P293 – Nutrition, Health and Related Claims

Submitter responses to questions 27-74 of the Initial Assessment Report

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CHAPTER 1: ISSUES ARISING FROM THE CLAIMS CLASSIFICATION FRAMEWORK

1.1 'WHOLE-OF-DIET' CLAIMS

Question 27

Do you think the examples of whole-of-diet claims provided in the Policy Guideline are claims made in the context of the appropriate total diet; and do you think the way the claimed benefit is expressed determines where the claim is positioned in the Claims Classification Framework?

Out of 147 submitters, 52.4% (77 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	27	17	5	2	51
Government	6	2	-	-	8
Public health	10	3	-	-	13
Consumers	2	-	-	-	2
Other	3	-	-	-	3
Total	**48**	**22**	**5**	**2**	**77**

Overview

Thirty per cent of submitters (23) agreed that the examples of whole-of-diet claims provided in the Policy Guideline are claims made in the context of the appropriate total diet. Forty submitters agreed that how the claimed benefit is expressed determines where the claim is positioned in the Claims Classification Framework.

Agree the examples are claims made in the context of the appropriate total diet

There were 23 submitters that agreed that the examples of whole-of-diet claims provided in the Policy Guideline are claims made in the context of the appropriate total diet (NCWA, Nutrition Aust., PHAA (supported by ACA), Tomox, Aussie Bodies, AFGC, MasterFoods Aust. NZ, ANIC, Dairy Aust., DSM Nut. Prod, Horticulture Aust., Parmalat Aust., Wyeth Aust., NSW Food Authority, SA DoH, DAFF, WA DoH, Monash Uni – N&D Unit, Griffins Foods, Nutra-NZ, NZ MoH, Heinz Aust./Heinz Watties NZ).

Whilst agreeing with this, it was considered that this question was difficult to answer (Nutrition Aust.). It was also noted by other submitters that this was a particularly difficult issue, but one that is important to clarify, so that agencies engaged in nutrition education can provide dietary advice without contravening the Code (PHAA, ACA, SA DoH, Monash Uni – N&D Unit).

A reason provided for agreeing with this was that a 'healthy balanced diet' or a 'healthy diet' is referenced (Dairy Aust.).

It was noted by one submitter that these examples are relatively clear and simple. Claims that contain too much information are not useful to consumers (page 66 in IAR) (DAFF).

Some submitters did not explicitly answer this question but made comments as follows (DAA, NZDA, CML, NZJBA, Frucor, Unilever Australasia, Sanitarium Health Food Comp, ABC, MLA, GW Foods).

Although not specifically commenting on the examples of claims provided in the Policy Guideline, DAA, supported by NZDA, recommended that 'whole of diet' claims should be made in the context of a relevant healthy diet. A number of submitters generally stated that whole-of -diet claims are a form of claim made in the context of the appropriate diet (NZJBA, Frucor, ABC, MLA, GW Foods).

CML felt that whole-of-diet claims that don't reference a serious disease or condition could be considered 'dietary advice' in certain contexts (i.e. general information on a retail food brochure, promoting a range of foods). These claims should only be allowed on 'appropriate' foods that have some nutritional value, however this will need to be clarified.

It was considered that the examples of whole-of-diet claims provided in the Policy Guideline are appropriate claims as all claims are required to be substantiated (Unilever Australasia).

Sanitarium Health Food Comp agreed with FSANZ that the examples of whole-of-diet claims are risk reduction claims and not whole-of-diet claims.

Classification in the Claims Classification Framework

There were 40 submitters that agreed that how the claimed benefit is expressed determines where the claim is positioned in the Claims Classification Framework (NCWA, Diabetes Aust., DAA, NZDA, GI Ltd, Nutrition Aust., PHAA (supported by ACA), Tomox, Aussie Bodies, ANIC, CHC, CML, Dairy Aust., DSM Nut. Prod, GW Foods, Hort. Aust., National Foods, Wyeth Aust., Tas DoH&HS, NSW Food Authority, SA DoH, DAFF, WA DoH, Monash Uni – N&D Unit, NSW DoH - N&PA Branch, Auckland Reg. PHS, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZ Magazines, NZTBC, Fonterra supported by Mainland Products, Griffins Foods, Nutra NZ, NZ MoH, Heinz Aust./Heinz Watties NZ).

An explanation was given, that as the examples provided are risk reduction claims that are made in the context of the total diet, they should therefore fit within the claims classification framework and be substantiated and regulated accordingly (Nutrition Aust., PHAA, ACA, Hort. Aust., Tas DoH&HS, SA DoH, WA DoH, Monash Uni – N&D Unit). NSW DoH - N&PA Branch agreed that the examples provided are risk reduction claims and as such should be included in the Claims Classification Framework.

Also, the level of claim is wholly dependent on the way the claim is expressed – if it references a serious disease or biomarker, it is a high level claim (DAFF). Auckland

Reg. PHS and CHCH also agreed that classification is according to whether it references a serious disease/biomarker or non-serious disease or condition.

It was noted that the examples given do mention conditions that indicate the appropriate position in the classification framework (ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZ Magazines, NZTBC).

The framework clearly positions whole-of-diet claims, in addition to the need to substantiate the claims and not mislead the consumer, will ensure the claims are balanced and justifiable (Fonterra supported by Mainland Products).

Although not specifically agreeing that how the claimed benefit has been expressed determines the classification of the claim, Parmalat Aust. commented that they supported how the claimed benefit was expressed. NZFGC considered that the examples of 'whole-of-diet claims' provided in the Policy Guideline are whole-of-diet claims that should fall within the health claim framework. In addition, it was considered that whole-of-diet claims should be subjected to the same substantiation requirements as claims for individual foods, and that the claims classification would determine the level of this requirement. No further restrictions are warranted (NCEFF).

General comments

Some submitters did not explicitly answer the questions but provided the following comments (TCCA, Dr C Halais, Dr R Stanton, NCEFF, NHF Aust., NHF NZ, ABC, ASMI, Cadbury Schweppes, Food Tech. Assoc. of Vic., GW Foods, Goodman Fielder, MLA, National Foods, Sanitarium Health Food Comp, NSW DoH - N&PA Branch, TGACC, NZFGC, NZJBA supported by Frucor, Nutra-Life H&F, NZ V&PG Fed/NZFG Fed, NZFSA, Nestle, Unilever Australasia, Diabetes Aust., GI Ltd, CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA). Other general comments provided by submitters that did answer the questions above, are also included below.

It was suggested that unless the wording of the claim is prescribed by FSANZ, there is potential for misinterpretation by consumers. Health claims about fruits and vegetables as part of an overall healthy eating message are justified (TCCA).

NHF Aust. and NHF NZ believed that criteria for 'whole of diet' claims should, where possible, reflect the nutrient of emphasis within the claim, for example, the claim "a healthy, balanced diet that includes dietary fibre from a number of sources is one that can help reduce you risk of constipation" could only be permitted on foods that are at least a 'good source' of dietary fibre.

Whole-of-diet claims on processed foods

It was considered by one submitter that whole-of-diet claims should be examples/illustrations used to promote dietary guidelines and should be restricted to unprocessed or minimally processed foods that are natural sources of nutrients (Dr R Stanton). NZ MoH also thought it was appropriate that only certain categories of food

are allowed to make this type of claim, as they don't want unhealthy foods (not promoted by food and nutrition guidelines) to be promoted under this banner.

It was recommended that whole-of-diet claims consider the nutrient density of foods to highlight the fact that the 'claimed' food makes an important nutritional contribution to a healthy, balanced diet, not just to the intake of a specific nutrient. With the current obesity epidemic, it is essential that whole-of-diet claims be based on nutrient-dense foods, helping people get more nutrients from fewer calories (MLA).

Conversely, ASMI questioned why processed foods would be potentially excluded from whole-of-diet claims if they provide the nutritional benefits in context of total diet. Cadbury Schweppes also disagreed with the comment that it is not desirable that processed foods, including fortified foods, carry whole-of-diet claims. They noted that processed foods with a balance of nutrients may in fact be better than some fresh products where the level of nutrients may be unknown due to seasonal factors or where it is necessary to consumer high levels in order to received low levels of nutrients. Other submitters also considered that all foods are appropriate for claims since all claims require substantiation (GW Foods, Goodman Fielder, AFGC, MasterFoods Aust. NZ, National Foods).

The CMA reported confusion as to how whole-of-diet claims would be used, with some claims referred to in the context of the appropriate diet. They noted that some members of SDAC think that whole-of-diet claims should only be permitted on appropriate foods and that SDAC has also stated that it is not desirable to have processed foods, including foods fortified with other substances, carrying whole-of-diet claims, which raises the question as to what are processed foods, e.g. bread? They supported the use of whole-of-diet claims on all foods (except alcohol), including processed foods, e.g. confectionery. They challenged the use of the term 'appropriate foods', which indicates bias and promotes the concept of good and bad foods. It was reiterated that there is a role for all foods in a balanced diet, including confectionery as a treat food which can make a positive contribution to the overall diet, and is an appropriate a food as any for carriage of health claims, despite a small contribution to overall diet (2%) (submission outlines the vitamin and mineral content in 50g milk chocolate). In summary, they stated that foods should not be disqualified based on their nutritional profile, in particular energy, sugar, or fat content, providing there is enough of the specified component to achieve the claimed benefit when consumed as directed. Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA –NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch and CM of SA supported these views.

NZ V&PG Fed/NZFG Fed cautioned against the development of criteria around foods suitable/not suitable for carrying a claim. They explained that guidelines in relation to 'total diet' cannot be applied to individual foods and can be difficult to apply to individual food groups. Foods such as fruits (whether they are fresh, canned, juiced or frozen) are intrinsically high in sugar yet offer considerable nutritional value to consumers; and for some nutrients and biologically active substances (e.g. carotenoids) absorption is improved in the presence of small amounts of fat.

National Foods submitted that the point (p.43 of the IAR) "whole of diet claims should only be allowed on 'appropriate' foods" is redundant as foods such as bottled

water may appear to have little nutritional value, but are vitally important for hydration. They pointed out that processing foods (e.g. Vitasoy Soya milk) does not imply reduction of nutritional value as per the comments (p.43 of the IAR) that "it is not desirable that processed foods ... carry whole of diet claims". They argued that processed foods or foods fortified with other substances should have greater imperative to carry whole-of-diet advice to put their (incorrectly assumed) 'poor nutritional status' into context.

Dietary Advice

It was recommended that dietary advice should remain outside the Standard and should not be considered a health claim (Goodman Fielder, MLA, Unilever Australasia, AFGC, MasterFoods Aust. NZ, Dairy Aust., National Foods). Nestle also agreed that dietary advice should not be considered a claim and should fall outside of the requirements of a standard or guideline. They added that whole-of-diet claims are a form of a claim that is made in the context of the appropriate diet (Nestle).

It was believed that ‘whole of diet’ claims are potentially health claims but this is dependent upon the degree to which dietary patterns are linked to specific health aspects (NHF Aust., NHF NZ).

The need to differentiate between dietary advice and claims on products was strongly recommended by National Foods. They stated that whole-of-diet advice such as Dietary Guidelines is used by the food industry in general nutrition education programs, to support government leadership on healthy eating e.g. communications with health professionals. Nutrition and health claims directly related to food product nutrition marketing and promotion, could also be made in the context of a holistic dietary approach, but are subject to substantiation. National Foods opposed treating 'whole-of-diet' advice as nutrition and health claims as they believed it would fail consumers and industry in supporting public health education. They questioned if FSANZ will cover the resource cost of the food industry supporting initiatives in health education if the regulatory system prohibits 'whole-of-diet' advice? They agreed however that whole-of-diet claims are nutrition and health claims, directly related to food product nutrition marketing and promotion, and could also reasonably be made in the context of a holistic dietary approach (National Foods).

Although whole-of-diet claims should not always be coupled with a benefit such as risk reduction, the claim should be treated as a health claim when a benefit is stated. In the absence of references to disease risk reduction or other health benefits, whole-of-diet claims should be viewed as dietary advice rather than health claims (question 28) (National Starch, Solae Comp.).

Cadbury Schweppes considered that ‘whole-of-diet’ claims must always be coupled with a claimed benefit and to a specific nutrient(s) in the related foods (Question 28).

Claim examples provided in the Policy Guideline

It was considered by Dr R Stanton that the claim examples given were unlikely to be used. In addition she considered that constipation was wrongly classified as a non-serious disease, and a better example that might be used for a non-serious disease

would be "A balanced diet reduces your risk of ill-health and low energy levels". Regarding the example given for a serious disease, she considered that this was satisfactory and fitted within the classification framework (Dr R Stanton).

Sanitarium Health Food Comp commented that the examples given were very general as they were written, and therefore likely to be meaningless to consumers. They questioned the need to include the words "a healthy balanced diet that..." as they believed this is vague and unlikely to be applied or understood by consumers. Diabetes Aust. and GI Ltd agreed with this issue and said that the words "healthy [balanced] diet" do not have a lot of meaning in themselves for the average consumer and need to be 'fleshed' out as in the second example "A healthy diet that may lower the risk of … is one that is low in fats and includes fibre from a variety of sources including a variety of fruits and vegetables, and wholegrain and bran cereals."

This was further expanded by TGACC who noted that the words "healthy balanced diet" do not in themselves convey appropriate advice for consumers and could be misused as a 'tag line' in order to allow a number of health related claims that might otherwise be prohibited. More detail is probably required in order to make the dietary context meaningful to consumers (TGACC).

Other general comments

Tas DoH&HS considered that whole-of-diet claims should be clarified to ensure that nutrition education provided by government and non-government agencies does not contravene the Code.

A recommendation was made that whole-of-diet claims need to be defined (NZFSA).

Nutra-Life H&F commented that the diet should always be seen in terms of its totality, and any connotation limiting it to a reduced range of nutrients, which may result in unbalanced nutrition, should be avoided.

It was stated by Food Tech. Assoc. of Vic. that the question is not easily understood, and the word 'claim/s' is used five times in different contexts.

Dr C Halais commented that this question was not applicable if no claims are allowed.

Other comments provided but not in direct response to the question

Kellogg's Aust. support the communication of whole of diet, performance and wellbeing, life stage claims and sliming claims that are scientifically substantiated, reflective of current scientific opinion and communicated according to the Policy Principles that all claims are made in the context of the total appropriate diet.

NZFGC questioned the desirability of including the views of "some members" of the SDAC in the IAR in relation to whole-of-diet claims. They added that it would be of interest to know the views of the "other members". They considered that such views have no place in a document of this type as the statements can bias the need for constructive debate.

ACA noted that as a member of SDAC, they agreed with the comments made on page 43 of the IAR regarding whole-of-diet claims. They also considered that these arguments also apply to dietary guideline claims. Dietary guideline claims should only be allowed on appropriate foods that do not lead consumers to have unrealistic expectations of an individual product's ability to meet the dietary guideline in question e.g. a can of pumpkin soup would not significantly assist consumers in achieving the dietary guideline "The Australian Dietary Guidelines recommends a healthy diet containing at least five servings a day of vegetables".

Question 28

Should whole of diet claims always be coupled with a claimed benefit (for example, those illustrated in the Policy Guideline are linked to a risk reduction claim), or should whole-of-diet claims purely represent either the Australian Dietary Guidelines or the New Zealand Food & Nutrition Guideline? If the latter, do you consider the claim to be dietary advice, which would fall outside the scope of the regulatory framework for nutrition, health and related claims?

Out of 147 submitters, 52.4% (77 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	28	12	4	3	47
Government	5	2	-	-	7
Public health	10	4	-	-	14
Consumers	2	-	-	-	2
Other	5	2	-	-	7
Total	**50**	**20**	**4**	**3**	**77**

Overview

Less than 10 per cent of submitters (6) stated that whole-of-diet claims should always be coupled with a claimed benefit whereas 20 submitters stated that whole-of-diet claims do not necessarily need to be linked with a claimed benefit. Three submitters disagreed that they be coupled with a claimed benefit. Another three stated that all whole-of-diet claims should purely represent either the Australian Dietary Guidelines or the New Zealand Food & Nutrition Guidelines. Nearly 40 per cent of submitters (30) believed that communication of dietary guidelines is dietary advice, which falls outside the scope of the proposed regulations for nutrition, health and related claims. Seven stated that communication of dietary guidelines should be considered as part of the scope of the proposed regulations for nutrition, health and related claims.

Whole of diet claims coupled with a claimed benefit

There were six submitters that clearly stated that whole-of-diet claims should always be coupled with a claimed benefit (Diabetes Aust., DAA, GI Ltd, CSIRO – HS&N,

NZDA, Nutra NZ). Bakewell Foods submitted that a whole-of-diet claim should be coupled with a claimed benefit if it is linked to a serious disease.

A reason provided for this view was that not all dietary guidelines have been shown to be linked to a health benefit (CSIRO- HS&N).

It was further explained that if whole-of-diet claims are only allowed on foods that meet certain qualifying/disqualifying criteria then they would not be considered to be simple dietary advice and therefore they should be regulated (Diabetes Aust., GI Ltd). DAA added that whole-of-diet claims can also be representative of the Australian Dietary Guidelines because all claims are subject to inclusion and exclusion criteria.

Conversely there were 20 submitters who stated that whole-of-diet claims do not necessarily need to be linked to a claimed benefit (ABC, AFGC supported by MasterFoods Aust. NZ, Dairy Aust., GW Foods, Goodman Fielder, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZ Magazines, NZTBC, Griffins Foods, Mainland Products, NZFGC, NZJBC, Frucor, Nestle, Unilever Australasia) and three submitters opposed the need for whole-of-diet claims to be linked to a claimed benefit (DSM Nut. Prod., National Foods, National Starch). Cadbury Schweppes also said that in some cases whole-of-diet claims may be considered as dietary advice.

Reasons provided for these views were that they might be considered purely dietary advice/be representative of the Australian and NZ Dietary Guidelines (GW Foods, Bakewell Foods).

It was suggested that although food manufacturers may prefer to link this type of dietary advice, they should not be compelled to do so. If brand image is built using dietary advice alone, this would not pose any threat to public health and safety and therefore need not be drawn in to the framework (Mainland Products).

Although not agreeing that all whole-of-diet claims should be linked to a claimed benefit, a number of submitters noted that a whole-of-diet claim that is linked to a claimed benefit does fall within the scope of a health claim (Goodman Fielder, AFGC supported by MasterFoods Aust. NZ, Dairy Aust., GW Foods, MLA, National Foods, National Starch, Parmalat Aust., NZFGC, Unilever Aust.). Such substantiated compound claims, according to the Policy Guidelines, require regulation appropriate to the part of the claim that falls within the higher claim category (AFGC supported by MasterFoods Aust. NZ, Dairy Aust., GW Foods, National Foods, Parmalat Aust.). In the absence of references to disease risk reduction or other health benefits, whole-of-diet claims should be viewed as dietary advice rather than health claims (National Starch, Solae Comp.).

