – The provision of a system that is flexible yet enforceable – The provision of adequate information about food – Cost effectiveness • Refers to the Therapeutic Goods Administration, Guidelines for levels and kinds of evidence to support indications and claims (October 2001).

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Parmalat Australia Ltd	• Opposes Option 2, but no mention of supporting Option 1. • Strenuously objects to Option 2 for the following reasons: – Is inconsistent with the Policy Guidelines. – Consumers are already adequately protected against misleading conduct under general consumer protection laws as well as provisions in State and Territory Food Acts dealing with misleading conduct. – It is unclear what level of evidence will be required for a claim to be pre-approved by FSANZ. – Making an application to amend the Code involves significant time and imposes significant costs on industry. Such costs would be passed onto consumers or would prevent industry from launching new healthier products is the cost of development starts to outweigh the financial returns. The proposed approach seems to put greater weight on the enforcement cost burden on jurisdictions than the costs imposed on industry. In addition, the costs incurred by Government associated with assessing applications should be taken into account when assessing the overall cost burden. – Has the potential to stifle innovation in that it has the potential to limit the claims that can be made in respect of functional foods such as probiotics. This will impact existing products and directly impact industry revenue. This is particularly so given that applications to amend the Code will not be treated as confidential. Under the proposed approach the applicant will lose any competitive advantage from making the application – this is a serious concern. The extent that the loss of competitive advantage means that expected sales of a new product will be lower than they otherwise would have been represents yet another obstacle. – Has a particular concern about the impact of the proposal on probiotic/prebiotic claims and claims that can be made in respect of lactose free products. • Supports the approach in relation to HLHCs, but considers that such a prescriptive approach is unreasonable and unworkable when applied to GLHCs. GLHCs are by their very nature lower 'risk' than HLHCs, and different policy considerations should guide the regulatory approach taken. • Holds significant evidence in support of probiotic claims. A requirement that claims be pre-approved is particularly problematic where the evidence supporting the claim is quite specific as is the case with different strains of probiotics or combinations of strains of probiotics. • If so, this highlights the inflexibility of the proposed approach and the problems associated with requiring pre-approval of GLHCs. Using an industry self-substantiation model for uncontroversial claims such as the above example would be permitted. • However, under Option 2 it will be necessary to make an application to allow such a claim to be made. Notes that their yoghurt products have been in the marketplace for approximately 10 years and this issue risks continuity of trade for the product.
Sanitarium Health Food Company Australia & Sanitarium Health Food Company New Zealand (Sanitarium)	• Supports Option 1. • Model is similar to how claims have been managed for many decades. The nature, truthfulness and requirements of claims not to mislead, is already well protected by Fair Trading legislation. • The ACCC and NZCC have acted against claims that could be misleading, and neither body is likely to sit by and allow irresponsible claims to go unchallenged. On this basis, the enforcement load on the state and territory governments need not be any different to the current situation. • Option 1 allows new knowledge and claims from internationally reputable regulatory and other expert environments to be adopted without the need for further legislative burden or consumption of government resources. Self-substantiation also fosters innovation with real incentive for manufacturers to gain responsible first to market advantage, without preventing the remaining industry to follow. A competitive market driving towards healthier options will benefit consumer health. • The FSANZ preferred Option 2 appears to have pushed the burden of regulation heavily on to industry and will continually tie up FSANZ and industry resources to maintain Schedule 2. There will be little to no incentive to innovate if one has to expend resources to compile the supporting data, pay FSANZ to expedite one's proposed claim, and yet gain no market advantage due to the public process. This public process will give ample time for competitors to develop similar product and freely ride on the back of the claim once gazetted, thus

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	destroying any first to market advantage. • In addition credible claims from overseas will have to wait until put forward as a proposal or have someone mount the cost to get it expedited. Once again the cost and public process required provides little incentive for an individual company to do this. • Nevertheless if Option 2 is still pursued, then some key changes are needed to make it remotely workable: – Schedule 2 needs to be more completely 'unpacked' from the information already available from substantiation Methods 1 to 3. – FSANZ commitment to assess in market claims is honoured and expanded to include credible evidence from Method 4. – A mechanism is needed to keep Schedule 2 up-to-date with new claims. – GLHCs need to be given similar protection and treatment as afforded to HLHCs if the application is paid. This will provide at least some incentive to innovate a healthier food supply.
