

Submission to: **Food Standards Australia New Zealand**

In response to:

PROPOSAL P293 NUTRITION, HEALTH AND RELATED CLAIMS

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Issue No: 1.0

Issue Date: 30/3/2012

*"Sharing health and hope
for a better life"*

Table of Contents

Executive Summary.....	3
Introduction.....	5
General Comments on the Revised Proposal.....	5
Discussion.....	6
Redraft of the new standard	6
Additional restrictions in requirements	6
Issues of specific drafting clarity	7
Proposed method to regulate fat-free & % fat free claims.....	9
Sanitarium supports Option 1 (status quo).....	9
Proposed method to regulate health claims of a general nature	10
Sanitarium support for industry self-substantiation.....	10
Issues and changes needed to pre approved health claims.....	11
Health claims currently missing from Schedule 2	11
Mechanism to keep Schedule 2 up to date with new claims.....	11
Conclusions & Recommendations.....	12

Executive Summary

As a producer of health foods in Australia and New Zealand for over 100 years, Sanitarium Health and Wellbeing regularly communicates to the public regarding the benefits of choosing healthy foods through on-pack messaging and other means.

Sanitarium has previously provided comments regarding health and nutrition related claims. In each case we have given qualified support for the use of health and nutrition claims as a way to communicate particular health &/or nutrition benefits of a food or ingredient to consumers. Whilst many aspects of P293 have been improved with each round of consultation, the draft standard has retained schedules of pre approved claims. This leaves little scope for anything other than content claims for any nutrient or property not included in a schedule. Such an approach will leave the burden of maintaining and improving this regulation almost entirely on industry. The regulatory burden will be particularly heavy with respect to new health claims and innovation and may stifle food and health innovation.

Sanitarium's previous support for the full regulation of health and nutrition claims remains conditional on the appropriate consideration of the following issues:

Clarity of the revised draft of the standard

- Seeking a variation to add a health claim that is not described in Schedule 2 is deemed to be a high level health claims variation, but the process for changing the schedule merely refers to an editorial note. High level claim variations are likely to require resources that are typically only available to multinational companies, who have the ability to fund the adoption of claims across multiple international jurisdictions with associated sales revenues.
- Additional restrictions in requirements table namely:
 - Phytosterols and cereals
 - Additional functions for vitamin B12
 - Inclusion of plant source omega 3's to claims table
 - Review of fibre points for beverages
 - Carbohydrate claim restrictions
- Issues relating to specific drafting clarity namely
 - Nuts & seeds in the definition of food groups
 - Interpretation of reference food
 - Vitamin and mineral comparative claims
 - Using specific descriptors that are not in the same row as the property of the food.
 - Folate claims vs. Folic acid claims

Fat free claims

- While we support restricting these claims to foods genuinely low in fat (which is achieved by schedule 1), Sanitarium sees no compelling evidence to further complicate the use of fat free claims. It should be pointed out that option 1 is already beyond the current status quo in that it will give force of law to prevent marginal % fat free claims from being made. Given the potential for significant regulatory impact caused by the pursuit of any option other than option 1, all other options should be considered in the context of a new standalone proposal to vary standard 1.2.7 once it has been gazetted.

Regulation of health claims that are general in nature

- Sanitarium remains opposed pre-approved health claims that are general in nature on the basis that:
 - Pre-approval will slow, if not stifle innovation.
 - Pre-approval provides very limited incentive for an individual company to apply for an extension to schedule 1 or 2.
 - There is no mechanism to routinely update schedule 2, as new knowledge emerges from other reputable regulatory or expert environments.
 - The list as it is fails to address suitable claims currently available in other reputable regulatory environments. A pathway to achieve consistency of claims across international, reputable regulatory environments should be clearly defined.

Introduction

Preamble

Sanitarium Health and Wellbeing began in 1898 with the vision to help people 'learn to stay well'. Our mission is to **'inspire and resource our community to experience happy, healthy lives'**. We have been committed to this philosophy for over 100 years and it is the reason we exist today. Sanitarium also believes that good business is based on trust, respect and community involvement.