ANIC made a similar comment, in their view to be a health claim, whole of diet claims should be linked to a claimed benefit, e.g. risk reduction.

Hort. and Food Research Institute of NZ stated their view that health claims must relate to specific foods or specific components in foods.

Whole-of-diet claims representing Dietary Guidelines

A small number of submitters stated that all whole-of-diet claims should purely represent either the Australian Dietary Guidelines or the New Zealand Food & Nutrition Guideline (NCWA, DSM Nut. Prod., Sanitarium Health Food Comp.). Northland Health Dietitians submitted that whole-of-diet claims should relate to the Australian Dietary Guidelines or the NZ Food and Nutrition Guidelines. NZFSA said that whole-of-diet claims should be consistent with the Guidelines.

Heinz Aust./Heinz Watties NZ said that whole-of-diet claims may be based on dietary guidelines.

There were 30 submitters that believed that communication of dietary guidelines is dietary advice, which falls outside the scope of the proposed regulations for nutrition, health and related claims (AFGC supported by MasterFoods Aust. NZ, ANIC, NCWA, Dairy Aust., DSM Nut. Prod., Goodman Fielder, GW Foods, MLA, National Foods, Parmalat Aust., Tas DoH&HS, NZFGC, Nutra NZ, Hort and Food Research Institute of NZ, Unilever Australasia, Nestle, Mainland Products, Cadbury Schweppes, Sanitarium Health Food Comp., CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA).

Reasons provided by these submitters for this view were that:

- Dietary advice given by health professionals does not relate to sales of individual products and should therefore not be regulated as health claims (Tas DoH&HS);

- Whole-of-diet claims should represent the NZ Food and Nutrition Guidelines and therefore become an extension of the education process of these guidelines and is therefore outside the framework for health claims (Hort. and Food Research Institute of NZ);

- Whole-of-diet claims do not necessarily constitute a health claim and that communication stemming from the Australian or NZ Dietary guidelines may be dietary advice and should not be considered part of Standard 1.2.7 (CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA);

- The claim example 'A healthy balanced diet includes fibre from a number of sources' is dietary advice (not coupled with a condition), which falls outside the scope of the framework (ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, NZTBC, NZ Magazines);

- If not linked with a claimed benefit these claims should not be included in this discussion (Unilever Australasia); and

- Eat Well Australia Guidelines, Recommended Dietary Intakes and strategies such as the Healthy Diet Pyramid are government developed or supported (NCWA).

Fonterra commented that whole-of-diet claims or dietary advice will only fall outside the scope of this framework if it cannot be inferred that the product is linked to supporting the dietary advice, in which case it wont be a claim. The key is to determine whether or not the label or advertisement is representing that the food product provides health benefit and if so it comes within the claims framework, whether or not it involves references to official guidelines.

A small number of submitters felt that communication of dietary guidelines should be considered as part of the scope of the proposed regulations for nutrition, health and related claims (CHC, Northland Health Dietitians, NZDA, Griffins Foods, TGACC, NZFSA, Naturo Pharm). Their comments are below.

TGACC noted that 'whole-of-diet' claims can stand alone as relevant nutritional advice in theory, but the statement needs to be relevant to the food (see example under the 'Appropriate Foods' heading below).

Dietary advice should be within the regulatory framework so as to protect consumers from false and misleading information. The ability of consumers to make health judgements will depend on their knowledge about the nutritional requirements. In the absence of such knowledge, the consumer's ability to discern accurately a food's health or nutritional value is diminished. Consumers may come to the false understanding that their health requirements are covered by a particular range of foods that have been marketed in the most favourable light possible (CHC).

Foods allowed to have whole-of-diet claims should adhere to strict qualifying/disqualifying criteria (Northland Health Dietitians). NZFSA said that whole of diet claims should fall within the scope of the Classification Framework and be bound by any qualifying/disqualifying criteria. An individual's diet should not be skewed outside recommended guidelines due to whole of diet claims (NZFSA).

If the whole-of-diet claim represents the NZ Food & Nutrition Guidelines, NZDA does not see the claim as dietary advice, which would fall outside the scope of the regulatory framework for nutrition, health and related claims. If the food manufacturer or marketer wished to give pure dietary advice guidance to consumers, this could be achieved as separate nutrition information communications e.g. on posters and flyers. This would avoid consumer confusion between product marketing and nutrition advice (NZDA).

Dietary advice should be within the regulatory framework so as to protect consumers from false/misleading information (TGACC).

Griffins Foods believed that dietary advice given in association with a food should be relevant to that food, which would constitute a claim.

It was considered by Dr R Stanton that dietary advice should not relate to specific products and so would fall outside the scope of the regulatory framework. She also

submitted that dietary advice applied to particular products should be regulated as any other claim (Dr R Stanton).

Naturo Pharm gave the example that any dietary advice appearing on a food label, packaging or in advertising should be viewed in the context of the whole packaging/advert and should therefore be subject to review. They also recommended that dietary advice should be true and consistent with the Australian Dietary Guidelines and/or NZ Food and Nutrition Guidelines.

Could be coupled with a claims benefit or represent dietary guidelines

Some submitters highlighted that a whole-of-diet claim could be either coupled with a claimed benefit, or could purely represent dietary guidelines (NHF Aust., NHF NZ, Tomox, CML, Nutritional Phys. Research Group).

NHF Aust. and NHF NZ added that this was provided they are use appropriately and do not mislead consumers about the nature of the food on whose label or promotional material the claim appears. For claims that emphasise a particular nutrient, the criteria for carrying that claim should relate to that nutrient, and may include additional criteria depending on the nature of the claim (NHF Aust., NHF NZ).

Tomox noted that the latter is dietary advice when quoting from these guidelines and not directed towards a product, however to make such claims the product should contain significant quantities of the food in question. Claims such as "milk and water are the best drinks for children" could have a beneficial effect (Tomox).

Nutritional Phys. Research Group recommended that where the whole-of-diet statement refers to reduction of a specific risk, it should be treated as a health claim.

Total diet

Sanitarium Health Food Comp stated that some claims made in the context of 'total diet' can become wordy and some of the meaning lost. They recommended that claims in a 'total diet' context be mandatory in the wording of high level claims, but used only 'where appropriate' in general level claims. They noted that "calcium is good for strong bones and teeth" succinctly conveys the intended message and they are unsure how this claim would read if considered as part of the 'total diet'. In added they pointed out that the example "calcium is good for strong bones and teeth" used as a function claim (p.26 of the IAR) does not make reference to the 'total diet'.

Appropriate foods

Some submitters expressed concern that general dietary advice may be allowed on inappropriate foods (Nutrition Australia, ASMI). Nutrition Australia provided an example of a statement about fruits and vegetables in a healthy diet on a Confectionery bar with fruit puree added. ASMI and TGACC considered the whole-of-diet statement needs to be relevant to the food, i.e. if the reduction of a risk in context of total diet involves high fibre, low fat and low sugar but the product in question was only high fibre and low fat, it is questionable whether the ‘whole of diet’ claim is appropriate for that food. It was added that it was not appropriate to omit the

'condition' the food did not fulfil in order to be able to make the whole-of-diet claim (ASMI). TGACC added that it is essential that consumers do not falsely perceive that their health requirements are met by certain foods that have been purposely marketed in a specific way.

NSW DoH - N&PA Branch agreed with the suggestion that 'whole of diet' claims only be allowed on 'appropriate ' foods and not on foods that have limited or insignificant nutritional value. They suggested that this would need to be adequately defined.

Claim pre-requisites will prevent the use of dietary guideline recommendations on inappropriate foods, as this would constitute a misleading claim (DAFF).

A potential problem with allowing claims related to dietary/food and nutrition guidelines to be interpreted as dietary advice was noted, in that this exposes a loophole through which claims for low fat/salt/sugar foods of low nutritional value could be marketed. Therefore there would have to be inclusion criteria to cover this and fruit and vegetables may be the only exception (Auckland Reg. PHS).

Cadbury Schweppes also noted that consumers may perceive that foods with a 'whole of diet' claim contain appropriate levels of all nutrients, which may be misleading or deceptive (Cadbury Schweppes).

It was noted that although in most cases 'fresh is best', some processed foods are better than fresh, e.g. homogenisation and heating improves health benefit of tomatoes. New developments in functional foods may also develop greater benefits (Crop and Food Research Institute NZ).

Conversely Aussie Bodies believed the second point raised by SDAC that processed foods or fortified foods not carrying whole-of-diet claims to be short sighted and inappropriate. This would cause problems in relation to what is regarded as a processed food, e.g. cheese is often cited as part of a healthy whole diet, but is processed. They also questioned whether tomato paste should be considered as more processed although it is less processed than most cheeses.

Definitions

It was recommended by a number of submitters that a definition of dietary advice is needed in the Standard. This was because dietary advice given by health professionals does not relate to sales of individual products and should therefore not be regulated as health claims, however a statement about the role of a food group in the diet, made on individual food products, implies a health claim and should be regulated accordingly (PHAA, ACA, SA DoH, WA DoH, Horticulture Aust., Tas DoH&HS). NZFSA also recommended clarification around the boundaries of dietary advice and health claims. They queried at what point does dietary advice become a health claim?

UK FSA campaign regarding excessive sodium consumption and a complaint made by the Salt Manufacturers Association that the ad misled people into believing that any amount of salt could kill you was pointed out. This highlights the importance of

making the distinction between dietary advice and health claims (SA DoH, WA DoH).

Some of the above submitters also considered that 'whole-of-diet' is a term that doesn't fit the examples given - they are health claims made in the context of the total diet (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit, Horticulture Aust.).

Cadbury Schweppes sought clarification as to what constitutes 'whole of diet'.

It was recommended that there is a definition of 'whole-of-diet' claims included in a glossary (NZ MoH). The NZ MoH also sought clarification about this type of claim as it is not explicitly included in the framework and they were unclear how this may be used.

General regulation of whole-of-diet claims

Although not specifically answering the questions, some submitters explained how they thought whole-of-diet claims should be regulated in general.

A number of submitters stated that any voluntary information that relates to a food product should be regulated as a claim whether or not it references dietary guidelines (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit, Horticulture Aust.). It was considered by another submitter that whole-of-diet claims should be treated the same as individual food claims in terms of their requirements. This is flexible and increases the possibilities of useful information being produced for consumers.

NSW DoH - N&PA Branch considered this a difficult issue, as it was unclear as to how and why manufacturers would choose to use a 'whole of diet' claim that wasn't linked to a claimed benefit. They went on to say that it may be that if dietary advice was split from the regulatory framework it would be an easy 'no cost' option for manufacturers who didn't want to go down the path of substantiating a claim. The fact that the product contained general dietary advice may be enough to imply a health benefit. This would not be a desirable outcome. They recommended that it is important to make a distinction between whole of diet claims and nutrition education to ensure that agencies can continue to provide dietary advice without being seen to be contravening the Food Standards Code.

DAFF also thought that on their own, dietary guideline claims would fall into the general level claim category, as they do not reference a serious disease or biomarker, and are low risk (DAFF). Heinz Aust./Heinz Watties NZ considered that whole-of-diet claims should be treated as general level or high level claims depending on the wording and should fall within the scope of the regulatory framework.

Fonterra submitted that citation of dietary advice based on official dietary guidelines should not require substantiation beyond reference to the accredited organisation that has developed the guidelines. Promotion of healthy diet/good dietary practice (e.g. advertising, direct mail etc) by Dairy Australia, NHF, Gut Foundation, Osteoporosis and Diabetes organisations should continue to be permitted. This education may

reference a link between food and a serious disease and condition but is general advice that is substantiated and there is public benefit in its release.

PB Foods stated that whole-of-diet claims should be allowed when in line with recommended dietary guidelines and further substantiation should not be required. They also said that the question on what constitutes general dietary advice is a separate issue. Nutrition Australia also considered that general dietary advice purely representing either the Australian dietary guidelines or the NZ food and nutritional guidelines should be allowed on labels. They added that they agreed with statement from SDAC regarding total diet claims (page 43 IAR).

General comments

TCCA noted that this is a complex and confusing question. They recommended that 'whole-of-diet' claims should not form a part of the health claims framework unless under very clear and strict criteria where FSANZ can be confident that the product making such claims makes a net contribution to health without risk of making a net detriment. They added that this only seems likely where pre–approved claims and associated strict inclusion criteria can be put in place. A broad claim recommending or implying dietary advice should not be left to food manufacturers to make. There is far too much room for interpretation here to ensure that the objectives of FSANZ will be served by claims as broad as this (TCCA). Whole diet claims should not fall outside the regulatory framework (Crop and Food Research Institute NZ).

An advantage was pointed out, that linking whole-of-diet claims with a claimed benefit helps educate the consumer and can avoid misleading claims (Crop and Food Research Institute NZ).

Other comments in answer to the question were:

- "Yes they need to be specific." (Aussie Bodies);
- "Yes." (Food Tech. Assoc. of Vic); and
- "Not applicable if no claims are allowed." (Dr C Halais).

Other comments provided but not in direct response to the question

Tas DoH&HS highlighted the need for clarification of the difference between dietary advice regarding food groups and nutrition, health and related claims in relation to food products, because this could have a major impact on nutrition education programmes. Nutrition education programmes need to be able to highlight categories of foods/nutrient profiles that are likely to result in healthier or less healthy diets.

In relation to the need for a clear delineation between dietary advice and claims in relation to food products, SA DoH recommended that any regulation should not hinder efforts to implement nutrition education programmes and should highlight categories of foods/nutrient profiles that are likely to result in healthier or less healthy diets. They noted that a key difference in the motive for making a claim is that

specific food products carrying a claim generate product sales, whereas making claims about categories of foods is equivalent to a focus on nutrition education.

Campbell Arnott's Asia Pacific recommended that the Australian Dietary Guidelines and the NZ Food and Nutrition Guidelines should be permitted to be referenced on packaging and other materials. They noted that they guiding principles in the development of health claim regulations should be consistent with and complement Australian and NZ national policies and legislation including those relating to the nutrition and health promotion, fair trading, industry growth and international trade and innovation.

In addition they recommended that wellbeing type statements should be permitted to highlight foods that have benefits for nutritional status and/or maintenance of energy levels. They noted their consumer research which indicates that a state of wellbeing is desired by consumers, and that the provision of nutrients/biologically active substances in health foods/ingredients can hep them to achieve this state. Consumer surveys reveal that consumers feel that food and diet are the only tools they still control to improve their quality of life (Campbell Arnott's Asia Pacific).

National Foods strongly recommended that FSANZ differentiate between dietary advice and claims on food products, particularly in communication to health professionals.

The Beer, Wine and Spirits Council of NZ commented that any potential health claim would be made redundant if a nutritionally sound diet was not followed or if any food type or product was eaten in excess or over the recommended daily intake.

Nestle noted the views from SDAC regarding whole-of-diet claims that are expressed in the IAR, regarding processed foods carrying whole-of-diet claims. They said that many foods, such as wheat, meat and milk for example, should be processed in order to make the foods with edible or safe to consume. They recommended that there should not be a distinction drawn between whether the food is processed or not, with respect to making claims, as all foods are appropriate in a whole diet.

AFGC considered it irresponsible of FSANZ to have included selective view expressed by members of an advisory committee in this IAR and concludes its purpose was to direct the responses to questions 27 and 28 towards greater restrictions on the use of claims. The outcome notes prepared from the first face-to-face meeting of SDAC and supplied to SDAC members did n not reflect any of the quotes used in the IAR (page 43). AFGC concluded that the 'views' included in the IAR must have been selected by FSANZ from those submitted after the face-to-face meeting.

1.2 PERFORMANCE AND WELLBEING CLAIMS

Question 29

Given the general requirements that claims express a specific, rather than broad health benefit/outcome, do you think that general wellbeing claims or general performance claims that do not reference a specific benefit should be prohibited?

Out of 147 submitters, 57.1% (84 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	29	19	5	2	55
Government	5	2	-	-	7
Public health	10	4	-	-	14
Consumers	2	-	-	-	2
Other	5	1	-	-	6
Total	**51**	**26**	**5**	**2**	**84**

Overview

One-third of submitters (28) supported the prohibition of general wellbeing claims or general performance claims that do not reference a specific benefit, whereas more than half (43) opposed this prohibition. Another five submitters implied that they did not support prohibition of general wellbeing claims and four submitters thought that the prohibition should be based on whether the claim was objective or subjective. One submitter recommended treating these claims as function or enhanced function claims.

Supported prohibition

There were 28 submitters in support of the prohibition of general wellbeing claims or general performance claims that do not reference a specific benefit (NCWA, TCCA, Diabetes Aust., DAA, NZDA, Dr R Stanton, GI Ltd, NHF Aust., NHF NZ, Nutrition Aust., PHAA (supported by ACA), Aussie Bodies, CML, DSM Nut. Prod., Food Tech. Assoc. of Vic., Hort. Aust., Tas DoH&HS, NSW DoH - N&PA Branch, NSW Food Authority, SA DoH, Wa DoH, CSIRO- HS&N, Monash Uni – N&D Unit, Auckland Regional PHS, Northland Health Dietitians, Naturalac Nutrition, NZ MoH).

The main reasons provided by some of these submitters for supporting their prohibition were in relation to:

- The difficulty in being able to measure any effect (subjective assessment) (Nutrition Aust., PHAA, ACA, Hort. Aust., SA DoH, WA DoH, Tas DoH&HS, Monash Uni – N&D Unit); and

- The difficulty in being able to substantiate these claims (Dr R Stanton, Nutrition Aust., PHAA, ACA, Hort. Aust., Tas DoH&HS, NSW Food Authority, SA DoH, WA DoH, Monash Uni – N&D Unit, NZ MoH).

Additional reasons for supporting prohibition of wellbeing claims in relation to substantiation were that:

- The terminology is confusing and ill defined, giving the impression of a benefit that is unlikely to be substantiated (NHF Aust. supported by NHF NZ);

- The requirement that claims are based upon 'convincing' levels of scientific evidence to reduce the possibility of misleading members of the public. Unless the wording of the claim is prescribed by FSANZ, there is potential for misinterpretation by consumers (TCCA);

- They usually have no evidence and no meaning (CSIRO – HS&N);

- The term is too subjective making it difficult to define and could lead to large numbers of claims being made that can neither be proved nor disproved (DAA). Such claims are high on inference and low on substantiation, and yet difficult to prove or disprove (NZDA); and

- General 'well being' or 'performance' claims can be very misleading and almost impossible to substantiate, or refute (NSW Food Authority).