Simplot Australia	• Opposes both options. • As per the AFGC submission, recommends that further work on P293 is delayed until after the independent Review of Food Labelling Law and Policy.
Sugar Australia Pty Ltd	• Opposes Option 2, but no mention of supporting Option 1. • Acknowledges self-substantiation of GLHCs may create some difficulties for enforcement agencies. However, pre-approval of GLHC relationships is not supported for the following reasons. Sugar Australia considers that the proposed approach will: – Impose an overly prescriptive regulatory burden that is not consistent with the public health and community risks – Negate competitive advantage by imposing a public approval process for any new GLHC. – Provide less flexibility for bring new products with evident consumer benefits to market. – Impose an unjustifiable financial burden on industry to bring such products to market. – Significantly increase the time-line for bringing products to market. It is expected that a manufacturer will have gone through a process of assuring themselves of the validity of the claim before making a possibly paid application to FSANZ. The timeline for this would be similar to that of a self assessment process. The proposal for pre-approval by FSANZ adds an additional assessment process of approximately 12 months. Furthermore, the time for assessment is likely to be extended if FSANZ is not adequately resourced to meet the additional work load.
The Food Technology Association of Australia	• Supports Option 2. • Offers more certainty for industry as to what claims will be permitted without the onus for providing proof. It also provides the opportunity after introduction of the new Standard to perceive what other claims may in due course be required. Also this Option will immediately provide regulation that should be enforceable particularly in regard to companies who currently are able to sell products in an unfettered manner with a variety of claims that would become immediately non-compliant on gazettal.
Unilever Australasia	• Opposes both options. • Supportive of the Policy Guideline and of a framework for claims. • Notes there are existing claim frameworks and regulations in other developed countries – some have been in existence for a period of time and others are still evolving – it should be possible to leverage the optima elements of these existing systems to facilitate the implementation of a system in Australia/New Zealand • Challenge the current consultation in proposing higher regulatory burden/barriers for GLHCs. • Notes that substantiation and enforceability issues relating to GLHCs, raised by the Ministerial Council, form the most substantial opposition to the nutrition, health and related claims framework. FSANZ have presented two options: Option 1 – a modified version for substantiation provided more defined requirements for Methods 1-3 however there were not significant changes proposed for Method 4. The Consultation Paper presents this option, however already it is not considered sufficient to address enforcement requirements. Option 2 – FSANZ are required to pre-approve all GLHCs.

Submitter	Comments
	• Option 1 is not considered to be sufficiently prescriptive to promote consistent enforcement. • Option 2 requiring pre-approval of GLHCs imposes a pre-approval process on existing nutrient function claims, an additional regulatory burden. This is a very significant change in direction for GLHCs; we can understand the issue for enforcement with the current proposal placing the onus to evaluate substantiation for GLHC on enforcement. • Our concern is that this Proposal has been in place for some time, brand owners have been working to put in place the proposed substantiation requirements over a significant time period, investing in substantiation methodology and documentation in preparation for the implementation of the Nutrition and Health Claims framework. The new Option 2 is extremely restrictive. • Does not support either of the options presented for GLHCs and supports the separation of GLHCs from the Proposal so that nutrition content claims and HLHCs can be progressed.
Wyeth Nutrition (Wyeth)	• Supports Option 2. • This new process would provide FSANZ with greater oversight to prevent misleading claims while still allowing for innovation and education.
Yakult Australia Pty Ltd	• No preference stated for either Option. • The proposed approach for GLHCs can be seen as restrictive to the food industry in terms of product development and innovation.
Government	
Department of Health – South Australia	• Supports Option 2. • Would relieve a substantial amount of the potential cost and resource burden from enforcement agencies and creates a more level playing field for industry, in particular, small industry. • With regard to the pre-assessment of GLHC relationships, seeks clarification of the statement in the Consultation Paper regarding the potential to enable a greater range of GLHC relationships to be considered. Although SA Health appreciates FSANZ's expertise in the area of scientific evaluation, it is queried what other 'relevant factors' will need to be taken into account in the decision making process. • For the sake of clarity, confirmation is also sought that Methods 1-4 as proposed in the Final Assessment will no longer be utilised in the assessment of claims. • With regard to confidentiality, assurance is requested that granting this confidentiality will not result in jurisdictions not being able to provide input into the approval of GLHCs as part of the FSANZ assessment process.