Sanitarium has a strong history of educating the community about healthy eating and healthy lifestyles. All of Sanitarium's activities have twin goals in mind - to provide healthy foods that actively improve our community's health and well-being, and to offer easy-to-understand nutrition information and practical health advice.

Sanitarium Australia and Sanitarium New Zealand are owned and operated by Australian Health & Nutrition Association Limited and New Zealand Health Association respectively. We produce over 150 products and employ approximately 1700 people in our manufacturing and distribution sites throughout Australia and New Zealand.

Sanitarium welcomes the opportunity to comment on the development and evolution of the Australia & New Zealand Food Standards Code. We believe we can provide a unique perspective and give valuable suggestions into the food policy and standards development in Australia and New Zealand.

Information contained in this submission has been drawn from the experiences of Sanitarium, and contains no commercial-in-confidence material – unless otherwise highlighted.

General Comments on the Revised Proposal

Sanitarium commends the efforts that FSANZ has put into the development of a regulatory system for health and nutrition claims that seek to meet the interests of consumers, food industry and regulatory bodies. This new draft Standard and accompanying information has provided greater clarity and ease of interpretation, however we feel there are still a number of issues to be addressed.

- Regulation of health claims via a pre-approved list, and further restriction of content claims appears to have pushed the burden of this regulation almost entirely on to industry.
- The regulatory burden will be particularly heavy with respect to obtaining new health claims and innovation.
- Even given an expansion of schedule 2, we remain convinced that self substantiation as a better regulatory model. In the absence of self-substantiation, a routine mechanism for adding to schedule 2 on the basis of advancing knowledge with respect to diet related disease is sorely needed, along with appropriate incentives that make it easy and cost-effective for individual companies to innovate and propose new health claims. The justification for a claim might be complex but the application process must be straight-forward and cost effective, especially when community health stands to benefit.

Discussion

Redraft of the new standard

Overall Sanitarium supports the structure of the draft standard, with its format of simpler clauses. However we are concerned that the redrafted standard (relative to the Final Assessment Report FAR), appears to have retained material changes noted in our previous submission.

Material changes to the intent of the draft standard represent a breach of due process, in that material changes are not part of the present directive on submissions - to make the standard easier to understand. They may also have unintended cost implications. These implications may invalidate the cost benefit analyses that underpin the justification for the standard.

Additional restrictions in requirements

Whilst the structure and certain clauses within the Standard required major revision to ensure clarity, the schedules did not require substantial revision. In that regard the table to clause 11 (at FAR) has been converted to schedules 1 & 2 with an additional column to separate specific descriptor conditions and general claim conditions. In most cases this has proceeded fairly seamlessly. However in some cases material changes have been introduced. Our comments on these material changes are set out in the following table.

Clause	Issue, description & suggested solution
Schedule 2 Part 3	Phytosterols, phytostanols and their esters Condition (b) in Column 4 requires 0.8g total plant sterols per serve for all foods. In the previous draft this requirement was restricted to “edible oil spreads standardised by Standard 2.4.2”. Given the narrow band of allowable sterol concentrations permitted for cereals, this would force minimum serve sizes of 42g when many cereals have a 30g serve size. Requiring larger serve sizes would appear counter to strategies designed to address obesity, especially in the subgroup that these foods would be useful for. Suggested reword condition (b) in column 5 to read: (b) for edible oil spreads standardised by Standard 2.4.2, the food must contain a minimum of 0.8 g total plant sterol equivalents content per serving.
SCHEDULE 4 1	Removal of fibre points for category 1 beverages The revised Nutrient Profiling Scoring Criterion (schedule 3) still does not permit category 1 foods to score fibre points. If not counting fibre points prevents an increase to the number of healthier alternatives to standard cordials and fruit drinks, this would appear to be counter to the general need for the population to consume more fibre. Then this change appears contrary to previously stated policy principles ¹ , In addition, not allowing category 1 foods to score points for fibre will also result in a hampering of industry innovation in the area of healthy beverages with naturally occurring or added fibre, e.g. fibre rich smoothies. Suggested re lettering clause 1(d) to 1(e) and inserting clause 1 condition (d) to read: (d) fibre points in accordance with item 6 of this Schedule (F points); then {remove editorial note}