Other reasons were that:

- They do not satisfy the Policy Guideline that all benefits should be specific (Monash Uni – N&D Unit, Dr R Stanton, TCCA, SA DoH, WA DoH, Hort. Aust., PHAA, ACA);

- Specificity is a hallmark of the new initiatives and should be consistent throughout (Aussie Bodies);

- Claims are only helpful to consumers when a clearly defined benefit is stated. Use of vague or subjective claims will weaken the impact of the claims that have been properly researched and substantiated (Hort. Aust., SA DoH, WA DoH);

- There is significant potential for claims to be considered misleading in this area due to the numerous interpretations of wellbeing. Prohibition of general claims that do not reference a specific benefit in favour of specific claims could rule out a number of well-being claims (Tas DoH&HS); and

- Consumption of any food can be said to "improve energy" and the consumption of any food (e.g. McDonalds, chocolate, chips etc) can lead to a 'positive effect on well being', in a psychological sense (NSW Food Authority).

Prohibition of these claims was also supported in the interests of protecting the public from misleading claims. It was noted that if these claims are allowed it is likely that the market place will be inundated with these types of claims that would confuse

consumers, reduce consumer confidence in the system, in turn undermining substantiated claims (NSW DoH - N&PA Branch).

It was noted that 'Healthy Option' brands can be useful indicators to consumers that a range of foods has particular nutritional qualities. Where qualifying claims are made (that is nutritional criteria or claims such as low fat), then the 'healthy option' branding could be considered as merely signposting the claim. In line with this it was recommended that standard criteria are developed for healthy eating symbols and slogans used by food manufacturers, retailers and endorsers. This should distinguish between products that are all round healthy products and those indicating that the product is a healthier version of an unhealthy product (SA DoH, WA DoH, Hort. Aust.).

It was recommended that definitions of 'wellbeing' and 'general wellbeing' are developed (Food Tech. Assoc. of Vic.).

Oppose this prohibition

There were 43 submitters who explicitly opposed prohibition of general wellbeing claims or general performance claims that do not reference a specific benefit; or who supported that these claims be permitted (ABC, AFGC supported by MasterFoods Aust. NZ, Bakewell Foods, Cadbury Schweppes, CHC, Dairy Aust., F&B Importers Assoc., GW Foods, Goodman Fielder, MLA, National Foods, Parmalat Aust., PB Foods, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZ Magazines, NZTBC, Fonterra, Griffins Foods, Mainland Products, NZ Dairy Foods, NZFGC, NZJBA, Frucor, Nutra NZ, NZFSA, Heinz Aust./Heinz Watties NZ, Nestle, Unilever Australasia, CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA).

The main reason given for supporting that these claims be permitted was that such claims should be allowed based on their ability to be substantiated (ABC, Griffins Foods, AFGC supported by MasterFoods Aust. NZ, GW Foods, Bakewell Foods, MLA, Parmalat Aust., NZJBA, Frucor, Nestle, Unilever Australasia, Goodman Fielder, Fonterra, Dairy Aust., Heinz Aust./Heinz Watties NZ, CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA).

The CMA added that wellbeing and performance claims in general tend to be less specific and are more difficult to categorise because of the subjective nature of the term, however this is not a valid reason to prohibit them. They proposed that there is a place for wellbeing and performance claims and as such they should be allowed in the Standard for health claims, based on their ability to be substantiated (this view was supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA).

It was noted that these claims are currently made and are low risk (PB Foods). A prohibition on general well-being and performance claims would have a significant impact economically (refer to p.32 of their submission for details) (National Foods).

Mainland Products noted that 'general wellbeing' may be widely interpreted. In addition it was considered that a balanced diet and food enjoyment are associated with general wellbeing and that current food packaging/advertising uses non-specific implied claims as a pointer to general wellbeing. For example:

- McDonalds campaign: "I'm loving it";
- Gregg's coffee: "For a relaxing cup of Gregg's Red Ribbon Roast...Relax and enjoy";
- Tea: "acts to keep the functions of the body in good order", "will keep your mind sharp and your body feeling healthy", "used as a natural remedy in South America";
- Bottled water: "Refresh yourself with Pump"; and
- Soy milk: "I can't afford to let my body down and So Good never does" (Mainland Products).

They also stated that a prohibition of such claims would lead to astronomical costs incurred by Mainland Products Ltd and other food manufacturers.

Fonterra felt it was not clear why performance and wellbeing claims should be prohibited. They added that there is little risk in broad claims such as "good for you" or "nutritious" as these are generally seen as marketing expressions. If the intention is to prohibit these on products due to high energy levels or other disqualifying criteria, that should be explicitly discussed in a guideline. Consumer pushback on unwarranted statements is likely to self-regulate the market, and no claim can be misleading. Fonterra stated that the FSANZ document has not expressly explored the notion that a claim must express a specific benefit, as it has not defined the scope of claims within the framework. They support that a claim should be outside the framework where it is not a content claim and does not express a link between diet and the human body (i.e. not a health claim). Claims outside the framework should not be prohibited but regulated according to general marketing codes and fair trading law (Fonterra).

National Foods also believed these claims should be regulated based on their ability to meet Trade Practices legislation e.g. Yoplait Optimal has the tag line "a good deed for your body" which they state is 'marketing creativity' and too broad to be meaningful to consumers on a health platform.

It was suggested that if general wellbeing or performance claims need to be regulated, they can go into a guideline (Heinz Aust./Heinz Watties NZ). The question “If market research found that a “comfort food” contributed to emotional wellbeing what evidence do FSANZ have to prohibit such a claim?” was also asked by this submitter. In addition it was noted that “puffery” is a well accepted concept in marketing law (Heinz Aust./Heinz Watties NZ).

PB Foods submitted that these claims will be ‘regulated’ by consumer acceptance.

Another view was that general claims have to be allowed for and the classification framework will capture them (ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZTBC).

It was noted that the Policy Guideline allows for well-being claims if they are made within the context of the total diet (Dairy Aust.).

Cadbury Schweppes expressed some concerns with the wording used in the examples given. 'Improves sports performance' does not appear to fit into this category as it infers functionality and many would question what part of the sports performance is going to be improved.

MLA provided references for major qualitative and quantitative consumer research (Dangar Research, 2001), which found that 78% of people believed diet has an influence on health and 69% believed food can affect emotional and physical wellbeing. They commented that this is a major paradigm shift in consumer's attitudes towards health and nutrition and provides a major opportunity to motivate consumer to choose healthier, nutrient dense foods.

The difficulty of distinguishing between general and specific benefits and outcomes was raised by NZFGC. Griffins Foods stated that it was difficult to differentiate between specific and general claims without examples. Dairy Australia expanded on this by saying that if challenged, heart disease could be considered broad, as this is a generic term for a number of heart-related conditions (hypertension, hypercholesterolaemia, stroke, etc). The same is true for cancer, as there are many types.

CHC commented that 'wellbeing' implies 'general good health'.

There were another five submitters who implied that they did not support prohibition of general well being claims (Tomox, ASMI, TGACC, Lazarus Scientific Research, Tegel Foods). Their comments are as follows:

Tomox recommended that general wellbeing claims should only be allowed relating to the whole diet or to inclusion of the basic food groups. They would like to see some positive claims being made about feeling good by eating well.

Two submitters noted that they do not have an issue with general wellbeing claims or general performance claims that do not reference a specific benefit. Ultimately wellbeing is 'what is good for a person'; consequently they do not see this as an issue (ASMI, TGACC).

Lazarus Scientific Research submitted that wellbeing or performance claims should be treated differently to other general or high level claims. They noted that it could be difficult to distinguish between physiological and psychological functions since generally psychological conditions are mediated by physiological responses. Therefore, this may place unnecessary restrictions in relation to claims around mood and cognitive performance (memory, alertness etc).

Tegel Foods support any statement that can be substantiated by a manufacturer.

Objective versus subjective claims

Some submitters outlined that some wellbeing and performance claims may be objective and some may be subjective and the prohibition should be based on this.

It was suggested that health claims in which benefits are purely subjective, such as psychological wellbeing, should be prohibited (National Starch, Solae Comp.). To ensure health claims are meaningful to the consumer, general wellbeing claims need to link to a specific benefit, which can be measured objectively – such as a physiological benefit (National Starch, Solae Comp.). Solae Comp. added that it is very difficult to define and measure 'wellbeing' and 'performance'.

Sanitarium Health Food Comp. agreed with this issue and stated that 'well being' claims should be allowed but in addition to a specific and measurable effect, as claims referring to a food being good for your wellbeing are broad and potentially misleading.

Similarly Hort. and Food Research Instit. of NZ agreed that general level claims with reference to 'wellbeing' or 'performance' should be prohibited but claims directed at a specific function related to wellbeing and performance be permitted with appropriate substantiation.

Nutritional Physiology Research Grp recommended treating these claims as function or enhanced function claims.

General comments

Some submitters did not directly answer the question but made the following comments.

NCEFF noted that if the substantiation system is robust enough, this is a non-issue. They also questioned how the effect is measured.

Nutra-Life H&F stated that in Australia 'wellbeing is classified as a therapeutic claim, either in terms of maintaining, promoting or enhancing it. They regarded the general use of 'wellbeing as defined by FSANZ as a 'mother care' statement and thought it is probably not quantifiable.

Dr C Halais said this question was not applicable if no claims are allowed.

Other comments provided but not in direct response to the question

The AFGC (supported by MasterFoods Aust. NZ) noted that page 44 of the IAR refers to the views of SDAC and TEG in relation to performance and well-being claims. However the SDAC outcomes notes do not reflect the view presented in the IAR that 'both TEG and SDAC considered they [performance and wellbeing claims] should be treated separately'. The SDAC and TEG outcome notes do not reflect that 'it was recognised by TEG and SDAC that wellbeing claims are difficult to categorise and the meaning 'wellbeing' and other similar terms are subjective'. Neither of the TEG and SDAC outcome notes reflect that ' an issue was raised as to whether

performance claims and well-being claims should only be made in relation to a physiological function, as opposed to being made in relation to a psychological wellbeing'.

AFCG concludes that the comments in the IAR purported to reflect views expressed by SDAC or TEG are either:

- Those recorded contemporaneously by the FSANZ authors reflecting their outcomes from the SDAC/TEG meetings; or

- intended to add credibility to the FSANZ authors vies on the matter.

AFGC considered it irresponsible of FSANZ to have included views at variance with the recorded outcome of the meetings and concludes its purpose was to direct the response to question 29 towards greater restrictions on the use of claims.

The Consumer's Institute of NZ commented that they oppose permission of general wellbeing and general performance claims, as these cannot be substantiated, e.g. 'prevents aging', 'enhances performance'.

NZ Beef and Lamb Marketing Bureau submitted that broad wellbeing claims and general performance claims should be allowed as these are as relevant to consumers as specific health benefits. They recommended that these would fit most easily into the general level claims category.

Conversely, ANA submitted that these claims should be prohibited as they are too broad and cannot be defined to the consumption of a particular food. They added that other vague terms such as 'prevents aging', 'makes you alert', 'flushes out toxins' also need to be avoided. Wellbeing claims are more difficult to substantiate and if it cannot be substantiated, it should not be allowed. OAC NZ also considered that general wellbeing claims should be prohibited, because achieving an acceptable, high level of substantiation for these would be difficult.

ACA also stated that well-being claims should be prohibited in the Standard as they are meaningless. They added that wellbeing claims are vague and can be interpreted differently by different people, and well-being is difficult to evaluate. They noted that well-being refers to overall state of health or wellness including mental and physiological.

ACA submitted that performance claims must refer to a specific benefit such as improving performance of a particular organ or physiological system, otherwise they should not be permitted. This is consistent with the policy guideline that states that claims must refer to specific benefits rather than general benefits.

1.3 LIFE STAGE CLAIMS

Question 30

Are there any unintended impacts of regulating claims that refer to normal life stages as general level claims?

Out of 147 submitters, 45.6% (67 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	21	14	4	-	39
Government	6	2	-	-	8
Public health	9	3	-	-	12
Consumers	2	-	-	-	2
Other	5	1	-	-	6
Total	**43**	**20**	**4**	**0**	**67**

Overview

Nearly 40 percent of submitters (25) indicated that they were not aware of any unintended impacts of regulating life stage claims as general level claims. Some added this was conditional on the claim being accurate, substantiated and not presented as a disease state or condition. Concerns related to excess consumption of the substance being claimed and 'medicalisation' of the food supply. Some submitters commented that life stage claims could be either a general level or high level claim depending on the nature of the claim, i.e. the substantiated benefit rather than the life stage itself, so classification must be on a case-by-case basis. Some submitters recommended prohibition of these claims or regulation as a high level claim only.

No unintended impacts

Twenty-five submitters indicated that they were not aware of any unintended impacts of regulating claims that refer to normal life stages as general level claims (Bakewell Foods, CML, CHC, DSM Nut. Products, MLA, DAFF, Sanitarium Health Food Comp, Wyeth Aust, CSIRO HS&N, TGACC, Diabetes Aust., GI Ltd, Tomox, NZFSA, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Fonterra, Griffins Foods, NZ Magazines, NZTBC, Nutra NZ, NZDA, DAA).

It was added that this was so long as the claims were:

- Accurate (Sanitarium Health Food Comp.);
- Substantiated (Sanitarium Health Food Comp, Wyeth Aust); and
- Not presented as a disease state or condition, for example, menopause is a normal life stage highly at risk of being presented as a disease or condition (TGACC).

Wyeth Aust. gave the example of a claim such as "this food contains X mg of phytoestrogens. Phytoestrogens may be beneficial for women after menopause" that could be regulated as a GENERAL LEVEL CLAIM under the proposed definitions.

It was noted that if there is a reference to a particular serious disease etc associated with a particular life stage (e.g. sarcopenia and osteoporosis in old age), then it becomes a high level claim (DAFF, NZDA, DAA, Griffins Foods). It was recommended that it is important that these continue to be treated as serious diseases and thereby come under high level health claims rather than general level claims. It was added that the elderly are a vulnerable group who are high consumers of dietary supplements and "health" food products which claim to improve physiological function (Russell et al., 1999) (NZDA supported by DAA). Fonterra also recommended explicit specification that life stages are not to be viewed as serious conditions.

CML pointed out that it is well recognised that certain groups of people (based on WHO defined life stages) have special needs, so these claims should also be permitted and regulated.

It was noted that life stages simply identify a target group, and industry should be encouraged to tailor claims to specific segments of the population if relevant (Fonterra).

Classification as a general level claim

Other submitters considered that claims that refer to normal life stages would generally be considered as a general level claim (ABC), according to the definitions (Aussie Bodies). Nutritional Physiology Research Group were unsure of any unintended impacts, although noted that the quoted example "symptoms of menopause" could be considered as a 'condition' under general level claims.

National Foods Limited agreed that a normal life stages such as pregnancy are not diseases or conditions and are a general level claim. They submitted that all claims must be substantiated and the management of general level claim that refer to normal life stages is commensurate with risk. They believed that population life stage groups are likely to be interested in foods targeting their life stage, and that there are already such products available e.g. soymilk containing isoflavones from menopausal females. Also, calcium rich foods are beneficial for pregnant and lactating women, who have higher dietary calcium requirements so communicating this to this group will benefit their nutritional status. They recommended the inclusion of a qualification of the status of life stage claims and an indicative list in the user-guide, which would include examples of life stages, e.g. pregnant and lactating females.

Permission of life stage claims as general level claims

Two submitters believed that providing the claims satisfy the requirements of a general level claim, then reference to normal life stages, as general level claim should be permitted (National Starch, Solae Comp.). PB Foods supported that life stage claims should be permitted to market the product to the "target group".

Impacts of regulating life stage claims as general level claims

Some submitters clearly indicated that there were some unintended impacts of regulating life stage claims as general level claims (Tas DoH&HS, NSW Food Authority, WA DoH, Food Tech. Assoc. of Vic., Dr C. Halais).

It was added that any claim has to be justified (Food Tech. Assoc. of Vic.). Two of these submitters also pointed out that the claim could be either a general level claim or a high level claim (see below for further comment (NSW Food Authority, Food Tech. Assoc. of Vic.).

One concern that was expressed was that regulation of life stage claims as general level claims could lead to excess consumption in the general population if a general level claim were allowed, because requirements for specific nutrients may differ with life stage, e.g. vitamin D requirements in pregnancy and lactation are higher. If vitamin D general level claims are allowed this could induce vitamin D toxicity in those that are non-pregnant or non-lactating. Toxic levels for vitamin D are about 10 times requirements (Dr Christine Halais).

Other submitters implied that there might be some unintended impacts of regulating life stage claims as general level claims, by making some of the comments that follow.

Medicalisation of the food supply

Another concern was the growing trend towards medicalisation of normal physiological changes (Tas DoH&HS, WA DoH, SA DoH, PHAA (supported by ACA), Monash Uni – N&D Unit). This has resulted in a range of products to "treat" symptoms despite the fact the 'conditions' related to normal life stages, e.g. menopause, are not classed as serious disease (WA DoH, SA DoH, Monash Uni – N&D Unit, PHAA (supported by ACA)). The claims that are made need to be substantiated to ensure they are not misleading or deceptive in promoting consumers to think that normal physiological changes need to be 'treated' (Tas DoH&HS, NSW DoH – N&PA Branch). Some submitters were concerned that regulation of life stage claims as general level claims could contribute to this issue (Tas DoH&HS, Dr R Stanton, NSW DoH – N&PA Branch).

It was thought that there is potential for "therapeutic" claims, particularly in relation to menopause, and therefore recommended that a suitable risk strategy be put in place, for instance, a prohibition on menopause related claims (WA DoH, SA DoH, Monash Uni – N&D Unit, PHAA (supported by ACA)).

Nutra-Life H &F believed that a term such as "relieve the symptoms of menopause" should be regarded as a therapeutic claim although they thought that "may be beneficial in menopause" would avoid this. They suggested life stages be defined and should not be linked to diseases such as arthritis, Type 2 diabetes etc.

ASMI were also concerned that a lack of regulation on claims referring to normal life stages can result in such lifestyles changes being presented as a disease state i.e.

menopause is a normal life stage highly at risk of being presented as a disease or condition.