Department of Human Services - Victoria	• Opposes both options. • Believes GLHCs are not able to be adequately regulated under the current Food Act. • The recommended Option 2 is unenforceable as drafted. • Both options have not addressed the fundamental issues cited at Final Assessment so the same issues apply, i.e. the draft Standard will: – be difficult to enforce or comply with in both practical and resource terms; and – places unreasonable cost burden on industry or consumers. • Believes that neither Option is consistent with the original policy intent to allow health claims that are truthful, responsible, balanced and do not create unrealistic impressions of health benefits. • Further prescription may be inconsistent with policy principles and costs to government and industry need to be put into perspective in relation to the benefits. • Notes that cost benefit analyses undertaken have found net benefit to allowing health claims but are not definitive about the most appropriate approach. • It could be argued there is sufficient regulatory protection through trade practices legislation. • GLHCs are marketing tools. The inclusion of a Standard to regulate marketing is a new approach; current food regulation is not designed to deal with this and proportionate enforcement tools would be needed.

Submitter	Comments
	• Both options have either substantiation criteria or wording which is not clear cut and open to interpretation. Any breach of the Food Act must be proven beyond reasonable doubt and Courts are required to interpret wording of the Acts narrowly and any benefit of doubt goes to the defendant. The wording of the draft Standard makes it inevitable that the burden of proof threshold required will not be met in most instances. The disconnect between the Standard and the Act will be discredit on the food regulatory system. • There are more enforcement mechanisms under the fair trading legislation, a lower burden of proof is required and courts can impose order to prevent misleading conduct. Trade practices law is designed to deal with marketing claims. • Option 1 has significant enforcement issues with the interpretation of evidence. Support the general approach of self substantiation in the alternative approach proposed in Option 1, this approach is not possible to enforce. • Option 2 is not commensurate with the level of risk associated with GLHCs and consequently fails to adhere to a number of principles in the Policy Guideline. • Aware a number of jurisdictions support pre-approval of GLHC as proposed under Option 2, but considers that Option 2 would place an unreasonable cost burden on regulators. While it reduces burden on jurisdictions in evaluating evidence, it creates a significant administrative burden in responding to industry applications for both jurisdictions and FSANZ. Victoria will be unable to bear the resource costs. • One company has suggested as many as 200 of their existing claims would have to undergo the application process. • The opportunity costs that arise for FSANZ and regulators should be carefully considered in dealing with what are marketing issues compared to the core business of protection of health and safety. • Option 2 places unreasonable cost burden on industry. A quick survey suggests a large number of existing GLHCs have not been pre-approved and will need to undergo the application process. Smaller companies who cannot afford this will be disadvantaged. • Costs to industry include keeping up with ongoing changes made to the Standard and restricted innovation in an area that is not high risk. • Option 2 does not give sufficient regard to obligations under the FSANZ Act to ensure an efficient and internationally competitive food industry. • The Standard should be developed both for existing claims and, in line with best practice regulatory principles, aim to remain relevant and effective over time. Concerned with ongoing bureaucracy and administrative burden associated with changing scientific environment. • The Application process outlined in Option 2 does not provide clarity and certainty for industry. Innovation and marketing (including health claims) are inherently linked, e.g. a new product to improve heart health with want to be promoted using a GLHC. • In order to ensure development and reformulation for healthier products, and provide information of how the public can improve their overall health, it is essential that industry are absolutely clear: – about what evidence is required to make a successful GLHC and, therefore, where there are opportunities for innovative new products to be developed to address wider public health concerns; – that investments made in time and money to make applications for new health claims will be worth their while. • The minimum amount of evidence required by FSANZ needs to be made clear to industry. This would prevent a situation where FSANZ can arbitrarily refuse claims based on shifting level so required evidence, e.g. if factors beyond scientific certainty can be taken into account, using these as a basis to refuse an application. • Maintaining confidentiality of applications is paramount to providing certainty industry will attain a competitive advantage. Therefore do not agree with inconsistency with HLHC approach in terms of confidentiality of applications. • Do not consider it reasonable to expect companies to pay for applications for GLHCs with no first mover advantage. Recognise this would require a change to legislation but given the existing approach for HLHCs, the principle should apply for all claims.
Dept Health & Human Services Tasmania	• Supports Option 2. • Would provide certainty and a level playing field for industry and reduces the risk posed to consumer confidence in the food supply. It also reduces the burden of enforcement by jurisdictions.