¹ Final Assessment Report P293 NUTRITION, HEALTH & RELATED CLAIMS 11 April 2008 pp11

Clause	Issue, description & suggested solution
Schedule 1 and or 2	<p>Clarity around claims for alpha linolenic acid and linoleic acid.</p> <p>We note disappointingly that any pre-approved claims for alpha linolenic acid (ALA) and linoleic acid (LA) are missing. These are biologically essential nutrients in the diet, yet are unfairly disadvantaged by their absence from both schedule 1 and schedule 2 of the draft standard. Both ALA and LA have adequate intakes for good health, set within the Nutrient Reference Values (NRV's) for Australia and New Zealand. It is clearly an omission that both content and health claims for these essential nutrients are missing.</p>
Schedule 1	<p>Additional claim for vitamin B12</p> <p>Vitamin B12 is required as a co-factor for the enzyme L-methylmalonyl-CoA mutase, which is involved in the TCA cycle. Therefore, a claim regarding the role of B12 for normal energy production is warranted.</p>
Schedule 2	<p>Rationale regarding the conditions for carbohydrate content claims.</p> <p>In column 5 of schedule 2 of the draft standard, there is the condition for carbohydrate claims requiring a food to contain at least 55% of the energy from carbohydrate. Sanitarium questions the rationale for this condition. While it is generally accepted that healthy diets reflect a high carbohydrate profile, the macronutrient profile of the total diet is the outcome of the carbohydrate content of each food and relative amount of each food consumed over the day. Applying this total diet context to a single food is therefore inappropriate. Sanitarium notes that other groups have defined carbohydrate foods based on the actual amount of carbohydrate in grams. For example, the GI symbol program defines a high carbohydrate food as one providing around 10g carbohydrate per serve (see http://www.gisymbol.com.au/join.php). Sanitarium therefore recommends that the conditions for carbohydrate claims be modified to regulate claims based on the actual amount of carbohydrate in grams, either per serve, or per 100g.</p>

Issues of specific drafting clarity

The table below lists specific clauses where the draft Standard either misses an issue, or is worded in such a way that ambiguity could arise.

Clause	Issue, description & suggested solution
2 interpretation food group	<p>Definition of food groups:</p> <p>Sanitarium notes that nuts (tree nuts) & seeds are excluded from all food groups in the drafting of the new standard, therefore it is unclear as to whether the draft standard will allow for claims to be made regarding nuts & seeds and foods made from them. Nuts & seeds are primary foods, and should be included in a food group. Sanitarium therefore recommends that FSANZ amend the current food groups and include nuts & seeds in an appropriate group. We note that nuts & seeds are grouped along with other 'protein foods' in dietary guidelines materials, including the recently drafted revised Dietary Guidelines for Australian's.</p> <p>Sanitarium notes that analogues derived from legumes and cereals mentioned in Column 1 of the Table to clause 3 in Standard 1.3.2, are included within subclause (c) of Clause 2 (Interpretation). However, it is unclear as to whether other analogues of milk and milk products are specifically excluded and therefore prevented from making comparison</p>