Nutrition Aust. also noted menopause as one area where there could be issues. They noted the popularity of Soy-Lin bread (and other soy products), which reflects a need in the female population for relief of the symptoms of menopause using food rather than supplements and commented that there is likely to be more of this type of product development with the introduction of the Standard. They thought there should not be a prohibition on menopause type claims, however if they are regulated under general level claims it is difficult to see how general statements could be distinguished from claims that have a substantiated basis similar to that for high level claim.

Tas DoH&HS added that if claims to life stages are substantiated and socially responsible as set out in the policy principles this is likely to be less of an issue. They noted concerns over the interpretation of 'socially responsible' and suggested that this could be defined. The WHO Code of Marketing of Breast-milk Substitutes resulted in the Marketing in Australia of Infant Formula Agreement to protect infants (and their parents and carers) from inappropriate marketing. Misleading advertising included pushing the benefits of (expensive) toddler formula in place of a variety of nutritious foods for fussy eaters. They stated that this type of product and marketing is likely to promote fussy eating.

Another recommendation was that claim prerequisites should not permit health claims on foods marketed to vulnerable groups such as infants and children, except on whole foods such as fruit and vegetables (WA DoH, SA DoH, Monash Uni – N&D Unit, PHAA (supported by ACA)).

Claims Classification

A number of submitters commented that life stage claims could either be a general level claim or a high level claim depending on the nature of the claim. These submitters included Goodman Fielder and the submitters whose comments are recorded below.

Examples of a general level claim relating to non-serious aspects of menopause, such as hot flushes, sleeplessness etc) and a high level claim relating to serious diseases such as osteoporosis were given by NSW Food Authority. They therefore recommended the claims be treated on a case-by-case basis.

It was considered that as for any claim being made, the proposed benefit (and ability to substantiate it), determines whether it's classified as a general or high level claim. The same ruling applies to claims that reference a 'normal life stage' – they could be general or high level depending on the nature of the claim being made (Dairy Aust., NZJBA, Frucor, GW Foods). AFGC supported this and added that claims that reference normal life stages are likely to be of a general level nature, however circumstances could exist where a substantiated claim that references a 'normal life stage' could be a high level claim. They recommended the early involvement of industry to road test the system, as this is the most likely way in which such types of

claims are likely to be discovered. Parmalat Australia and MasterFoods Aust. NZ also supported these comments.

Nestle agreed that it is what is 'claimed' that classifies the statement, not the life stage. They added that generally a life stage claim would be general level because life-stages are considered a part of the usual growth or development of the body not a serious disease or condition.

It was further recommended that life stage claims be considered in tandem with implied claims, because life stage health claims can be implied in the branding of a range of products without a health claim ever being stated (WA DoH, SA DoH, Monash Uni – N&D Unit, PHAA (supported by ACA), Horticulture Aust.).

These submitters went on to say that life stage products often target the *concerns* of a group of the population rather than the actual need. There is therefore a risk that products can be inappropriate or misleading. Life stage claims will need to be evaluated for implied meaning to identify whether they should be regulated as general or high level claims (supported by Tas DoH&HS).

Mainland Products agreed that life stage claims should be general level claims unless they also refer to a specific disease. They recommended that the word 'condition' be removed from the definition of serious disease to alleviate confusion.

NZFGC submitted that there are considerable benefits in including normal life stages into the regulatory framework. While the majority of life stages will probably fall within the ambit of general level claims, there will conceivably be claims that could fall within the ambit of high level claims. Thus normal life stages could govern both high and general level claims. They added that there might be opportunities for industry to develop such claims to target specific sectors of the population.

Dr R Stanton recommended that in general, life stage claims should not be permitted. She added that some life stage claims will be high level claims, especially if they associate the stage of life with disease, and further recommended that that there should be pre-approved claims only in relation to life stages. NSW DoH - N&PA Branch supported this and suggested these claims could be included as high level claims to allow them to be assessed and ensure they do not constitute a therapeutic claim.

Implied Meaning/Misleading Claims

A range of concerns relating to the applicability of health claims more broadly to different life stages were expressed. These related to claims that refer to ‘contains X% of daily requirements for Y’, which invite the question “whose daily requirements?” If a claim like this is made, the Recommended Dietary Intake (for the identified nutrient) must be applicable to the population group being targeted. This has potential to be misleading to consumers. If general level claims were also in a legally enforceable Standard, there is likely to be less scope for foods bearing problematic general claims pertaining to life stages being released onto the market (TCCA). Northland Health Dietitians thought that as general level claims are easily implemented this may present an abundance of such claims given that individuals

may perceive life stage as more relevant/influential in the present than health/disease claims. This may result in consumer confusion.

Auckland Reg. PHS and Northland Health Dietitians agreed that to avoid any unintended impacts, general level claims should be covered in the Standard. It was added that there should be strict inclusion/exclusion criteria (Northland Health Dietitians).

Other comments

It was thought that it may be argued that the natural iron store depletion in an infant of about 6 months is the effect of a normal life stage. It was questioned whether this claim could this be argued to be a life stage claim: "Iron stores are naturally depleted in infants of approx 6 months. Foods rich in iron are beneficial for reducing the risk of iron deficiency / anaemia?" (Heinz Australia/Heinz Watties NZ).

A recommendation was made that it must be ensured that such claims are not too general, for example, a claim such as 'this product may relieve the symptoms of menopause' is far too general and any claim must relate to the component(s) within the food that may have this effect (Cadbury Schweppes).

NCEFF commented that depending on the reach of regulation; school and community based nutrition education programs would be regulated, textbooks audited and there are implications for freedom of speech in the community. They noted that some studies suggest that consumers prefer health claims that refer to promotion of general health rather than those associated with illness (Svederberg, E., 2002). In the USA, most claims on foods relate to general health rather than specific diseases (Caswell, J, 2003). This would support allowing such claims to be made, provided they can be substantiated.

It was recommended that consideration be given to the aging process and reduction in performance, e.g. sarcopenia (recognised disease), declining memory (not a

It was noted that New Zealand does not permit therapeutic claims, while only certain classes of therapeutic goods are permitted in Australia under the current regime, however FSANZ suggests that any claim that references a normal life stage will effectively be a general level claim. The argument that puberty, acne, PMT, erectile dysfunction may be considered as life stages, was put forward (Naturo Pharm).

Unable to comment

NCWA and NZ MoH commented that they were unable to provide any information regarding unintended impacts of regulating claims that refer to normal life stages as general level claims.

Unilever Australasia considered that this is difficult to determine but it should become clearer as the system progresses and claims can be road tested.

Other comments provided but not in direct response to the question

Although not in direct response to this question, SA DoH stated that they supported the prohibition of all claims regarding 'life stage' and considered life stages a normal development stage of life and not a condition.

1.4 SLIMMING CLAIMS

Question 31

How do you think 'slimming claims' should be regulated? Please provide your rationale and supporting evidence.

Out of 147 submitters, 48.3% (71 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	22	15	3	-	40
Government	6	2	-	-	8
Public health	10	5	-	-	15
Consumers	2	-	-	-	2
Other	5	1	-	-	6
Total	**45**	**23**	**3**	**-**	**71**

Overview

Less than half the submitters (32) stated that slimming claims should be permitted or regulated as either a high level or general level claim. Twenty-five submitters wanted slimming claims to be prohibited. Of these submitters, nine said that slimming claims should be regulated as general level claims, 16 said that (if permitted) they should be regulated as high level claims, and 12 said that the wording of the claim would determine whether it should be regulated as a high level or general level claim.

Discussion

Thirteen submitters made comments in answer to this question but did not clearly indicate whether they supported 'slimming claims' being regulated under the Nutrition, Health and Related Claim Framework (NSW Food Authority, WA DoH, CML, Horticulture Aust., ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZ Magazines, NZTBC, National Starch, Nutrition Physiology Research Group). Their comments are included in the following discussion.

Support slimming claims

A number of submitters indicated that 'slimming' claims should be permitted and regulated under the Nutrition, Health and Related Claims Framework, providing they are substantiated in the same was as any other health claim (Nestle, Unilever Australasia, Aussie Bodies, ABC, AFGC, MasterFoods Aust. NZ, ASMI, Bakewell Foods, Cadbury Schweppes, Dairy Aust., F&B Importers Assoc., Food Tech. Assoc. of Vic., GW Foods, Goodman Fielder, Lazarus Scientific Research, National Foods, Parmalat, PB Foods, Sanitarium Health Food Comp., Solae Comp., CSIRO – HS&N, Fonterra, Griffins Foods, Mainland Products, NZFGC, NZJBC, Frucor, Nutra NZ, Crop and Food Research, DAFF, NCWA, DSM Nut. Prod, NCEFF).
Reasons provided by submitters for regulating 'slimming' claims were that:

- 'Slimming' claims offer the food industry the opportunity to support government initiatives in tackling obesity by increasing the availability of 'healthy' foods and drinks, with less calories and with reduced portion sizes (National Foods);

- 'Slimming' claims offer incentives to food industry to pursue research and development innovation and to communicate these benefits to interested consumers. National Foods has a Weight Watchers endorsement on Pura Tone milk and they strongly recommend that 'slimming claims' should be permitted to prevent a discordance within the nutrition and health claims (National Foods);

- Research commissioned by Aussie Bodies shows that a large percentage of the population is interested in weight loss and many of these people are seeking clarity about what foods are suitable for their weight loss goals. This research indicates that in the absence of clarity on food labels in relation to weight loss, consumers either turn to unreliable anecdotes from their social networks, and/or default to foods that are 'low fat' in an assumption that they intrinsically assist weight loss, even if those foods have correspondingly high sugar or other nutritional profile in-appropriate for weight loss (Aussie Bodies);

- 'Slimming' claims should be regulated in the same context as other claims that refer to a physiological condition (Unilever Australasia);

- With the growing obesity problem, products that aid in reducing weight are useful to consumers (Fonterra); and

- Body weight is a physiological condition; therefore a food that claims to assist in weight management would require substantiation and would be expressed in the context of an appropriate total diet (AFGC, MasterFoods Aust. NZ, Dairy Aust., Goodman Fielder, Nestle, National Foods, NZJBA, Frucor).

An example of this last point was provided by Dairy Australia who launched their 'Dairy and Weight' campaign to health professionals earlier this year. Reporting on the research, three serves of dairy foods, as part of reduced-calorie diet, was shown to reduce body weight and body fat (Zemel 2004). This research is acknowledged by the NHMRC in their Clinical Practice Guidelines for Overweight and Obesity in Adults (NHMRC 2003) (Dairy Aust.).

It was recommended that 'slimming claims' are regulated because misinformation surrounding the ability of a food or nutrient to influence weight reduction is rife and causes public confusion. Science clearly shows that effective weight loss requires a multi-factorial approach, which includes positive lifestyle change. Regulation will protect reputable firms, which have good scientific support for the weight-reducing efficacy of their product while excluding those who exploit the current loopholes to gain market advantage (National Starch).

Conditions that should be required in order to make a 'slimming' claim were recommended:

- Information about the contribution of a serving of a food to daily energy requirements should be included (Mainland Products);

- The context of the regime may be needed to prevent the claim from being misleading, e.g. diets high in dairy calcium have been shown to assist in weight loss as part of a weight reduction regime as compared to low dairy calcium diets and high calcium supplemented diets (Fonterra);

- Claims must be written in the context of an appropriate total diet i.e. it is unlikely any food will help people lose body fat, as all foods contain calories, however depending on the scientific evidence, it may be appropriate to refer to a 'low fat diet', 'low GI diet' or 'high fibre diet' as beneficial for weight control (Sanitarium Health Food Comp.);

- 'Slimming' claims can be very misleading and a whole of diet context is required. It is very important that the concept of energy intake is expressed (Crop and Food Research); and

- Slimming/weight loss/weight management is regarded as a therapeutic claim for list-able medicines and requires as part of advertising that reference be made to sensible lifestyle factors including diet and exercise. Such claims might be acceptable provided there is proper dietary context as to the specific role of the product in terms of total diet (ASMI).

Some of the submitters above went on to indicate whether 'slimming' claims should be regulated as general level or high level claims**.** Those who submitted that they be regulated as general level claims were CSIRO – HS&N, DAFF, Fonterra, Mainland Products, Nutra NZ, Sanitarium Health Food Comp, Aussie Bodies, National Foods and DSM Nutritional Products. Reasons provided for categorising them as general level claims were:

- They relate to a transitional and non-serious physical condition (DSM Nutritional Products);

- Obesity could be a serious condition but the condition of being overweight is not necessarily so. This categorisation needs to be clarified as overweight may be viewed as a biomarker, or as a condition that predisposes to biomarkers (e.g. high blood pressure) and disease (e.g. cardiovascular) (Fonterra);

- If they avoid mentioning 'obesity' they can be classified as general level claims and substantiated as such (Mainland Products);

- They should not be a high level claim as consumers do not need to have their excess weight diagnosed by a health professional (Aussie Bodies);

- Unless weight is deemed to be a biomarker, and it is directly referred to (DAFF); and

- Body weight is a physiological condition and therefore any food claiming to assist with weight management is considered to be a nutrition function claim. Slimming is not a serious disease as weight management for many people can be cosmetic, not remedial (National Foods).

Those who submitted that 'slimming claims' be regulated as high level claims were Crop and Food Research, Cadbury Schweppes, NCWA, Food Tech. Assoc. of Vic., and Lazarus Scientific Research. Reasons provided for categorising them as high level claims were:

- The consequences of obesity are serious diseases (Crop & Food Research):

- In light of current obesity issues, as slimming must relate to the whole diet (Cadbury Schweppes); and

- The target consumer would be overweight or obese, which are known risk factors for many serious diseases and/or conditions, e.g. CVD, diabetes, cancer (Lazarus Scientific Research).

It was added that they should only be regulated as high level claims if provable and if they withstand TPA scrutiny (Food Tech. Assoc. of Vic).

Other submitters said that the wording of the claim itself would determine whether it is a general level or high level claim (AFGC, MasterFoods Aust. NZ, Nestle, Unilever Australasia, F&B Importers Assoc., GW Foods, National Foods, Parmalat, Dairy Aust., NZJBA, Frucor, NCEFF). NCEFF added that it would also depend on the consequences of the claim on healthcare management (if relevant).

Another suggestion for regulating these claims is to use the current 'Weight Management Code of Conduct' as a guide. Misinformation regarding food/nutrients and weight reduction abounds and causes widespread confusion within the public. The market is very susceptible to "silver bullet products" for weight loss when the science clearly shows that effective weight loss requires a multi-factorial approach, which includes a positive change in lifestyle. Less reputable companies exploit the current loopholes to gain market advantage. A very clear message needs to be sent that only companies with good scientific support can make weight reduction claims and reputable firms can meet the regulations safe in the knowledge that "fly-by-night" companies will be excluded from the market and open to prosecution should they disregard the regulations (Solae Comp.).

Oppose slimming claims be permitted

A number of stakeholders, mainly from the public health and government sectors, submitted that slimming claims should be prohibited (Auckland Reg. PHS, Canterbury DHB, Northland Health Dietitians, NZDA, Tas DoH&HS, NSW DoH - N&PA Branch, SA DoH, CHC, Monash Uni – N&D Unit, TCCA, Diabetes Aust., DAA, Dr C Halais, Dr R Stanton, GI Ltd, NHF Aust., NHF NZ, Nutrition Aust., PHAA, ACA, Tomox, NZ MoH, NZFSA, NZ Dairy Foods, TGACC). Although not specifically stating that 'slimming claims' should be prohibited, and supporting them as being regulated as high level claims, WA DoH and Horticulture Australia also made the comments specified below.

It was added that this was unless they are allowed in other areas of the Food Standards Code (NZFSA).

Submitters provided reasons for wanting slimming claims to be prohibited:

- In the absence of evidence as to how such claims could effectively be controlled and conveyed to consumers (TGACC);

- No single foods have intrinsic weight reducing properties (Auckland Reg. PHS, Tas DoH&HS, NSW DoH - N&PA Branch – N&PA Branch, TCCA, Diabetes Aust, DAA, NZDA, GI Ltd, Tomox, Canterbury DHB) unless it contains a stimulant (which would make it a novel food) (Dr R Stanton);

- Weight loss relates to the overall energy balance of the diet (Northland Health Dietitians, TCCA, DA, NZDA, NZ Dairy Foods, Canterbury DHB);

- Consumption of high quantities of low energy foods can contribute to weight gain and weight control is related to multiple factors (TCCA);

- 'Slimming' claims have great potential to mislead (Auckland Reg. PHS, NSW DoH - N&PA Branch – N&PA Branch, SA DoH, CHC, TCCA, Dr R. Stanton, NHF Aust., NHF NZ, PHAA, ACA, Monash Uni – N&D Unit, Nutrition Aust, NZ MoH, TGACC); and

- Potential is high for misleading claims based on the desperation of consumers willing to try anything to lose weight (Tas DoH&HS).

Some of these submitters recommended that if 'slimming' claims are to be permitted, they should be regulated as high level claims (NHF Aust., NHF NZ, Nutrition Aust., NZ MoH) as they reference overweight and obesity which are serious diseases and are biomarkers for other serious diseases e.g. heart disease (Tas DoH&HS, NSW DoH - N&PA Branch – N&PA Branch, SA DoH, WA DoH, Monash Uni – N&D Unit, CML, Horticulture Aust.). It could be argued that obesity fits within the serious disease definition, as although it can be treated without consulting health professionals, the levels of long term success are extremely low (Tas DoH&HS).

Nutrition Aust. added that high level claim classifications would be hard to justify, unless overweight/obesity is regarded as a serious disease (generally regarded as a risk factor for a number of diseases) or BMI as a biomarker.

An alternative to regulating them under the Nutrition, Health and Related Claims Standard was that they could be accommodated in the Special Foods Standard (NSW DoH - N&PA Branch – N&PA Branch, NSW Food Authority).

Other similar suggestions were:

- Food formulated for very low energy diets should be defined/labelled as such (TCCA) and subject to other legislation, e.g. Medicines Act/Therapeutic Goods Act (Auckland Reg. PHS);

- These claims should be covered by comparative claims based on energy, carbohydrate and fat content (Tomox); and

- FSANZ should develop a list of generic claims about energy balance and overweight/obesity (NHF Aust., NHF NZ).

Although these submitters recommended that 'slimming claims be prohibited, it was stated that:

- Any food in the context of the total diet could potentially be considered slimming as long as energy intake is less than expenditure (Tas DoH&HS); and

- Some slimming claims might be acceptable providing there was proper dietary context as to the specific role of the product in terms of total diet (CHC, GI Ltd).

Other general comments

CML stated that if these claims are to be permitted, they should be regulated. Nutrition Physiology Research Group agreed they need to be regulated and added that they must be well substantiated as they generate great interest, attract scepticism and could undermine the health claims strategy.