Submitter	Comments
	• The Department supports consistency across the Code, e.g. the 'prohibit unless specifically listed' principle is also used for genetically modified foods. • Option 2 could be implemented immediately within the existing legislative framework and additional GLHCs could be included when substantiated. • Opposes Option 1, which is a modified industry self-substantiation model because: – The existing voluntary industry Code of Practice on Nutrient Content Claims has not be effectively implemented, monitored or enforced. – While this amended Option provides clearer guidance on the data requirements for GLHC relationships to meet a 'convincing' level of evidence, the onus is still on the regulatory agencies to determine if the evidence meets the substantiation requirements. Option 1 may therefore result in reduced consumer confidence and industry certainty, and increased enforcement costs to the community (including regulators). • Notes that under the FSANZ Act, HLHCs are subject to confidentiality provisions. Lack of confidentiality could be a concern for industry seeking approval for new GLHCs.
Department of Health - Western Australia	• Supports Option 2. • The pre-market approval will reduce the risk of confusion in both the granting of applications and monitoring of compliance. Regulatory burden on both industry and enforcement agencies will be reduced. • Option 1 is open to misinterpretation, inconsistencies. • Option 2 may also allow for the collection of evidence to support an assessment of the public health effectiveness of the Standard.
New Zealand Food Safety Authority (NZFSA) with in principle support from the Ministry of Consumer Affairs	• Supports Option 2. • This approach provides certainty to both industry and regulatory regarding the substantiation of GLHCs. The burden of enforcement by jurisdictions is reduced by this Option compared with Option 1. This addresses the concern at first review that it is difficult to enforce and/or comply with in both practical or resource terms. • The pre-approval of GLHCs greatly reduces the resource burden on enforcement agencies. Option 2 also provides clarity for industry with respect to food- health relationships which are permitted as the basis for GLHCs, thus enhancing the ability of industry to comply with the Standard. • The increase in certainty for GLHCs, and the knowledge that permitted food-health relationships have undergone assessment prior to claims based on them being allowed should increase consumer's confidence in the food regulations system. • Notes that applications for GLHCs do not have the protection of confidentiality or first to market advantage that is conferred by the FSANZ Act on applications for HLHCs. The confidentiality or first to market advantage is also conferred by the FSANZ Act on applications for novel foods. This could potentially negate any advantage gained with the novel food application. Recommends FSANZ to consider amending the FSANZ Act to confer the same level of protection to applications relating to all health claims. • Option 1 does not address issues raised at First Review, particularly in relation to the regulation and substantiation of GLHCs i.e. it is difficult to enforce and/or comply with in both practical or resource terms. • Option 1 retains the approach proposed at Final Assessment which placed the onus of assessing the substantiation dossier for claims on the enforcement agencies. NZFSA reiterates previous comments made that it does not have the level of resource required to undertake this assessment and that the level of proof required to enforce non-compliance in a court of law is not believed to be attainable for a food-health relationship and therefore GLHCs substantiated by Method 4 will not be able to be enforced.
NSW Food Authority	• Supports Option 2 (marginal preference). • Have significant concerns that it would restrict industry innovation and flexibility.
Queensland Health	• Supports Option 2. • Agrees that Option 2 would provide greater certainty and specificity for industry and enforcement agencies and ensures a level playing field

Submitter	Comments
	for industry. It would reduce the burden of enforcement on jurisdictions with respect to those claims as compared to the Proposal in Option 1 and reduces the risk of inconsistent enforcement by jurisdictions. • The fact that food-health relationships have undergone assessment by FSANZ prior to claims being permitted on foods should lead to increased consumer confidence in the food supply. • Agrees that Option 2 also confers benefits from potentially greater flexibility in decision making processes due to factors beyond scientific certainty being able to be taken into account. This allows, for instance, claims to be considered in the context of broader public health objectives, such as claims about sodium. • Considers that Option 2 addresses the use of the 'prohibit unless specifically listed' principle which is used elsewhere in the Code. • Opposes Option 1. Notes that the proposed amendments for this Option do provide clearer guidance to industry on the data requirements for GLHC relationships that would meet a 'convincing' level of evidence. However, enforcement agencies must still determine if the evidence meets substantiation requirements. Has previously raised concerns about the capacity of jurisdictions to undertake such assessments and whether such assessments will meet the test required by the Courts. In addition, individual enforcement agencies may reach different conclusions about substantiation resulting in inconsistent enforcement. Thus this Option would likely reduce industry certainty about ultimate compliance and result in increased enforcement costs. • Option 1 also favours larger industries with the resources to conduct or commission compilation of evidence to substantiate a claim. • Option 1 does not address our concerns raised at First Review, particularly in relation to the enforcement and scientific substantiation of GLHCs.