Clause	Issue, description & suggested solution
	<p>claims. There are now a number of nut-based milk analogues available in Australia and New Zealand, which provide consumers with a plant-based alternative to dairy milk, as well as soy and rice milk. Sanitarium recommends that the wording within subclause (c) refer to 'milk and milk products as standardised in Part 2.5 and their analogues', or words of similar meaning.</p>
<p>2 interpretation reference food</p>	<p>Reference food, interpretation</p> <p>Subclause (a) and the accompanying editorial note in the definition of a reference food are difficult to interpret. Subclause (a) specifically states that a reference food is of the same food type as the food for which a claim is made and that has not been further processed'. The first example in the editorial note to this definition refers to reduced fat milk compared to whole milk. Yet, reduced fat milk is 'further processed' to remove fat, so the example does not appear to comply with the reference food definition. The meaning of 'further processed' needs to be clarified so the clause is consistent with the example.</p>
<p>8</p>	<p>Vitamin and mineral comparative claims</p> <p>The current drafting states that claims comparing the vitamin or mineral content of a food with that of another food must not be made. It is unclear as to whether the intent of this clause is just to prevent comparative claims between foods from different food groups (e.g. comparing the levels of iron in breakfast cereal to that in, say eggs), or whether the standard aims to prevent claims regarding the vitamin or mineral content of foods within the same food group (e.g. the calcium level in lite milk compared to the calcium level in calcium-enriched milk), or both. Sanitarium believes that it is useful to allow comparisons of vitamin and mineral content of different foods within the same food group, which act as substitutes for each other. For example, enabling the claims regarding the calcium content of enriched soy beverages to dairy milk is reassuring to consumers who need or choose to replace dairy products with soy, advising them that enriched alternatives provide equivalent calcium levels.</p>
<p>11 (1) & (8)</p>	<p>Claims where the 'Specific descriptor' is not in the same row as the 'Property of food'.</p> <p>It is not clear if claims are restricted to the terms specified in column 3 for each food property (each row in column 1 of schedule 1), or if the term could be used as long as it is mentioned elsewhere in column 3 and the food complies with an equivalent condition from column 4. For example Cholesterol only has 'Low' or 'Reduced' style claims mentioned in this row. However some foods are free of cholesterol and can meet the 'no detectable' requirements needed to make the claim. These foods can sit within food groups that contain cholesterol; hence it would be valuable for the consumer to know of alternate equivalent products that are 'cholesterol free'. Cholesterol free claims currently have a legitimate existence in the market place.</p> <p>Suggested reword subclause 3 to read:</p> <p>(c) equivalent to the specific claim conditions in Column 4 for the relevant descriptor.</p> <p>Note: It is recognised that lactose, trans fatty acid and gluten claims are governed by subclauses ((5) & (7))</p>

Clause	Issue, description & suggested solution
16	<p>Process for adding a new claim to the schedules is unclear.</p> <p>A variation to add a health claim that is not described in Schedule 2 is deemed to be a high level health claims variation, but the process for changing the schedule merely refers to an editorial note. High level claim variations are likely to require resources that are typically only available to multinational companies.</p> <p>“New health claims deemed to be high level health claims”: this is confusing as there is no definition of “high level health claim in the proposed standard only a reference to a definition of “high level health claims variation in the Editorial note</p>
Schedule 1 & 2	<p>Folate vs. Folic acid claims</p> <p>Much stronger health claims are permitted for Folic acid than folate. However in the transitional standard 1.1A.2 3 (ea) only the “L-methyltetrahydrofolate, calcium” form is excluded from making maternal folate claims in the Table to subclause (3) (e). It is unclear whether folic acid, which may have been stabilised in the food by the use of mildly alkaline buffering salts, would still be eligible to make folic acid claims.</p> <p>Suggested reword Folic acid claim in SCHEDULE 2 column 1 to read:</p> <p>Replace ‘Folate’ with ‘Folate (including L-methyltetrahydrofolate, calcium)’</p> <p>Replace ‘Folic acid’ with ‘Folic acid (including Folic acid stabilized via pH adjusting salts)’</p>

Proposed method to regulate fat-free & % fat free claims

Sanitarium supports Option 1 (status quo).