It was suggested that certain weight control-based claims e.g. 'weight management' might be acceptable provided there was proper dietary context as to the specific role of the product in terms of the total diet (TGACC, ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Cadbury Confectionery, Naturo Pharm, NZ Magazines).

Although supporting 'slimming claims' the term 'slimming' should be eliminated as no food is intrinsically slimming, and individual foods need to make up an appropriate whole diet which contains the food item that is being promoted, even if the claim relates to appetite control (CSIRO – HS&N).

It was also stated that any claim to reduce weight would be a therapeutic claim and any slimming claim (weight management) should be in the context of reduced food

intake with a balanced diet and exercise, which would be a general level claim. Claims to reduce the risk of conditions associated with obesity should be high level. This is a very vulnerable area and one where consumers are at risk from misinformation (ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Cadbury Confectionery, Naturo Pharm, NZ Magazines).

A number of innovative foods will be implying such claims in any case i.e. Atkins low carbohydrate foods (ASMI, TGACC). These claims are tightly controlled under the Therapeutic Goods Act and the same provisions should apply to foods (CHC, TGACC).

Concerns were raised about the use of individual product names e.g. *Slims* crisps and Weight Watchers brands and how they should be regulated (NZDA, Tas DoH&HS). Weight Watchers could be classified as a slimming claim or an implied health claim or a nutrient content claim and clarification is required for substantiation requirements (Tas DoH&HS, SA DoH, WA DoH, Horticulture Aust.,). It was also suggested that they could be a life stage claim (targeted at women) (in addition to the previous statement). Each 'loophole' that can be found in the proposed framework weakens the impact of responsible claims that are well substantiated, e.g. the benefits of eating more fruit and vegetables as part of a healthy diet (SA DoH, WA DoH, Horticulture Aust.,). This highlights the need for a strong standard that allows substantiated claims and prevents consumer confusion over product branding and claims (Horticulture Aust.).

Related claims e.g. BMR, appetite suppression; should be classified as general level claims as they are not recognised biomarkers for a serious disease or condition (Lazarus Scientific Research).

It was agreed that claims such as 'low fat', 'reduced fat' and 'low joule' are not slimming claims (Nestle, AFGC, MasterFoods Aust. NZ, Dairy Aust., National Foods). The example provided in the IAR is clearly a general level claim whereas claims such as 'low in fat', 'reduced in fat' or 'low joule', are not health claims unless linked to a disease or a condition, then they would be a general level or high level claim (NZFGC).

Many unsubstantiated claims are currently made without reference to Recommended Dietary Intakes, which is confusing to consumers (NCWA).

Other comments provided but not in direct response to the question

Health claims regarding foods or ingredients that have been shown to offer an advantage for weight control regimes should be classified as general level claims to encourage the use of the substantiation process and highly relevant claims. These claims should be made in the context of an appropriate diet and/or exercise regime (Campbell Arnott's Asia Pacific).

Slimming claims should continue to be prohibited (ANA, Consumers' Institute of NZ, OAC NZ). Attributing 'slimming' properties to a single food is misleading (OAC NZ) and this promotes the good food/bad food model rather than the total diet message that nutrition experts believe is more likely to promote better health and nutrition

(Consumers' Institute of NZ). Unless a food has an intrinsic weight reducing property, it is illogical for a food to be able to claim that it can assist weight loss (ANA). Weight control is attributable to multiple factors (OAC NZ).

ACA also submitted that slimming claims or claims referring to a product's weight reducing properties should not be permitted. They explained that weight reduction is a result of negative energy balance therefore it is highly unlikely that an individual product will lead to weight reduction. Given the focus on addressing and preventing obesity in Australia, slimming claims may create unrealistic expectations of the capacity of a single food to have a slimming effect and may play on some consumers vulnerability and desire for a 'quick fix' to their weight problems.

1.5 ENDORSEMENTS

Question 32

What are the impacts on industry, enforcement agencies and consumers in regulating endorsements as nutrition, health and related claims?

Out of 147 submitters, 56.5% (83 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	29	17	6	3	55
Government	6	2	-	-	8
Public health	10	4	-	-	14
Consumers	2	-	-	-	2
Other	4	-	-	-	4
Total	**51**	**23**	**6**	**3**	**83**

Overview

Industry groups generally felt that the impact in regulating endorsements, as nutrition, health and related claims, would be significant through administration, legal and labelling costs. Further costs related to potential duplication of compliance costs and education materials. Some stated that the definition of an endorsement was vague as to how related claims were interpreted, putting at risk industry and consumer confidence in quality and reliability of endorsement programmes. A few submitters believed the impact on industry would be minimal. Others noted positive impacts such as having a level playing field (for industry), the availability of a range of foods, which had been through the substantiation process and represented healthy choices (for consumers), and greater clarity (for enforcement agencies).

Discussion

Four submitters noted that as outlined in the Policy Guideline, the policy principles: give priority to protecting and improving the health of the population; support

government, community and industry initiatives that promote healthy food choices by a population; and must align with national policies and legislation relating to health and nutrition promotion. Endorsements therefore need to demonstrate that they have a positive effect on food choices, independent of other nutrition, health and related claims (Dairy Aust, SA DoH, WA DoH, Horticulture Aust).

NHF Aust/NHF NZ were concerned about proposals for addressing endorsements, in particular:

- A lack of clarity about how endorsements will be defined;
- A lack of clarity about how endorsements will fit within the new regulations; and
- New regulatory provisions imposing excessive administration constraints on reputable public health programmes such as the 'Tick' programme which as a result could negatively impact on public health.

They noted that lack of clarity may put at risk industry and consumer confidence in quality and reliability of endorsement programmes, reducing industry involvement and ultimately the public health impact of reputable programmes. Imposed administrative constraints would result in significant delays in implementing changes to an endorsement programme's eligibility criteria, reducing the ability to keep pace with changing public health needs and the changing market place.

NHF Aust/NHF NZ acknowledged that there are 'endorsements' and 'logos' currently in the market place which are not underpinned by a reputable health organisation, and potentially mislead consumers. As a consequence, they firmly supported the need to regulate these endorsements and logos.

Horticulture Aust. noted that in the United Kingdom, logos and endorsements by health charities and medical associations have slipped "between the regulatory cracks" (Food Commission 2002).

NHF Aust/ NHF NZ noted that the Ministerial Policy Guideline defines 'endorsement programme' in the glossary of terms as 'in the commercial sense – an advertising testimonial an instance of public endorsement of a product for advertising purposes.' However, they believed that this was a very vague and inadequate definition on which to base regulatory provisions and provided dictionary definitions of the term 'endorsement' which included 'validate', 'sanction', 'approve' and 'support'. They noted that a food endorsement could potentially be:

- A statement on packaging (or in advertising) from a reputable individual (e.g. doctor or other professional) attesting to the virtues of a food;
- A similar statement from an organisation (this could be a health organisation, or some other type of organisation); and
- A symbol, logo or trademark, which represents an organisation or individual's 'approval' of a food. This organisation need not necessarily be a health organisation, or even a third party – e.g. 'smart spot' logo introduced by PepsiCo

to identify healthier options in the company's own product portfolio (www.smartspot.com).

Sanitarium Health Food Comp asked for clarification around what is considered an endorsement. They questioned whether endorsements included celebrities supporting a brand, or independent organisations such as the International Diabetes Institute. In addition, they recommended that celebrities should not be considered an endorsement, as they believed that this would severely limit advertising and marketing potential for industry.

The NZFSA noted that in order to consistently enforce the regulations, clarity is required regarding when an endorsement is classified as a claim.

National Foods recommended that endorsements should be defined as "a commercial contract between an endorsing agency and a commercial food business entity", which would remove the regulation of food endorsements inadvertently covering food industry 'self-endorsement' programmes. They gave the example of Yoplait Petit Miam that contains a 'calcium guarantee' logo on the pack, relating to one serve of the fromage frais or yoghurt supplying at least 25% of the RDI for calcium for Australian children. National Foods believed that this is a nutrient content claim and should not interpreted as an endorsement.

Horticulture Aust. and SA DoH questioned whether the Dietary Guidelines and the Guide to Healthy Eating would be regarded as endorsements, dietary advice or total diet context for claims. They stated that although national nutrition guides are considered as dietary advice when in isolation, these guides constitute substantiation of a nutrition, health or related claim when applied to a food product label or promotion of food products. If a food product references the national nutrition guides as substantiation, a claim is being made (Horticulture Aust., SA DoH). The SA DoH gave an example of Campbell's Velish Soup range, which states that the packet contains 3.3 serves of vegetables, and references the Australian Guide to Healthy Eating "Nutritionists recommend that we eat 5 servings of vegetables a day, but with the demands of today's busy lifestyle most of us find it difficult to do this. Velish is the delicious easy way towards 5 a day." SA DoH believed that this is a high level claim because the recommended number of serves had been determined to reduce risk of serious disease.

In contrast, Horticulture Aust. considered that any endorsement program stating the number of fruit or vegetable serves contained in a product might be classified as a general level claim, or might sit outside the proposed framework. An endorsement programme that refers to the risk reduction of eating fruit and vegetables would be classified as a high level claim because of reference to serious disease. Issues of 'serving' size and 'what counts' relate directly to the risk reduction of serious disease and would therefore be a high level claim. Horticulture Aust. believed that both scenarios would require strict criteria to be met before a product could carry an endorsement.

Heinz Aust/Heinz Watties NZ noted that clarity is required as to how 'related claims' may be interpreted with regards to endorsements. Heinz Aust/Heinz Watties NZ

believed that endorsements by organic bodies or Plunket, for example, are not considered to be 'related claims'.

NHF Aust/NHF NZ noted that in Section 8.2 of the IAR, a Certification trade mark (CTM) distinguishes goods or services in respect of origin, material, mode of manufacture or some other characteristic, from goods or services not certified. The 'Tick' programme was mentioned as an example of a CTM used in relation to food. They noted that the ACCC, IP Australia and the Intellectual Property office of New Zealand (IPONZ) assess the 'rules' underpinning CTMs (which form the basis of agreements to use the trademark). They added that the process for obtaining approval of a certification programme is very rigorous, involving submission of all rules and schedules for review, a period of 'advertising' of the proposed rules and/or changes to them for external comment and a final assessment prior to approval being granted. They gave the example of the examination by the ACCC of the 'Tick' programmes CTM (and rules) which requires the ACCC to be satisfied: that the programme is competent to act as a certifying body; and the rules are not detrimental to the public, and are satisfactory having regard to principles of restrictive trade practices, unconscionable conduct, unfair trade practices, product safety and product information within the Trade Practices Act 1974.

Given that the underlying purpose of the new provisions for nutrition, health and related claims is to protect consumers from misleading and deceptive claims, the fact that CTMs have been approved by ACCC, IP Australia and IPONZ and that the CTMs 'owner' has been found to be a suitable certifying body should provide sufficient 'quality assurance' and obviate the need for any further 'approval' by FSANZ. NHF Aust/NHF NZ proposed that CTMs should be the means by which reputable endorsement programmes are distinguished from those with the potential to mislead consumers.

NHF Aust/NHF NZ have proposed that:

- The only endorsements permitted under the new regulations should be endorsement programmes that are represented by CTMs, which are governed by the Certification rules of the CTM;

- An endorsement should be considered a general level claim if the logo (trademark), purpose and principles underpinning the programme do not reference serious disease or a biomarker;

- If the endorsement references serious disease or a biomarker, then it should be a high level claim; and

- Endorsing-type statements or testimonials that are from medical or health practitioners such as dietitians and chiropractors, or reference the advice of such practitioners, should be considered high level claims unless they make only general reference to healthy eating or generally healthier food choices.

Dairy Aust. gave a dairy industry example of a trademark 'Dairy Good', which is currently on 2000 Australian products and identifies dairy products or foods with a dairy component that are not less than 90% Australian origin. Dairy Aust. regarded

this trademark, (example included in their submission), as a general level claim given that it refers to product content.

NHF Aust/NHF NZ believed that classification (general versus high level) of CTM endorsement programmes should be stated in the new Standard to provide clarity for industry, consumers and enforcement agencies. However, they recommended that criteria for such programs should not be listed in either the standard or in a guideline, as currently proposed under Regulatory Options 2 and 3.
In addition, NHF Aust/NHF NZ stated that if the criteria for CTM endorsements were included in either the standard or guideline then FSANZ would be required to review any changes to the CTM (including its 'rules'). They noted that this additional administrative step would:

- Represent a duplication of effort with the review and approval undertaken by ACCC, IP Australia and IPONZ; and

- Have implications for public health due to time delays in having changes approved (would take minimum of 18 months to gain all approvals and changes to criteria. This includes the usual 3-6months for changes to the rules of a CTM plus time for the FSANZ review and gazettal process).

Those submitters that considered the impacts on industry of regulation of endorsements for nutrition, health and related claims noted the following:

- An equitable playing field for endorsing agencies (DAA, NZDA, Food Tech. Assoc. of Vic., Nutrition Aust, PHAA (supported by ACA)), which are associated with the prevention or management of serious disease (Diabetes Aust, GI Ltd);

- Market advantage opportunities and increased profits that would outweigh endorsement costs (DAA, NZDA), which are a relatively small proportion of the overall marketing cost of a food/beverage (DAA, NZDA, Diabetes Aust);

- Removal of risk of prosecution (Food Tech. Assoc. of Vic);

- Products would be easier to market (Food Tech. Assoc. of Vic);

- Would create more work/employment opportunities (CSIRO- HS&N);

- Increased informed and credible choice for industry (GI Ltd);

- The impact would be minimal (Goodman Fielder, NZFGC, NZJBA, Frucor, Parmalat Aust.) from endorsements that represent general level claims (Heinz Aust/Heinz Watties NZ);

- The impact would be significant (Unilever Australasia, AFGC, Masterfoods Aust NZ, ABC, F & B Importers Assoc) and might severely limit the mutually beneficial relationships between industry and the endorsing organisations as

regulatory requirements are uncertain and/or they become more onerous (Unilever Australasia);

- Additional costs (Nutra NZ) associated with legal issues and administration (Coles Myer), substantiation (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA - NZ Branch, CMA – NSW Branch, CMA - QLD Branch, ICA, AFGC, Masterfoods Aust. NZ) which may be from:
    - Duplication, compliance and enforcement costs (National Foods, William Wrigley Junior);
    - Costs of re-labelling or re-formulating products (Bakewell Foods, National Foods, William Wrigley Junior, AFGC, Masterfoods Aust NZ, Heinz Aust/Heinz Watties NZ, Nestlé);
    - Deleting or re-launching products and promotional materials, packaging costs (Bakewell Foods, National Foods, William Wrigley Junior, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA - NZ Branch, CMA – NSW Branch, CMA - QLD Branch, ICA, AFGC, Masterfoods Aust NZ, Nestlé);
    - Consumer query costs and loss of market share due to the increase in costs being passed on to the consumer (National Foods, William Wrigley Junior);
    - Forgoing licences already paid to endorsing agencies (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA - NZ Branch, CMA – NSW Branch, CMA - QLD Branch, ICA).

- Increased bureaucracy (Nutra NZ).

Nestlé noted the main impact would be where current endorsements are considered high level claims and thus require pre-approval by FSANZ. They expressed concern that the endorsing organisation would be unable to submit their application until the Standard is gazetted and would pay for the assessment so it would be available in the least amount of time. They noted, however, that given the Standard development process, this would still be after the end of the transition time for the Standard. As a consequence, manufacturers would have to remove product label endorsements until approval is obtained, which would be an additional cost.

Two submitters believed that it is important that endorsement programmes that state or imply a nutrition, health or related claim comply with the requirements of the framework, and this would help to maintain a fair trading environment (NSW DoH – N&PA Branch, SA DoH, Monash Uni-N&D Unit) and ensure consumers are informed about the purpose of the endorsement (Monash Uni-N&D Unit).

The SA DoH quoted from Raynor et al., (2001) that operators of endorsement programmes argue that they have a beneficial impact on product development and nutritional composition, and that modifications are often associated with reducing risk of disease. Thus, such programmes also help consumers. This argument was also mentioned in the submission from WA DoH.

PB Foods noted that the NHF ‘Tick’ programme is followed by many companies and has become relevant in judging the nutritional value of a product. Given that criteria are linked to nutrition content claims, PB Foods believed that they should be regarded

as general level claims and warned that industry would incur costs if the new criteria do not align with NHF 'Tick' criteria. Tegel Foods believed the impact might be significant if well-supported endorsements such as the NHF 'Tick' were not permitted then there would be a cost to remove them. The Tas DoH&HS believed that if endorsements such as the NHF 'Tick' programme were considered as general level claims, then manufacturers might choose the 'Tick' programme rather than making an explicit health claim as it would require less substantiation. Tas DoH&HS queried whether this would be classified as an 'implied' health claim that would lead to a 'halo' effect, thus potentially misleading consumers.
Fonterra suggested that if endorsements were regulated as a claim, they would most likely be an implied claim. They noted that there is some difficulty with ambiguity with implied claims, for example the NHF 'Tick', if viewed as:

- A link to heart disease, then endorsements would be high level claims and would become illegal under the framework unless made in the context of total diet; and

- A link to heart health, then endorsements could be a general level claim.

The NSW Food Authority considered that the control of endorsements, which clearly relate to a serious disease such as heart disease or diabetes, is vital to the success and integrity of this Standard. They noted that the ability of the Heart Foundation to clearly contravene the health claims prohibition was often referred to by manufacturers wishing to make implied health claims and clearly undermined the existing Standard. The NSW Food Authority believed that endorsement programmes should be regulated according to the level of their claims.

CML considered that regulation would be necessary as health benefits are often implied as a result of the links created between an organisation and a product.

The Auckland Reg. PHS believed that endorsements should be judged on a case-by-case basis. For example, they suggested that the NHF 'Tick' should be viewed as a content claim but a GI symbol should be interpreted as a high level claim, as it is claimed to impact on a serious condition and there is an established biomarker. In contrast, Dr R Stanton noted that if endorsements in the form of a NHF 'Tick' were subject to the same scrutiny, requirement for proof and disqualifying criteria, some manufacturers having the NHF 'Tick' might lose it. This would assist their competitors who have identical products but have not paid the royalty to carry the 'Tick'.

Two submitters recommended that endorsements, which refer explicitly or implicitly to a biomarker or serious disease/condition, would be considered a high level claim and would be prohibited unless pre-approved by FSANZ and specified in the Standard. Endorsements that do not refer explicitly or implicitly to a biomarker or serious disease/condition would be considered a general level claim and would be permitted provided the claim complied with any criteria and conditions specified (William Wrigley Junior, Horticulture Aust).