Other	
Australian Self-Medication Industry Inc (ASMI)	• Supports Option 2. • Concerned that there is no level playing field between food products carrying therapeutic claims and therapeutic goods; and that this will not improve. • The marketplace at present is crowded with food products which carry therapeutic claims, both proven and unproven GLHCs and HLHCs e.g. Goji juice and Acai berry. Some claims are permitted at present, but the majority are not. Although there is provision for monitoring food claims and for enforcement of the regulations, very little enforcement activity is evident. Thus unscrupulous food companies are encouraged to continue making unproven and illegal claims for their products. The proposed system will do very little to change this. In contrast, the TGA regularly audits the manufacturing, labelling, claims, evidence and advertising of therapeutic goods. Where breaches are found, the TGA may enforce stringent penalties including cancellation of listing or registration; product recalls; and heavy fines. • Sponsors of therapeutic goods must list or register their products before sale, and hold evidence to support their claims. In the case of products which carry HLHCs, sponsors register these products and therefore pay tens of thousands of dollars in application fees. In addition sponsors are required to provide an exhaustive dossier of data on evidence and safety, whether or not that data is common knowledge already. In contrast, food companies will be free to use any of the claims in Schedule 2, including HLHCs. For example, a product containing low salt will be able to make a claim related to lowering blood pressure, and a fruit or vegetable product could claim to reduce the risk of cardiovascular disease, without any requirement to prepare evidence or safety dossiers, and without paying a cent in assessment fees. • Sponsors of therapeutic goods must pay for extensive laboratory testing to ensure the identity, stability and therapeutic activity of their products. In contrast, food companies may simply refer to nutrient tables and assume that the data apply correctly to their products. In the case of a vitamin water, there is no enforcement for the producer to provide that the quantity or even identity of the vitamins added to the product actually match the label claim at the time of manufacture, or at the end of shelf life. • Sponsors of therapeutic goods are frequently reminded of their responsibilities, and spend considerable time and effort studying TGA publications and guidelines, as well as attending industry seminars and workshops, to ensure that they fulfil these responsibilities. We do not see any provision in Proposal P293 for education of food company management regarding their duties with respect to therapeutic

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	claims. • Regarding the evaluation of evidence supporting Schedule 2 claims, commends FSANZ for its considered and balanced approach. Emphasises the ongoing need for consistent and competent evaluators. • Acknowledges the high quality of the work invested in this document, we fear that without requirements for relevant product testing, and without effective enforcement against breaches of the Standard, unethical companies will continue to ignore the law and the playing field will be more uneven than ever.
Complementary Healthcare Council of Australia (CHC)	• Supports Option 2 (in principle). • Option 2 would provide certainty around GLHCs for industry, consumers and enforcement agencies. Considers that this Option is the most appropriate as all health claims would be pre-approved after evaluation by FSANZ; this would minimise the number of unsubstantiated claims currently being made by food products. Also considers that by having a list of pre-approved claims would assist with the issue of inconsistency with respect to enforcement within the different States and Territories for foods making illegal health claims. • Concerned with the lack of description around what would be suitable evidence to support health claims for foods. Believes many of the health claims listed in the draft Standard are similar to therapeutic claims used for listed medicines (such as complementary medicines) under the Therapeutic Goods Act 1989 and Therapeutic Goods Regulations 1990, noting that Proposal P293 does not allow 'therapeutic claims to be made on foods'. For this reason, recommends that the level of evidence used to support health claims should be to the same standard as those applied to therapeutic goods and has concerns with the 'greater flexibility in the level of evidence that may be presented' under this Option. • Notes that for simple nutrition content claims, the company needs to hold evidence that the product contains the relevant component(s) in the amount(s) being claimed, and must meet any qualifying or disqualifying criteria specified in the draft Standard. The company who is manufacturing or marketing the product is not required to prove that the quantities claimed at the end of the products use-by date. Furthermore, the manufacturer or marketer of the product does not need to show compliance with the claim for each batch and every batch, nor that the process used to manufacture the product is validated and give consistently reproducible results each and every time. Suggests that these issues be considered further by FSANZ. • Notes the options address issues of enforcement, but strongly urge a commitment from relevant State/Territory authorities to act in an appropriate and timely manner. Cannot fully support any further development of the Standard without being reassured that enforcement and existing complaints systems will be effective.