Aside from restricting these claims to foods genuinely low in fat (which is achieved by schedule 1), Sanitarium sees no compelling evidence to further complicate the use of fat free claims. It should be pointed out that Option 1 is already beyond the current status quo in that it will give force of law to prevent marginal % fat free claims from being made. Responsible food promotion is already becoming subject to an increasing number of standards², these should be given an opportunity to demonstrate their effectiveness before stronger measures are considered. Given the potential for significant regulatory impact caused by the pursuit of any option other than Option 1, all other options should only be considered in the context of a new standalone proposal to vary standard 1.2.7 once it has been gazetted.

Question	Comment (just highlight issues not ‘more manageable’)
3. Do you support option 1 (status quo), option 2 (voluntary action through a code of practice), or option 3 (regulate with additional regulatory requirements for fat-free and % fat-free claims)? Please give your reasons.	<ul style="list-style-type: none"> Option 1 is already beyond the current status quo in that it will give force of law to prevent marginal % fat free claims (typically between 90-96%) from being made. FSANZ own research indicates that “Many consumers are sceptical about fat-free claims, particularly on foods of lower nutritional value.” The policy principle of proportionate response does not warrant a stronger regulatory response. A code of practice (option 2) is unlikely to be universally followed. Without some form of enforcement mechanism, the result would be similar to that achieved with CoPNC, responsible manufacturers doing the right thing being undermined by

² Codes of practice for food promotion in Australia and New Zealand

<http://www.adstandards.com.au/process/theprocesssteps/specificproductsandissues/foodandbeverageadvertising> and http://www.asa.co.nz/code_children_food.php

	<p>companies willing to ignore the code of practice.</p> <ul style="list-style-type: none"> • Option (3a) would restrict claims on many more products than the stated intent of capturing high sugar snack foods. Foods not meeting the NPSC are already restricted from making anything more than content claims. This option would also prevent content claims with respect to fat for these products. Given the significant regulatory impact, pursuit of this option should only be considered as a new standalone proposal to vary standard 1.2.7. • Option (3b) not supported. However it is hard to assess this option as the threshold has yet to be determined. Therefore pursuit of this option should only be considered as a new standalone proposal to vary standard 1.2.7. • Option (3c) not supported. However it is hard to assess this option as the categories are yet to be determined. Therefore pursuit of this option should only be considered as a new standalone proposal to vary standard 1.2.7. • Option (3d) not supported. However it is hard to assess this option as the threshold has yet to be determined. Therefore pursuit of this option should only be considered as a new standalone proposal to vary standard 1.2.7.
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Proposed method to regulate health claims of a general nature

Sanitarium support for industry self-substantiation.

Previous drafts of the health claims standard differentiated High Level Health Claims (HLHC) from General Level Health Claims (GLHC). Whilst Sanitarium has supported the need for HLHC to be pre-approved, we have consistently remained opposed to pre-approved GLHC. The current draft no longer differentiates between these types of claims. Therefore in continuing to voice our opposition to pre-approved health claims, we are referring to health claims of a general nature (GLHC) and not claims that could be regarded as HLHC.

Sanitarium supports the industry self-substantiation model for the regulation of health claims of a general nature (not High Level). This model, whilst of some concern to enforcement agencies, is actually very similar to how claims have been managed for many decades. The requirements that claims not mislead and be truthful, is already well protected by Australian and New Zealand consumer law. A formal (self substantiated) health claims standard would provide the framework for assessing credible evidence underpinning claims such that the scientific aspects meet the due diligence requirements of consumer law.

The Australian Competition & Consumer Commission (ACCC) and New Zealand Commerce Commission (NZCC) have both showed themselves to be willing to act 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.

In any case, consumer law has precedence over the food standards code. This is evidenced by the approach taken on country of origin claims and 'free from' claims, where the view of the ACCC & NZCC drive the content of the food standards code on these issues.

The self-substantiation model also allows new knowledge and claims from internationally reputable regulatory environments to be adopted without the need for further legislative burden or consumption of government resources.