TCCA recommended that endorsements made by a health-related organisation should be considered as high level claims and subsequently approved by FSANZ. Two

submitters recommended that all endorsements should be classified as high level claims because of the way they are perceived by consumers (SA DoH, WA DoH).

ANIC recommended that endorsements that consist of a logo or certified trademark be classified as general level claims, while endorsements that include the name of a disease in the logo or endorsement graphic be classified as high level claims.

Eight submitters believed that endorsement programmes should meet the same regulatory requirements for general level claims or high level claims for consistency, and to ensure the integrity of the health claims framework (National Starch, Solae Comp, Dr R Stanton, Nutrition Aust, PHAA (supported by ACA), NZFGC), and to the level required in law by that claim (NZ MoH). Although the criteria for each endorsing body might vary, supporting evidence must satisfy the minimum agreed level as dictated in the Standard or Guideline for general level claims. This approach should mitigate any unfair advantage gained by a company using an endorsing body, over those companies that do not (National Starch, Solae Comp).

Heinz Aust/Heinz Watties NZ believed that the impact depended on what the endorsement represents. They suggested that if current endorsements are not approved as high level claims, removal of these endorsements would result in a significant impact on the cost and timing to change labels.

The CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA - NZ Branch, CMA – NSW Branch, CMA - QLD Branch, ICA) recommended that FSANZ consider internationally accepted endorsements that may be utilised in the domestic market now or in the future. They noted that if high level claims were regulated, the endorsement agency would be responsible for seeking the necessary pre-market approval. If a general level claim, the endorsement agency would be responsible for obtaining and holding appropriate substantiation documentation.

Dairy Aust. stated that the impact would be highly dependent on whether endorsements are considered general level or high level claims. If endorsements were classified as high level claims, they believed that the impact on industry, endorsers and consumers would be considerable unless the endorsement became a pre-approved health claim. For example, Dairy Aust noted that if the NHF ‘Tick’ was considered a high level claim and did not receive pre-approval for inclusion in the Standard, the Heart Foundation would have to submit substantiation documents or remove the symbol from the pack, which would have cost implications and disadvantage those consumers who currently use the symbol to assist in their product selection. Dairy Aust noted that a Heart Foundation 2001 consumer survey found that this related to 60% of consumers.

In addition, they noted that regulation of endorsements would also affect education resources endorsed by third parties and website information. Dairy Aust. have produced a range of nutrition education materials often in association with various health organisations/professionals and considered that this is an important role in the promotion of healthy living. Accordingly, they have expressed concern that the prohibition of endorsements relating to health claims would cause difficulties for

health promotion organisations working with food industry partners to disseminate health messages.

Examples of current educational activities undertaken by Dairy Aust. that would potentially be prohibited or restricted include:

- Educational resources, which are used by health professionals, schoolteachers and consumers. These resources are reviewed or produced with assistance by professional organisations such as Nutrition Australia;

- Advertising and direct mail, many of which have been reviewed by credible third parties such as the DAA or NHF Aust/NHF NZ;

- Television community service announcements in collaboration with the Garvan Institute, Victor Chang Institute, National Asthma Council and DAA; and

- Health Promotion Week (with support from Osteoporosis Australia, the 'National Healthy Bones Week').

Dairy Aust. recommended that exemption should be granted to organisations like themselves that communicate the benefits of a (core) food group to health professionals and consumers. If an exemption is not granted, a four to five year transitional period should be permitted, allowing time for the necessary applications to be made to ensure compliance with the Standard.

Nestlé noted that FSANZ needs to determine if they are able to access in a timely manner all of the endorsements that might be submitted for approval. They suggested that if endorsing organisations choose not to pay for the application, then products would not carry the endorsement for a significant period of time and manufacturers are not likely to pay the organisation for the use of the endorsement over this period of time. They believed that this would be detrimental to the whole programme as there would be no funding for it.

Sixteen submitters recommended that there should be a 'grandfathering' clause relating to endorsements (F & B Importers Assoc, Nestlé, AFGC, National Foods, Masterfoods Aust. NZ, William Wrigley Junior, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA - NZ Branch, CMA – NSW Branch, CMA - QLD Branch, ICA) that are currently used on product labels. This clause could be based on the provision of the substantiation dossier and the application submitted to FSANZ for assessment (Nestlé). The AFGC (supported by National Foods, Masterfoods Aust. NZ) considered that this would be necessary to permit the orderly replacement or substantiation of any found to be non-compliant. The CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA - NZ Branch, CMA – NSW Branch, CMA - QLD Branch, ICA) recommended that allowance is taken into consideration for the time required by FSANZ to approve an application for an endorsement claim – a process for which they deemed is likely to exceed 12 months.

The AFGC (supported by Masterfoods Aust NZ) suggested that endorsing agencies would require compliance beyond the nutritional criteria about which the endorsement is sought.

NZ Dairy Foods suggested that regulation would give industry an independent endorsement of their product meeting the needs of certain customers with health related problems.

National Foods believed that food endorsement programmes such as the NHF 'Tick' programme drive product improvements, for example Pura Tone milk. They suggested that endorsement programmes be allowed as general level claims, which would encourage targeted product development to offer consumers healthier foods.

National Foods believed that food endorsement programmes provide benefits such as an improved food supply in line with Dietary Guidelines, increased consumer choice of healthier foods, a competitive food industry, support for government health promotion messages and economic support for nutrition research or consumer education.

The MLA noted that endorsement programmes play an important role in the development and implementation of nutrition communications by food industry. In particular, endorsement of nutrition communication ensures that it is trustworthy, credible and scientifically based. Standards set by endorsement programs provide benchmarks for best practice and incentives to improve the food supply. For example, the Heart Foundation's 'Tick' programme provided a major incentive for the red meat industry to develop lean red meat products. MLA expressed concern that removal of this incentive would have an adverse impact on the supply of lean red meat products.

Griffins Foods believed that although endorsements should comply with the final regulation, they preferred that currently accepted endorsements are not made illegal by the regulation. Mainland Products supported the status quo for non-regulation of endorsements as they considered that regulation would prove to be complicated.

GW Foods considered the impact could be a major issue if pre-approval is required.

Bakewell Foods recommended a uniform approach to enforcement of claims to remove all current varying standards, for example school canteens, Heart Foundation, Diabetic Association.

Cadbury Schweppes suggested that the Ministerial Council set up a mechanism to approve all endorsement programmes, in particular those where use of the endorsement programme to promote a product may infer that there are health or nutritional benefits associated with the product.

The Coeliac Society of Aust requested that an endorsement for foods suitable for a gluten free diet (specifically, the words 'endorsed by the Coeliac Society of Australia' on food packaging, in conjunction with their trademark registered logo) to be included in pre-approved claims. They noted that this would become more relevant if 'gluten free' continues to be defined as 'no detectable gluten' and the test for gluten becomes more sensitive (e.g. 1 ppm). With increasing sensitivity of testing methods (currently

5 ppm) background contamination might mean that no food would be absolutely 'gluten free'. They noted the ACCC's position that 20 ppm or less cannot be defined as 'gluten free', and as such the Coeliac Society of Aust believed that such food is suitable for gluten free diets. The Association of European Coeliac Societies recently approved this Standard.

The impacts on enforcement agencies in regulating endorsements as nutrition, health and related claims were suggested to be:

- The removal of ambiguities and provision of greater clarity and definition (DAA, NZDA, Diabetes Aust, Nutrition Aust, PHAA (supported by ACA));

- Endorsing organisations would conduct their own product/packaging checks before product approval is granted (GI Ltd);

- A reduction in workload, as they would only need to deal with the endorsement agency who would then regulate the use of their endorsement (NZ Dairy Foods);

- Difficulty in regulating endorsements made by recognised organisations (CHC); and

- The need for considerable resources to monitor general level claim endorsements, whereas enforcement agencies currently do not have the resources or funding to monitor substantiation of endorsements.

For consumers, submitters suggested the following impacts of regulating endorsements would include:

- Benefits from having a range of foods available which represent healthy choices within a food group and which have been through a substantiation process (DAA, NZDA, Diabetes Aust), increased informed and credible choice (GI Ltd) if there is more substantiation (NCWA) and greater clarity, honesty and credibility in claims (CSIRO - HS&N), especially if the endorsing organisation is a scientific institution (DSM Nut Prod);

- The prevention of deceptive or misleading endorsements (DAA, NZDA, Diabetes Aust, WA DoH);

- A higher degree of protection of public health and safety (WA DoH);

- Increased monetary costs (Nutra NZ, NCWA), as industry would pass on the costs of compliance (NCWA, AFGC, Masterfoods Aust. NZ);

- Confusion arising from the wholesale removal of pre-existing trusted endorsements (that no longer comply with the new regulation), followed by their reappearance on the same products at a later date (Nestlé); and

- Additional bureaucracy (Nutra NZ).

CML suggested that some endorsing organisations (e.g. the Heart Foundation) might be perceived as having more credibility than others (e.g. McDonalds), although they acknowledged that the reason for the endorsement (whether concerned about health, profits or some other reason) would become less relevant if the actual health claim is correct and has been substantiated.

Tas DoH&HS considered that further research is required to determine how consumers perceive endorsements. They believed that these issues are complex and there is insufficient data to make a considered comment. Further research would help to maintain a fair trading environment and would ensure that consumers are informed about the purpose of the endorsement. This view was supported in the submission from the NSW DoH – N&PA Branch. The Tas DoH&HS noted that 53% of consumers have a high level of trust in endorsements (Paterson et al (2003) Food Labelling Issues: Quantitative Research with consumers, Evaluation Report series No.4, FSANZ).

NZ MoH suggested that consumer understanding could be tested for products that are endorsed by, for example, medical organisations (does that imply a health benefit).

Three submitters noted evidence from the UK Food Standards Authority suggesting that consumers do not group claims in the same manner as the proposed substantiation framework. There was also evidence to show that consumers trust charities and other third parties more than the food industry, thus endorsements are a useful and powerful communication tool for the food industry (SA DoH, WA DoH, Horticulture Aust.).

The ASA (supported by Cadbury Confectionery, Naturo Pharm Ltd, NPANZ, Assoc. of NZ Advertisers, NZTBC, NZ Magazines) suggested the rules for endorsements could be covered in an advertising code similar to the way they have been included in the Code for Therapeutic Advertising.

The ACCC stated that one of the objectives of the Trade Practices Act (TPA) is to prevent anti-competitive conduct, thereby encouraging competition and efficiency in business and resulting in a greater choice for consumers in price, quality and service. They suggested that the TPA recognises that some objectives of Australian society may not always be met by the operation of competitive markets; therefore exemptions from the application of the TPA are available. Authorisation and notification procedures under the TPA provide exemptions to specific parts of the anti-competitive provisions but not to the consumer protection provisions. Depending upon their exclusive nature, the ACCC suggested that endorsement schemes might require authorisation or notification under the TPA.

Canterbury DHB considered the main implication to be resources, although they did not define whether this applied in part or to all industry, enforcement agency and consumer groups.

Food Tech Assoc of Vic believed that if endorsements were regulated, stakeholders would know where they stand (Food Tech. Assoc. of Vic).

The NCEFF noted that regulation of endorsements is a social issue that requires analysis of the role of the organisation, its position in society and the general societal acceptance of endorsement as an activity.

Since Dr C. Halais has opposed the use of health, nutrition and related claims, her view was that this question was not applicable.

Other comments regarding the issue but not in direct response to the question

The ANA recommended that to avoid consumer and industry confusion it is important that all third party logos or seals of approval fit within the claims classification framework and their classification is clearly stated within the Standard. In addition, the Consumers' Instit of NZ considered that a comprehensive definition of endorsement, which would include logos or seals of approval, testimonials from health organisations, and certification trademarks is required.

The Cancer Society NZ (supported by Rotorua Branch and Waikato/Bay of Plenty Division) believed that the inclusion of trademarks in the regulatory scheme is crucial. Trademarks may represent either:

- A public good function that focus on health promotion (e.g. NHF 'Tick' programme); and

- Commercial gain and marketing (e.g. GI symbol)

Thus, Cancer Society NZ believed FSANZ should consider the distinction between the two representations. They indicated that if only high level claims are permitted and trademarks remain acceptable, there is a risk that a number of 'trademarks' might exploit such a potential loophole. In light of this, they suggested that criteria are needed to prevent this effect without curtailing good public health promotion.

The SA DoH considered the NHF 'Tick' programme to be an 'implied' high level claim, because the NHF states its purpose "is to improve the heart health of Australians and to reduce disability and death from heart, stroke and blood vessel disease". SA DoH stated that the NHF 'Tick' is a certification mark that has objectively verifiable characteristics when applied to a product that includes nutrition criteria.

The ACA believed that all health-related endorsement campaigns should comply with the Standard and that a review of existing endorsement campaigns should be undertaken by FSANZ to ensure consistency with the Standard. They stated that if endorsement programs were excluded from the Standard, a range of endorsement programs could evolve as a way of bypassing the onerous requirements of the Nutrition, Health and Related Claims Standard.

Kellogg's Aust. agreed that endorsement programmes should be allowed and agreed with the Policy Guidelines that they should be regulated according to the claim which is being made (e.g. a product endorsement that is based on it meeting specific nutrient criteria would be a general level claim, while an endorsement programme which

states that the product helps reduce the risk of serious disease should be a high level claim.

Furthermore, the ACA noted that until research has been undertaken in relation to how consumers interpret endorsements, they believed that all endorsement programmes should fall under the relevant health claims to which they refer, as they imply some health benefit.

The Cancer Society NZ (supported by Cancer Society Rotorua Branch and Waikato/Bay of Plenty Division) supported the proposal that endorsement programmes that state or imply a nutrition, health or related claim must comply with the principles and requirements of the relevant claims category.

The Consumers' Instit of NZ considered that endorsements are a useful educational tool for consumers. A key finding of a 2002 survey of their members found that endorsements and approvals from reliable and independent authorities, were considered important or very important to nearly 60% of respondents. Endorsements and approvals were rated more important than information on GM, food additives, animal rights issues, and country of origin, organic status, and brand names. Many respondents mentioned the NHF 'Tick' programme as a useful guide.

Beef & Lamb Marketing Bureau noted that endorsements such as the NHF 'Tick' programme have a positive effect on nutrition communications for the consumer and provide an incentive for industry.

Question 33

Who should be responsible for substantiating an endorsement that is considered a general level claim and hold the evidence to support the claim?

Out of 147 submitters, 55.8% (82 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	29	17	5	3	54
Government	6	2	-	-	8
Public health	10	4	-	-	14
Consumers	2	1	-	-	3
Other	3	-	-	-	3
Total	**50**	**24**	**5**	**3**	**82**

Overview

The majority of submitters from all stakeholder groups suggested that it would be the joint responsibility of endorsement agencies and manufacturers to substantiate an endorsement that is considered a general level claim, and hold the evidence to support the claim. The most common model was for the endorsing agency to substantiate the claim/endorsement and ensure it met the requirements of the Standard while the

manufacturer took responsibility for ensuring that the food carrying the endorsement met the requirements of the endorsing agency. However, a few submitters noted a conflict of interest if endorsing bodies were also responsible for substantiation. Some submitters stated that the endorsing agency should take responsibility. Others believed the responsibility lay with the manufacturer, producer or supplier.

Discussion of submitter responses

Twenty-four submitters responded that they believed the endorsing agency should be responsible for substantiating an endorsement that is considered a general level claim and holding the supporting evidence (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA - NZ Branch, CMA – NSW Branch, CMA - Qld Branch, ICA, Heinz Aust/Heinz Watties NZ, Tegel Foods, Auckland Reg. PHS, DSM Nut Prod, CSIRO - HS&N, Mainland Products, NZ Dairy Foods, NSW DoH – N&PA Branch, NSW Food Authority, Bakewell Foods, Parmalat Aust, F & B Importers Assoc, MLA, William Wrigley Junior).

Eleven submitters believed that the endorsing agency would be required to provide substantiation to the organisations it licences (William Wrigley Junior) and approves the endorsement to (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA - NZ Branch, CMA – NSW Branch, CMA - Qld Branch, ICA).

The CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA - NZ Branch, CMA – NSW Branch, CMA – Qld Branch, ICA) noted that individual organisations using such endorsements would need to demonstrate or substantiate compliance with the endorsement to an enforcement agent. The endorsing agent has the responsibility to ensure that those foods carrying their endorsement met the criteria.

Two submitters suggested that endorsing organisations should already be holding this information as part of their registration process (NSW DoH – N&PA Branch, NSW Food Authority).

F & B Importers Assoc stated that the endorsing agency should be responsible but the producer would have to establish that its food meets the criteria for the endorsement.

Although they did not specifically mention substantiation, three submitters recommended that the endorsement agency should hold evidence to support the claim (ANIC, Horticulture Aust, Lazarus Scientific Research). The rationale behind these recommendations was that endorsing organisations are responsible for approving claims to use the endorsement logo or mark on packaging (ANIC, Horticulture Aust), and given that it is the endorsing body that sets the criteria for the endorsement or use of a trademark, it should consequently be the endorsing body's responsibility to hold the evidence in support of the claim (Lazarus Scientific Research).

CML believed that organisations endorsing a claim should be ultimately responsible for both its substantiation and representation. They noted that information to substantiate would most likely be made available by the manufacturer, but would

need to be scrutinised carefully by the endorsing organisation to ensure its adequacy before promoting it.

Seven submitters believed that the responsibility for substantiation and holding the evidence should sit with the manufacturer (National Starch, Solae Comp), the manufacturer/applicant (Canterbury DHB), the company (TGACC, ASMI), or the producer or supplier of the food (NZ MoH, NZFSA).

Two submitters agreed that the manufacturer should carry the burden to rectify problems associated with either the substantiation or the products' ability to satisfy general level claim requirements (National Starch, Solae Comp). They suggested that enforcement agencies should approach manufacturers directly for clarification of claim issues. Canterbury DHB believed that although all claims require substantiation, endorsement should be responsibility of the manufacturer/applicant and should be pre-approved with overview by an inter-sectoral group, rather than left to enforcement agencies. Their view was that if the manufacturer/applicant held responsibility, it would not be an additional burden on public health resources with questionable gain.

NZ MoH believed that the producer of the food on the food label should hold responsibility, or if in another company a deputised organisation indicated on the label. The NZFSA believed that the responsibility should ultimately lie with the supplier of the food, however they could delegate to the endorsement provider. They noted, however that the supplier would need to be satisfied that the endorsing organisation held the required evidence. In addition, suppliers would still be obliged to ensure the endorsement could be substantiated even if they do not hold the evidence themselves. NZFSA believed that a clear process is needed for determining when an endorsement is considered to be a general level claim. Endorsements should be required to state what qualifying criteria have been set in order to grant the endorsement, which in turn must be consistent with the Regulatory Framework.