CSIRO	• No preference stated for either Option. • Cannot comment on the merits of Government Regulation or Policies.
GraceLinc Ltd	• No preference stated for either Option.
Natural Products NZ Inc (NPNZ)	• No preference stated for either Option. • Proposal P293 will standardise what companies are allowed to say on product labels and advertisements. All GLHCs and HLHCs are standardised for the claim wording and the mandatory advisory statements associated with the claim meaning. There will be no competitiveness between companies/products. All products satisfy the criteria listed in the Code to have a nutrition content claim, a GLHC or a HLHC will have exactly the same wording on packs/advertisements. • It is positive to see some regulations around endorsements and cause-related marketing statements. In particular the mandatory advisory statement that has to be included when a cause-related marketing statement is made. This will help consumers to understand the product is not endorsed by non-profit organisations (the cause – normally would have reference to serious disease as part of its name).
Therapeutic Goods Administration	• Supports Option 2. • Notes that in former submissions to this Proposal, it was strongly recommended that GLHCs be specifically regulated within the Standard. Stated that "The TGA recommends 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. Any other approach will almost certainly lead to a protracted period of varying

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	degrees of industry compliance with the attendant probability of consumers being misled and imposing an unnecessary burden on enforcement agencies in the interim, or as in the TGA's experience, enforcement not being possible in the face of a manufacturer's challenge to the legal status of the guidelines." • To that end, the inclusion of a specific list of pre-approved GLHCs in the Standard is an excellent change to the approach to regulating these claims.
Public Health	
Cancer Council Australia	• Supports Option 2. • Agrees that industry self-substantiation of GLHCs does not protect public health and safety. • The introduction of pre-approved GLHC has the added advantage of addressing any misleading examples within the marketplace in a consistent fashion.
Coeliac Society of Australia Inc	• No preference stated for either Option.
Dietitians Association of Australia (endorsed by the New Zealand Dietetic Association)	• Supports Option 2. • It has many of the advantages that DAA has sought in earlier submissions. • Notes the potential for Option 2 to limit innovation in the food industry as pre-market approval will decrease competitive advantage.
Fight the Obesity Epidemic (FOE)	• Supports Option 2. • Given that it appears that health claims are likely to be permitted in some form, has a very strong preference for Option 2. • Option 1 is not acceptable. Health groups do not have the resources to challenge every dubious claim, and even when challenges were eventually upheld, the damage would already have been done.
Glycemic Index Foundation (Ltd)	• Supports Option 2. • Believes that this option will provide the highest level of certainty and specificity for food industry and State and Territory enforcement agencies, and will engender greater consumer confidence in the health claim system.
National Heart Foundation of Australia (NHFA)	• Supports Option 2. • This Option has the benefit of promoting consistency for GLHCs and HLHCs, thereby lessening confusion for industry, consumers and enforcement agencies regarding conditions for making claims. • It has the intent of addressing the current inequity for nutrition content claims, improving the certainty and specificity of claims for industry and enforcement agencies due to existing differences of approach, views and interpretation of the current Code. • The disadvantages to this Option are: – The lack of confidentiality if a company invests time and funds into research and development in applying for a new GLHC, and loses its advantages as being the first product on market. – It creates unnecessary delays in getting products with GLHCs to market, as the approval process via FSANZ was intimated to be 9 months.