A self-substantiation framework, conditioned by consumer law would foster innovation, with real incentive for manufactures 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.

Issues and changes needed to pre approved health claims

As already mentioned above, the structure of the current draft remains committed to a preference for pre-approval for all health claims. This approach pushes the burden of this regulation heavily on to industry, and will continually tie up FSANZ and industry resources to maintain the health claims schedules. The regulatory burden will be particularly heavy with respect to innovation. There will be little to no incentive to innovate if one has to:

- expend resources to compile the supporting data,
- pay FSANZ to expedite ones proposed claim, and yet
- gain limited market advantage as competitors to develop similar product and freely ride on the back of the claim once gazetted.

In addition, credible claims from overseas will have to wait until put forward as a proposal or have someone with deep pockets 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, particularly smaller companies with limited resources (yet are commonly the most highly innovative).

Whilst pre-approved claims are apparently still being pursued, it is noted that some progress has been made to provide at least some protection to new (paid) health claims applications. However we suggest further changes are required to make it more workable:

- Schedule 2 needs to be more completely ‘unpacked’ (and hence expanded) from the information already available.
- FSANZ commitment to assess in market claims is yet to be honoured.
- A mechanism is needed to keep schedule 2 up to date with new claims.
 - The discussion paper notes that FSANZ intends to review claims emerging from the EU, but there appears to be no process to ensure these emerge as concrete proposals.
 - The discussion paper appears silent on approved health claims from other countries, a suitable method for incorporating suitable claims from all countries with reputable health claims needs to be developed.

Health claims currently missing from Schedule 2

Sanitarium recommends that additional claims be drafted into the proposed standard on the basis that they were missed in error during the 1st draft generation of schedule 2. These additional claims were provided in our previous submission dated 15th May, 2009

Mechanism to keep Schedule 2 up to date with new claims

During the focused industry consultation session in Melbourne (7th April 2009) FSANZ indicated that they would not be in a position to routinely update Schedule 2 on the basis that many of the credible claims emerging overseas may not be applicable in Australia and New Zealand. In this regard we note that industry bodies such as the Australian Food and Grocery Council (AFGC), New Zealand Food and Grocery

Council (FGC), the Australian Chamber of Commerce and Industry (ACCI) and industry players generally are well placed to gather emerging claims of interest at a pre-competitive level. While the burden appears to rest with these industry bodies to lobby and suitably focus FSANZ efforts on new relevant claims we do not envisage that there will be any lack of clarity at all around the relevance of international claims for Australia/New Zealand as a result of any issues surrounding the burden of relevance if industry itself is involved. The science behind any new proposal, the proper scope of FSANZ, can stand or fall on merit whereas the market relevance is a completely different thing.

Conclusions & Recommendations

Overall Sanitarium supports the format of the revised draft standard 1.2.7 relative to the version presented in the Final Assessment Report (FAR). However in the redrafting process, it would appear that some material changes have been made to the standard, which has not been subject to full public consultation. These material changes have implications that may invalidate the cost benefit analyses that underpin the justification for the standard. As such the material changes outlined above are not supported by Sanitarium.

For the regulation of non-High Level health claims, Sanitarium remains supportive of an industry self-substantiation model.

The fair 'trading acts' and their enforcement bodies are well placed to prevent irresponsible claims from going unchallenged. This model is actually very similar to how claims have been managed for many decades. On this basis, the enforcement load on the state and territory governments need not be any different to the current situation.

Given that pre-approved claims are still being pursued, then further changes will be needed to make it more workable such as; further expansion of Schedule 2 prior to gazettal, addressing the additional restrictions in the schedules, issues of specific drafting clarity, fair assessment of in market claims and a mechanism to keep schedule 2 up to date.

Sanitarium's support for the full regulation of health and nutrition claims remains conditional on reverting to the industry self-substantiation model for lower level claims, or at the very least, expanding the completeness of schedule 2 and addressing other related issues above.