Some submitters only referred to the responsibility of holding substantiating evidence of the manufacturer (Heinz Aust/Heinz Watties NZ, Tegel Foods, Nutra-Life H&F, the manufacturer/marketer (Fonterra, Mainland Products), the marketer/supplier (Parmalat Aust), or the company (CHC). Fonterra suggested that the manufacturer/marketer holding evidence should ensure adequate access to the substantiation (in a contract with the endorser). They also noted that the endorser would normally hold the substantiation for the criteria supporting the claim. Nutra-Life H&F believed the company making the claim should provide the necessary information to FSANZ, who would approve the claim based on the evidence. The CHC recommended that the company holding substantiating evidence should make it available to enforcement agents on request and failure to provide immediate access to documentation would be a serious breach of the Standard.

In addition, Fonterra (supported by Mainland Products) recommended that the regulations ensure companies are not penalised where there is unauthorised use of a company name or logo on a third party product. They believed that if the marketer/manufacturer cannot substantiate that its product had met the criteria for use of an endorsement or has not obtained permission for use of the mark, the entity perceived as having made the endorsement should not be liable.

Although their response did not specifically address the question, Aussie Bodies stated that the responsibility for the validity of the claim could be problematic, despite endorsements offering industry some positives in terms of promotion and consumers in terms of confidence. They suggested that it would be the company making the food or marketing the product that stands to benefit from the endorsement in terms of compliance with claim guidelines and noted that this would have the concurrent benefit of simplifying the issue for enforcement agencies.

Ten submitters suggested that the responsibility for substantiation of endorsements and/or holding evidence could be shared between the endorsing agency and the manufacturer (Unilever Australasia, Sanitarium Health Food Comp, Bakewell Foods, GI Ltd), or the food manufacturer/importer (Tas DoH&HS, SA DoH, Monash Uni – N&D Unit, PHAA (supported by ACA), Dr R Stanton).

Unilever Australasia noted that where an endorsed product has to meet specified criteria, the agency must ensure that these criteria are scientifically sound and the manufacturer must ensure that they meet the endorsers' requirements. Bakewell Foods recommended that once the manufacturer has produced a product they must hold a copy of the evidence along with the endorser. In contrast, the Tas DoH&HS and SA DoH noted that the endorsing body should be responsible for substantiating a general level claim and both this agency and the food company making the claim should hold the evidence.

Five submitters (SA DoH, WA DoH and Monash Uni-N&D Unit, PHAA (supported by ACA)) stated that substantiation is needed to support use of the endorsement in its entirety, including: explicit nutrition, health and related claims and application to each nominated food product or range of products, claims implied by the endorsement logo or branding (graphic or copy), and claims implied by the name of the endorsement agency (e.g. the Cancer Council, Heart Foundation, or Australian Fruit and Vegetable Coalition).

The ASA (supported by NPANZ, Assoc of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery) recommended that the endorser and the 'endorsee' should hold the evidence, which should be produced on demand for the regulator or the Advertising Approval agency. However, in response to question 32 they had also suggested that industry should be able to validate the endorsement, with written evidence from the endorsing agency so the regulator can easily verify it. In addition, they recommended it be a requirement that the manufacturer should hold documentation of the endorsement, and any valuable consideration given for the endorsement should be disclosed.

Naturo Pharm Ltd recommended that the endorsing body hold the evidence that the product met the standard and that the manufacturer holds the evidence that the product continues to meet the standard and that the recipe/formula is unchanged since the endorsement was granted. They also stated that the endorsing body needs clear standards under which endorsements are granted and ensures those standards are widely understood by consumers.

For food endorsement programmes that are considered general level claims, three submitters recommended that the endorsing association hold the evidence for the

endorsement criteria and the manufacturer/importer hold the evidence of compliance with the criteria (National Foods, Nutrition Aust, Griffins Foods). Five submitters believed that the company endorsing the product should be responsible for substantiating a general level claim (Diabetes Aust, DAA, NZDA) and both the company and the manufacturer should hold the evidence that product contains the correct amount of the nutrient/biologically active substance (Diabetes Aust, GI Ltd, DAA, NZDA).
GI Ltd indicated that both the endorsement organisation and the manufacturer should hold supporting evidence that the product contains the correct amount of the nutrient/biologically active substance. They also suggested that certified trademarks should accompany endorsements, as the certification process would protect consumers from false or misleading information.

PB Foods believed that, in general, the endorsement body needs to document that the criteria has been met and the manufacturing companies need to provide evidence that the product fulfilled the criteria by the endorsing company.

Twelve submitters considered that responsibility for substantiation and holding evidence would be dependent on the type of claim and its substantiation (Nestlé, Dairy Aust, PB Foods, NZFGC, ABC, AFGC, Masterfoods Aust NZ, GW Foods, Goodman Fielder, National Foods, NZJBA, Frucor). Whilst Nestlé noted that acceptance to the endorsement programme is usually controlled by the endorsing agency, they concurred with another six submitters that it is the manufacturers' responsibility to ensure that those products carrying an endorsement comply with the requirements of the endorsement programme (Nestlé, ABC, AFGC, Masterfoods Aust NZ, GW Foods, NZJBA, Frucor).

With regard to substantiating endorsement programmes, NHF Aust/NHF NZ proposed that:

- For endorsement programs that are both Certified Trade Mark (CTM) and general level claim, the certifying organisation should control the substantiation and certification requirements for the use of the CTM;

- General level endorsements via CTMs would not require FSANZ approval for changes;

- For CTM programmes that are high level claims, FSANZ should approve the substantiation; and

- Evidence that food products meet the criteria of the endorsement program should be based on laboratory analyses.

Dairy Aust. suggested that for product-based endorsement programmes that are both certified trade marks (CTMs) and general level, the certifying organisation should hold substantiating evidence for what the trademark represents and maintain the criteria for its use. For endorsement programmes that are considered high level, the endorsing organisation should apply for approval and then any products meeting the criteria should be eligible. Dairy Aust. noted, however, that this would be a duplication of the trademark validation process. In either instance, they recommended

that the manufacturer should hold the relevant documentation to demonstrate that their product adheres to the endorsing criteria.

If the endorsement was a high level claim or based on nutritional criteria, Nutrition Aust. believed that the endorsing body would need to provide the substantiation; otherwise foods would need to be approved on a case-by-case basis. Other submitters suggested that the endorsement agency would have responsibility to ensure that the endorsement meets the requirements of a high level claim (Nestlé) or conditions are met (ABC, AFGC, Masterfoods Aust NZ, GW Foods, Goodman Fielder, NZFGC, NZJBA, Frucor). Furthermore, the last eight submitters listed had noted that if the endorsement was linked to a claim such as risk reduction of serious disease, then the nature of the claim would require evidence to be presented to FSANZ for approval as a high level claim – in which case the manufacturer would be responsible for providing the evidence with the support of the endorsing agency.

Five submitters considered that all endorsements should be classified as high level claims, and the endorser should be responsible for gaining pre-approval for all endorsements (WA DoH, SA DoH, Monash Uni-N&D Unit, PHAA (supported by ACA)). TCCA indicated that any evidence for substantiating an endorsement should be lodged with FSANZ, as endorsements are likely to be 'implied' high level claims. Dr R Stanton stated that all endorsements from, for example, the NHF would constitute high level claims, and that substantiation should not be solely required from the endorsing body as they stand to gain financially from the endorsement and this would be a conflict of interest.

The issue of a potential conflict of interest where the endorsing body is also responsible for substantiation of the claim, such as State Departments of Health involved in social marketing campaigns (e.g. promoting fruit and vegetable consumption), was raised by an additional five submitters (Tas DoH&HS, SA DoH, Monash Uni-N&D Unit, PHAA (supported by ACA)).

CML noted that once an endorsement is substantiated it would still be possible for an endorsing organisation to misrepresent the product and therefore they should be fully accountable. Two submitters suggested that the endorsing body documents its understanding of the product benefits and how these will be discussed within the context of the endorsement programme (National Starch, Solae Comp) and the endorsing body should at all times display due diligence in terms of dealing with a company and its products (Solae Comp).

Cadbury Schweppes considered that endorsement programmes do not absolve the manufacturer from overall responsibility for the claims made on their product.

Whilst National Foods stated that responsibility for substantiation and holding evidence would be dependent on the type of claim and its substantiation, they acknowledged that product manufacturers in the country of origin could make substantiating evidence for imported foods available for evaluation in Australia or New Zealand. They did not consider it would be realistic to expect enforcement agencies to procure substantiation evidence from overseas manufacturers.

DAFF believed that substantiation and holding of evidence should be up to the individual endorsement schemes. They suggested that that the endorsement scheme substantiates the claim after which it would pass on the relevant evidence to any company using the scheme.

Two submitters considered that many endorsements would occur as part of the advertising campaign, where those endorsements may convey or imply a particular health benefit or professional recommendation to the consumer (ASMI, TGACC). They believed that this highlights the need for equity with the Complementary and over-the-counter medicines industry by having effective methods of advertising control, and considered it essential that there is a mechanism for verifying the substantiation of endorsements and compliance of the criteria of any endorsing bodies by State jurisdictions and ideally part of advertising control.

Since Dr C. Halais has opposed the use of health, nutrition and related claims, her view was that this question was not applicable.

Other comments regarding the issue but not in direct response to the question

The Consumers Instit. of NZ considered that the endorsement agency, as an independent verifier of product characteristics, should be responsible for substantiating an endorsement.

The Cancer Society NZ (supported by Cancer Society Rotorua Branch and Waikato/Bay of Plenty Division) believed that the endorsing organisation must maintain their criteria for endorsing a product and submit a proposal to FSANZ for pre-market approval.

Question 34

Can you provide examples of endorsements currently in the market place that may constitute a general level claim or a high level claim?

Out of 147 submitters, 52.4% (77 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	29	18	5	3	55
Government	5	2	-	-	7
Public health	7	3	-	-	10
Consumers	1	-	-	-	1
Other	4	-	-	-	4
Total	**46**	**23**	**5**	**3**	**77**

Overview

Submitters provided a range of examples of endorsements currently in the market place that may constitute a general level claim or a high level claim. These included GI Symbol, National Heart Foundation 'Pick the Tick', 'Tooth friendly', Dairy Good trademark/logo, Weight Watchers points system, Coeliac Society, Australian Institute of Sport, Sports Dietitians Australia, International Diabetes Institute 'Go for Gold', Kenman Super Naturals Confectionery 'Sids and Kids', '5+ a day' logo and various health professionals. There were divided views as to whether the National Heart Foundation and the GI endorsement symbols were a high level claim or a general level claim.

Discussion of submitter responses

Most submitters categorised the examples of endorsements that they gave as either high level claims or low level claims.

High Level Claims:

- **GI Symbol**
  (Auckland Reg. PHS, NSW DoH – N&PA Branch, SA DoH, WA DoH, Monash Uni - N&D Unit, Dr R Stanton, PHAA (supported by ACA))

- **G Symbol** endorsed by Diabetes Australia
  (Dr R Stanton)

- **National Heart Foundation (NHF) 'Pick The Tick'** program
  (SA DoH, WA DoH, Cadbury Schweppes, Monash Uni - N&D Unit, Dr R. Stanton, Nutrition Aust., PHAA (supported by ACA))

- **Velish Provincial Vegetable Soup** (references the Australian Guide to Healthy Eating)
  (SA DoH, WA DoH)

- **Cleanse Detox Fruit and Nut Bar**, by the Food Doctor in the United Kingdom. The following claim is made: "Cleanse – this bar made with oats…fortified with artichoke powder is designed to help you detoxify by removing the toxins from your body"
  (SA DoH).

- **Sids and Kids** (Kenman Super Naturals Confectionery)
  (TCCA)

- **Go For Gold Program**, operated by International Diabetes Institute
  (DAA)

Another example provided of an endorsement were companies who support Foundations, e.g. Osteoporosis Association, NHF in return for acknowledgement – the mention of the foundation or association is a way of including a disease state in the advertising of food. Under the framework this would probably imply a high level

claim (ASA supported by NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZTBC, NZ Magazines).

General-level claims:

- **GI** symbol
  (NZDA, Nestle, Unilever Australasia, ABC, AFGC, ANIC, Dairy Aust., GW Foods, Heinz Aust./Heinz Watties NZ, Goodman Fielder, Horticulture Aust., National Starch, Solae Comp. CSIRO – HS&N, Diabetes Aust., DAA, GI Ltd, NZJBA, Frucor)

- **NHF 'Pick the Tick'**
  (Auckland Reg. PHS, Heinz Aust./Heinz Watties NZ, Nestle, Unilever Australasia, ABC, AFGC, ANIC, Dairy Australia, GW Foods, Goodman Fielder, Horticulture Aust., National Foods, National Starch, PB Foods, Solae Comp., CSIRO - HS&N, GI Ltd, Tegel Foods, Fonterra, NZJBA, Frucor, Nutra NZ)

- **Toothfriendly** symbol
  (Cadbury Schweppes, CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, CMA-Vic Branch, and CM of SA)

- **Dairy Good** Trademark/logo
  (Dairy Aust.)

- **Weight Watchers**
  (National Foods)

- **Coeliac Society**
  (National Starch, Solae Comp.)

- **Australian Institute of Sport**
  (TCCA)

- **Sports Dietitian Australia**
  (TCCA).

Level of claim not specified or unsure how to categorise it:

- **NHF 'Pick the Tick'**
  (NZDA, Tas DoH&HS, NSW DoH-N&PA Branch, NSW Food Authority, Aussie Bodies, Bakewell Foods, CML, CHC, F & B Importers Assoc., Food Tech Assoc. of Vic, Lazarus Scientific Research, MLA, Parmalat Aust., Sanitarium Health Food Comp., Diabetes Aust, DAA, NZ MoH, NZFSA, Griffins Foods, NZ Dairy Foods, NZFGC)

- **Heart Smart**
  (Food Tech Assoc. of Vic)

- **GI** Symbol
  (Tas DoH&HS, NSW Food Authority, Bakewell Foods, Food Tech Assoc. of Vic, Lazarus Scientific Research, MLA, Parmalat Aust., PB Foods, Sanitarium Health Food Comp., Nutrition Aust, William Wrigley Junior, NZ MoH, NZFSA, CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, CMA-Vic Branch, and CM of SA).

- **Juvenile Diabetes Foundation**
  (Tas DoH&HS)

- **Diabetes Australia**
  (Tas DoH&HS, CML)

- **International Diabetes** symbol
  (Sanitarium Health Food Comp.)

- **Consumer testimonials**
  (ASMI, TGACC)

- **Patient charity groups**, e.g. Diabetes Australia, National Heart Foundation
  (ASMI, TGACC)

- **Government bodies**, e.g. Australian Institute of Sport
  (ASMI, TGACC)

- **NSW School Canteen Association – buyers guide**
  (MLA)

- **Jean Hailles Foundation**
  (Sanitarium Health Food Comp.)

- **Health Professionals**
  (Sanitarium Health Food Co, TGACC, ASMI)

- **Weight Watchers** brand
  (CML)

- **Coeliac Symbol**
  (Food Tech Assoc. of Vic)

- **Australian Institute of Sport**
  (Sanitarium Health Food Comp.)

- **Toothfriendly** symbol
  (William Wrigley Junior)

- **World Dental Federation** symbol

(William Wrigley Junior)

- **Orange Arthritis Appeal**
  (Nutra-Life H&F).

- **'5+ A Day'** logo
  (queried by NZFSA)

CML stated that Diabetes Australia endorses high glucose Confectionery (Candy Lane Jelly Babies) where a proportion of sales go to Diabetes Australia.

Nutra-Life H&F believed the Orange Arthritis appeal (orange juice company is the principal sponsor) is an example of an endorsement that may constitute a general or high level claim. They thought this could be seen as promoting orange juice for arthritis.

An example of an endorsement from a health professional - Kenneth Setchell, Prof of Paediatrics at the Children's Hospital Medical Centre and Uni of Cincinnati in the US (provided link to Sanitarium website on soy foods) was provided by ASMI.

Additional Comments

Some submitters outlined the reasons that they assigned the above endorsements as either general level or high level claims.

SA DoH and Monash Uni – N&D Unit stated that all endorsements should be classified as high level claims.

Reasons for the NHF Pick the Tick being categorised as a general level claim:

- It is not referencing a disease (Heinz Aust./Heinz Watties Aust.);

- It is based on products meeting specific nutritional criteria (Nestle, Unilever Australasia, Dairy Aust., Goodman Fielder, PB Foods, NZJBA, Frucor);

- It is a nutrient content claim (CSIRO – HS&N);

- It is viewed as supporting a healthy heart (Fonterra); and

- The endorsement is simply stating that the product is a healthier alternative to comparative products and therefore is suitable as part of a healthy eating pattern (GW Foods).

Reasons for the NHF Pick the Tick being categorised as a high level claim:

- The NHF is known to be associated with heart disease (Dr R Stanton);

- It is an implied high level claim because the NHF states it's purpose "is to improve the heart health of Australians and to reduce disability and death from

heart, stroke and blood vessel disease" (SA DoH, WA DoH, Monash Uni – N&D Unit).;

- The NHF Tick is a Certification Mark that has objectively verifiable characteristics when applied to a product that includes nutrition criteria (SA DoH, WA DoH, PHAA (supported by ACA)); and

- It relates to heart disease reduction (Cadbury Schweppes).

Some submitters noted why they were unsure whether the NHF Pick the Tick should be categorised as a high level or general level claim:

- It may be seen by consumers as implying risk reduction for cardiovascular disease (high level claim), or as simply healthy food choices for general good health (general level claim) and further consumer research is recommended to clarify this (NZDA);

- It could be a general level claim as nutrition criteria reflect the Dietary Guidelines and NHF consumer research indicates most consumers regard products bearing the Tick as healthier alternatives rather than products that reduce the risk of heart disease, however it could be a high level claim as the name of the organisation references a serious disease (NSW DoH – N&PA Branch);

- It depends on consumers' interpretation. If the Tick Food Program is considered to be a guide to making healthy food choices quickly and easily then it would fall into the general level claim classification; however, if the goal of the NHF is to improve the heart health of Australians and to reduce disability and death from heart, stroke and blood vessel disease or is interpreted as such by the consumer, then the Tick Program could be considered as a high level claim because of the reference to serious disease (DAA, Tas DoH&HS); and

- This program is well know for its association with the NHF and there is the possibility this association implies a claim for reduced risk of cardiovascular disease (Diabetes Aust., GI Ltd).