Obesity Policy Coalition	• Supports Option 2. • Agrees with FSANZ's view that the shift of responsibility for approval of GLHCs from enforcement agencies to FSANZ, and the prescription of the required wording for GLHCs, will ensure greater certainty and improve compliance by the food industry. It will also reduce the burden on enforcement agencies and provide for better certainty and consistency in enforcement across jurisdictions. • Most importantly, requiring FSANZ to take into account its FSANZ Act objectives in developing, reviewing or varying food regulatory measures, will ensure that public health considerations are required to be taken into account, that GLHCs made on food packaging are required to be clear and unambiguous – enabling consumers to make informed choices, and will prevent (so far as is possible) the use of

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	misleading and deceptive GLHCs. • Also share FSANZ's view that Option 2 is in line with the Ministerial Council Policy Guideline, as it will have a greater capacity to meet the Policy Principles. • While it may take longer for GLHC to be approved under Option 2, believes that any delay is justified by the need to ensure certainty, that claims are adequately substantiated and that public health is protected. The cost to industry of assembling the evidence should be no different than if the relevant manufacturer was required to satisfy itself that sufficient evidence existed to make the claim. Given the likely profit that a manufacturer will be able to make through the use of a new GLHC on its product, the cost of any application fee is likely to be significantly outweighed by the benefits of the application being accepted. • Encourages FSANZ to consider including an inbuilt review mechanism requiring FSANZ to evaluate any negative impacts of scheduled GLHCs every, for example, five years. This would ensure that GLHC would continue to be monitored and would allow any unintended consequences that may flow from the scheduling of GLHC to be addressed. Consideration should also be given to applying a similar review mechanism to HLHCs.
Public Health Association of Australia	• Supports Option 2. • Believes that pre-approval of GLHCs is the best way to ensure that public health and safety and provision of appropriate information to consumers is assured. • Considers that Option 2: – Would provide greater certainty for industry and enforcement agencies – Would result in greater consumer confidence – Addresses Ministerial Council concerns – Relaxes the burden on industry in terms of holding and interpreting evidence – Would provide certainty to bring a prosecution • Agrees with FSANZ holds responsibility and is central decision making point • Other advantages include greater objectivity in researching and interpreting evidence. Option 2 currently excludes biologically active substances in the absence of evidence for their role in nutritional health. This addresses our concerns about their previous inclusion. • Opposes Option 1 because: – It would require industry to assemble evidence and places a burden on industry, particularly small industry – may not have sufficient resources – Of inconsistencies in enforcement interpretations and conclusions – Of the significant enforcement burden – Of the ability for unsubstantiated claims to remain on the market pending enforcement action which can be lengthy and has the potential to mislead, deceive and confuse consumers – The experience of the industry regulated Code of Practice on Nutrient Claims has not instilled a high level of confidence in a self regulatory system.
The Royal Australasian College of Physicians (RACP)	• Supports Option 2. • Notes their disappointment that the use of health claims has been permitted in Australia and New Zealand. • Support for Option 2 is dependent on the form of the accompanying FSANZ framework for permitting claims, whether GLHC or other level claims. This framework must provide criteria which are robust, stringently regulated and developed with input from the public health and nutrition community. • In permitting health claims, requires adherence with WHO recommendations, highlighting the consensus among scientific and legal communities that a clear regulatory framework is the solution to reducing the number of vague, confusing and misleading claims. Such a

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	framework should reflect the permissibility of health claims that are consistent with national healthy policy, supported by scientific evidence, do not imply disease prevention, do not encourage bad dietary practice and are made in the context of the total diet. • FSANZ must develop robust criteria for permitting health claims to prevent industry from making claims with negative impact on health. The focus should be on actual health needs of the population. The benefits of allowing health claims are to facilitate healthier choices, attuned to public health priorities and specific long term health problems of the population. The impact on obesity and related non-communicable chronic diseases should be a priority when assessing health claims permissibility. This approach is condoned by WHO, who state that "to maximise the potential of nutrition labels and health claims to improve public health, regulations should be developed with long term dietary improvements across populations as their underlying goal". These concepts should be reflected in the framework for permitting GLHCs, specifically in relation to both the nature of the actual claims allowed, and the nutrient values of a product which would allow it to qualify to make a claim. • State legislation in Australia stipulates that whether stated or implied, the message conveyed on labels to consumers must not be misleading or deceptive, and any claim found to be deceptive or misleading is unlawful and penalties for this apply. It is not acceptable for a product to feature a health claim highlighting a positive aspect of a product when it is notably unhealthy in another respect. This is misleading and runs counter to public health promotion, particularly where the 'unhealthy' aspect directly cancels out the possible health benefits made in the claim. • Recognises that some claims may have roles in communicating general health messages to consumers, i.e. the benefits of dietary fibre. If the framework for claims is properly designed and regulated then there might be some positive outcomes from permitting health claims.