Other submitters did not state whether the NHF Pick the Tick symbol is a high level claim but made comments such as:

- The NHF Tick implies benefits to heart health (CML);

- The NHF Tick may imply reference to a serious disease (CHC); and

- Dons Lite Ham carries the Heart Tick, as it is lower in salt and saturated fat than comparable products (GW Foods).

Reasons for the GI Symbol Program being categorised as a general level claim:

- It is based on nutritional criteria (Unilever Australasia) and is a measure of glucose absorption (Nestle, AFGC);

- It is not referencing a disease or condition (Heinz Aust./Heinz Watties Aust., DAA);

- It is a marker of glucose absorption (NZJBA, Frucor);

- It is a nutrition function claim as it reflects the physiological effect of the food's carbohydrate (Dairy Aust.);

- The GI Symbol does not refer to any disease or serious condition, it signposts the food/beverages that meet a set of criteria, i.e. the GI value was obtained using the correct methodology and that the "GI is a ranking of carbohydrates in food according to their effect on blood glucose levels" and meets strict nutritional criteria (Diabetes Aust., GI Ltd);

- The GI symbol has previously been discussed with ANZFA/FSANZ and was classified as a nutrition function claim (Diabetes Aust., GI Ltd, DAA);

- The GI Symbol Program is a ranking of carbohydrates in food according to their effect on blood glucose levels. As the research is relatively recent, the concept of GI is still new to the public and does not have a strong association with diabetes (DAA); and

- The endorsement is simply stating that the product is a healthier alternative to comparative products and therefore is suitable as part of a healthy eating pattern (GW Foods).

Reasons for the GI Symbol Program being categorised as a high level claim:

- GL Symbol and GI Symbol are associated with diabetes and are a high level claim on the basis that they (a) imply a connection with diabetes even if it is not stated and (b) they imply or refer to blood glucose which is a biomarker for diabetes (Dr R Stanton); and

- GI/GL is a biomarker (SA DoH, WA DoH, Monash Uni – N&D Unit, PHAA (supported by ACA)).

Some submitters noted why they were unsure whether the GI Symbol Program should be categorised as a high level or general level claim:

- Depends on the consumer interpretation of GI as a tool for choosing healthy foods or referring to effects on blood glucose (Tas DoH&HS); and

- Depends on the context. Some GI labelling programs are linked to advice about general diet and diabetes (i.e. International Diabetes Institute) but others primarily promote advice of a general health nature (GI Symbol program). The former (i.e. International Diabetes Institute) would be seen more as related to diabetes because of the name. Classification hinges around whether GI is seen as a biomarker

because GI refers to the effect of carbohydrate in food on blood glucose levels (Nutrition Aust.).

Goodman Fielder noted that if the endorsement was linked to a claim like risk reduction of a serious disease then it would be considered high level.

Other comments made about the GI Symbol Program were that Burgen Breads and Tip Top 9 Grain carry the GI Symbol as they have been analysed for GI by an accredited laboratory and the products are lower in salt, fat and sugar and higher in fibre than comparable products (GW Foods). Some submitters noted who has the international rights to the intellectual property for the GI Symbol (University of Sydney, Diabetes Australia and the Juvenile Diabetes) (Tas DoH&HS) and that the intellectual property for the certification trademark is owned by University of Sydney (Diabetes Aust., GI Ltd, DAA).

Lazarus Scientific Research stated that the NHF Pick the Tick program and the GI symbol are implied health claims and depending on the endorsing body, could be perceived by consumers as high level claims (e.g. reducing the risk of heart disease or reducing the risk of diabetes). They believed that these types of endorsements and trademark symbols should be regulated by the Standard.

Dr R Stanton commented that the GI symbol and NHF Tick do not apply disqualifying criteria or make their criteria so flexible that they undermine consumer confidence.

With regard to the NHF Pick the Tick and the GI Symbol Program, Tas DoH&HS commented that while neither program specifically mentions disease or biomarkers, if the interpretation by consumers is an association with an agency working with disease, then this could be considered an implied high level health claim. There is the potential for this to be misleading for consumers if it is not regulated as a high level claim. They appreciate the ramifications for endorsement programs being considered as high level claims, but believe the principles need to be adhered to.

National Foods submitted that GI *per se* (not the endorsement program) is not a claim of any type, either general or high level and should not be captured under the regulation for claims. They also considered that the Dairy Good logo and organic certification are not relevant to the regulation of claims.

A claim about detoxifying properties of food would be a general level claim under the proposed classification framework (though doubtful it could be substantiated), however, the claim has been endorsed by the "Food Doctor" (UK) (who studied at the Institute of Optimum Nutrition, which covers complementary health not clinical nutrition), so should be regarded as high level. As part of the substantiation process, it would become evident that the claim is based on complementary health principles and not scientific evidence and is therefore not allowed (SA DoH, WA DoH).

Other endorsements were categorised for the following reasons:

- The Dairy Good trademark - general level claim as it is helping consumers recognise Australian dairy ingredients and dairy products (Dairy Aust.);

- International Diabetes Institute 'Go For Gold' - high level claim as it makes specific reference to diabetes (DAA);

- Australian Institute of Sport (Milo) – general level claim as it implies function/enhanced function (TCCA);

- Sports Dietitian Australia (Uncle Toby's Muesli Bars) – general level claim as it implies function/enhanced function (TCCA);

- Sids and Kids – high level claim as it is referencing a serious disease/condition (TCCA);

- An endorsement by the Coeliac Society could be a high level claim as it mentions a serious disease, however the product has the endorsement because of the absence of a specific food type rather than being a health claim, therefore consider it is not a high level claim (Nestle);

- Velish Provincial Vegetable Soup states the claim "3.3 serves of verges in this pack" and references the Aust. Guide to Healthy Eating – this is a high level claim because the recommended serves of vegetables has been determined to reduce the risk of serious disease (SA DoH);

- Tooth Friendly endorsement - general level claim as it signifies it is kind to teeth, does not promote dental decay due to absence of sugar, i.e. sugar free (CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, CMA-Vic Branch, and CM of SA); and

- Tooth Friendly endorsement - general level claim as it relates to tooth decay (Cadbury Schweppes).

The DAA supported programs that promote healthy eating to the Australian public but believed that endorsement programs require clarification of the intent and meaning and that independent research is required into how consumers interpret endorsements.

Mainland Products were unable to provide examples but believed that endorsements are a separate issue and the credibility of the endorsing organisation is sufficient to control the use of this without further regulation.

In the recent survey of health claims on food labels conducted by NCEFF in 2003, some examples of endorsements were identified. The preliminary results summary at Appendix 3 of their submission does not give details of those results, but they could be made available to FSANZ on request after further analysis has been completed (NCEFF).

Nutra-Life H&F pointed out that current Therapeutic Advertising Code in NZ identifies danger of contravening the Medicines Act by associating a product with a cause-related organisation.

Regarding the Toothfriendly endorsement, the CMA (supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, CMA-Vic Branch, and CM of SA) noted for sugar free gum the added benefit of stimulating salivary flow that helps neutralise plaque pH due to increased concentration of bicarbonate that enhances re-mineralisation.

CMA (supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, CMA-Vic Branch, and CM of SA) also noted that some products suitable for diabetics are endorsed in some countries but not in others, e.g. Chupa Chups endorsed by diabetic associations in Spain and New Zealand but not Australia, which may create difficulties with regard to endorsements in the future.

Other comments regarding the issue but not in direct response to the question

The NHF Aust. (supported by the NHF NZ) gave an overview of the Pick the Tick Program. Refer to the NHF Aust. submission for more information on:

- What is the Tick Program;
- What the Tick means;
- The Tick Program's nutritional criteria;
- Criteria review – outcomes for public health;
- Quality Assurance; and
- Public health impact of the Tick Program.

NHF Aust. (supported by NHF NZ) noted the importance of the classification of the Tick and any other permitted endorsement programs within the claims classification framework and that this is clearly stated within the new Standard.

Based on the Tick Program's aims, criteria for eligibility, rules and mode of operating, NHF Aust. strongly believes that the Tick represents a general level claim because the tick program:

- Addresses overall population health;
- Is based on the principles of healthy eating as recommended by a number of health authorities, not just Heart Foundation policies; and
- Criteria were not developed for people at risk of disease, and are not appropriate for such people.

They noted that their position is supported by research that demonstrates that a high proportion of consumers and health professions understand that products bearing the

Tick program CTM are suitable for everybody, not just people with heart disease or at risk of heart disease.

NHF Aust. (supported by the NHF NZ) noted that the Canadian Health Check Program operated by the Heart and Stroke Foundation of Canada is relevant to their submission. The requirements for third party endorsements, logos or seals of approval are provided in the 2003 Guide to Food Labelling and Advertising of the Canadian Food Inspection Agency. Endorsements do not have to be pre-approved but need to satisfy certain conditions to ensure they do not mislead or deceive; and they include the need for positioning within the total diet, avoidance of any suggestion that a food may prevent a serious disease and a statement explaining the reason why the logo is on the pack. The name of the third party must be included and the third party's nutrition recommendations must be consistent with Canada's Guidelines for healthy eating. They point out that the word 'heart' as part of the name of the third party information program is acceptable on labels in Canada, and even a heart symbol may be acceptable, provided the requirements to avoid consumers being misled are met.

Campbell Arnott's Asia Pacific recommended that the health claim regulatory system supports community initiatives such as high quality endorsement programmes. They considered the NHF Pick the Tick programme and the GI Symbol to be general level claims as they relate to product content and healthy eating, not a disease.

MLA recommended classification of endorsement programmes as general level claims.

Responses to question 32 that relate to question 34

William Wrigley Junior noted that an endorsement used by the Wrigley Company is the use of the World Dental Federation symbol, and that there is ample evidence to support the use of this logo, and it provides consumers with easily recognised symbols relating to dental hygiene.

The CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA NZ Branch, CMA NSW Branch, CMA - QLD Branch, ICA) noted that 'Toothfriendly' campaigns currently used by the confectionery industry, which encompass 'sugar free' Confectionery, offer endorsements that are as valid as for any other foods. They noted the consumer interest in dental hygiene and that 'Toothfriendly' information should be accessible to consumers.

Question 35

Can you provide any evidence that indicates how consumers interpret endorsement statements?

Out of 147 submitters, 40% (58 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	22	10	4	2	38
Government	5	2	-	-	7
Public health	7	2	-	-	9
Consumers	1	-	-	-	1
Other	3	-	-	-	3
Total	**38**	**14**	**4**	**2**	**58**

Overview

Many of the submitters gave evidence as to how consumers interpret endorsement statements by referring to the NHF 'Pick the Tick' Program. They quoted various surveys e.g.:

- NHF Newspoll Survey *(*Sept 2004);
- Noakes M & Crawford DA (1991) National Heart Foundation's 'Pick the Tick' program, consumer awareness, attitudes and interpretation, *Food Australia 43:262-66;* and
- Rayner, M (2001) Consumer use of health-related endorsements on food labels in the United Kingdom and Australia *Journal of Nutrition Education* 33 (1).

'Pick the Tick' endorsements on foods were interpreted as meaning that those foods were a healthier choice. They were also perceived to be low in saturated fat and salt, helped prevent heart disease, simplified the decision making process and provided extra information.

Discussion of submitter responses

A number of submitters that responded to this question mentioned evidence relating to the NHF Pick the Tick Program. The three actual references that were quoted were:

- NHF Newspoll Survey Sept 2004;
- Noakes M & Crawford DA (1991) The National Heart Foundation's 'Pick the Tick' program, consumer awareness, attitudes and interpretation., *Food Australia* 43:262-66, and
- Rayner, M (2001) Consumer use of health-related endorsements on food labels in the United Kingdom and Australia *Journal of Nutrition Education* 33 (1).

The NHF Aust. (supported by NHF NZ and referred to by National Foods) noted that a considerable amount of research has been undertaken in relation to consumer and health professional understanding of the 'meaning' of the 'Tick'. Evidence supports their view that the large majority of consumers and health professionals correctly understand that the Tick represents healthier choices for everyone. Their submission reports the results of research that were published in *Newspoll Survey* (September 2004). There were 1200 respondents 18years and over. The most prevalent type of (unprompted) response was one that indicated the food was 'healthier', and second most prominent response was one in which the relative content of nutrients was mentioned. When respondents were asked to choose between two options of meanings (one related to heart health and the other related to nutrient content) nearly twice as many chose 'the food meets guidelines for things like fat, salt or fibre content' (62%).

Consumer tracking, 1995-1998 and 2002-2003 studies show that the 'Tick" is seen by the majority of consumers as synonymous with healthier eating, rather than just being concerned with heart health (Pick the Tick Study, Newspoll, July 1995; Pick the Tick Study, Newspoll, June 1996; Meaning and potential for the Pick the Tick Program, Elliot and Shanahan, April 1998; Understanding the Role Played by the Heart Foundation's Tick Food Information Program, TNS, December 2003)(NHF Aust.).

Findings from a survey published in *Food Australia* (Noakes and Crawford, 1991) (Appendix 7 of the NHF Aust. submission), found a large proportion (60% of those that had seen the logo) of respondents correctly understood that the Tick means food was 'low in saturated fat and salt', and only a very small percentage (less than 3%) believed foods with the Tick were associated with curing heart disease, and 70% trust the Heart Foundation to make claims on food labels (NHF Aust.). Several other surveys were mentioned in the NHF Aust. submission.

Unilever Australasia and AFGC supported by Masterfoods Aust. NZ, stated that the Newspoll survey has shown that consumers interpret the NHF Pick the Tick endorsement to mean the food is a healthier choice and good for heart health.

AFGC supported by Masterfoods Aust. NZ also noted the *Noakes, 1991 s*hopper survey, and outlined it found that one year after the Tick was introduced in 1989 it found that '60% of those who had seen the logo, correctly interpreted it to mean that a food was low in saturated fat and salt'.

Dairy Aust. & National Foods reported a consumer survey in 2001 that indicated that 66% of consumers interpret the Pick the Tick endorsement to mean 'this food can help prevent heart disease', 78% of consumers interpreted the Tick on food to mean it is good for your health generally, and 94% understood that you cannot eat as much of this product as you like (http://www.heartfoundation.com.au/downloads/research%202001.doc). They added that the Heart Foundation's Tick Program provides information and evidence that health claims can have a favourable impact on consumers' knowledge and food choices.

SA DoH and WA DoH reported a NHF publication on evaluation of the 'Pick the Tick' program by Rayner et al., (2001) (Rayner, M (2001) Consumer use of health-related endorsements on food labels in the United Kingdom and Australia *Journal of*

Nutrition Education 33 (1)). They quoted from this "The symbol of a health-related food endorsement program is normally designed to obviate the need for much information processing. This is particularly the case with the Tesco Healthy Eating range. For some consumers the symbol simplifies the decision making process. For others, endorsements seem to constitute an extra piece of information. Many looked for evidence to support the endorsement rather than putting all of their faith in it."

Other interpretations of the results of consumer research regarding the NHF Pick the Tick were made but references were not given to the actual evidence:

- Most consumers regard products bearing the Pick the Tick symbol as healthier alternatives rather than products that reduce the risk of heart disease (NSW DoH – N&PA Branch);

- Consumers chose the products believing they are good choice for heart health (Goodman Fielder);

- This research suggests that products carrying the logo are generally considered as "good for me" (National Starch, Solae Comp.);

- The NHF tick is widely interpreted as being associated with heart health. (Parmalat Aust.);

- The heart tick is well received by consumers although some are sceptical (PB Foods);

- The NHF 'Tick' Program has been used since 1989 and the evidence, including surveys carried out by FSANZ, surrounding the use of the 'Tick' when making food choices show that consumers trust this symbol (Nestle).

NSW Food Authority, Nutrition Aust., and NZ MoH noted that they were aware of the research conducted by NHF.

CSIRO – HS&N stated that they have done work for NHF on the Tick program but this is only available with the National Heart Foundation's approval.

PB Foods noted that the NHF Tick has been used on milks. Auckland Reg. PHS commented that the Pick the tick is an evaluated program.

Regarding the glycaemic index, Auckland Reg. PHS stated that anecdotal evidence suggests that consumers misunderstand and overestimate the role of foods with a low GI, especially in relation to weight loss. A meta-analysis reveals that:

a) GI inconsistently affects satiety
b) Has an equivocal effect on weight.

(Raben A, Should obese patients be counselled to follow low - GI diet. Obesity Reviews 3; 245-256).

Two submitters mentioned the Newspoll Market Research-Omnibus Studies of main grocery buyers 18 years and over, in the years 2002-04, conducted by Gl Ltd on an

average of 500 people/survey, in the five mainland capital cities (Diabetes Aust., GI Ltd). Results from these surveys showed:

- 81-85% considered the GI useful for "everyone" for general health (GI Ltd);
- Approximately 70% said that it was either "somewhat" or "very likely" that they would use the GI symbol when shopping for food (Diabetes Aust, GI Ltd); and
- Respondents considered the GI useful for "everyone" for general health (Diabetes Aust.).

NCEFF noted a study of consumer reactions to different formats of health claims undertaken by Masters students of the University of Wollongong. This study examined the effect of an endorsement of claims by FSANZ, as well as the effect of split claims, on consumer reactions to the health claims. Appendix 4 of their submission provides a confidential summary of the preliminary findings from this research.

Aussie Bodies outlined that their research (focus groups) has found two differing attitudes; some consumers do believe that endorsements from a reputable organisation provide confidence in the product and it's claims/attributes; some believe that our society has become 'tick' crazy and are cynical about such endorsements.

The 'Dairy Good' trademark has 92% recognition amongst consumers (Bergent Market Intelligence 2004) (Dairy Aust., National Foods).
Research by GW Foods suggests that consumers do not link these endorsement programs to disease prevention, but rather they see them as being helpful to select healthier food alternatives.

TCCA have conducted research into consumer opinions of products endorsed with the SunSmart brand. Results indicated that consumers were positive about SunSmart endorsements, but that many consumers felt the company and products bearing such an endorsement must be appropriate, trustworthy, endorsed, reliable and monitored. They have acknowledged that these results cannot be directly compared with consumer interpretation of endorsement statements on food labels (TCCA).

No other referenced evidence was provided but submitters made further comments as follows.

The value of endorsements is that they provide a clear, accurate and simple message with regard to product attributes that they may be seeking which may influence their food choice. Consumers trust such endorsements as they are validated independently by reputable health based organisations and as such must be above reproach (CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, CMA-Vic Branch, and CM of SA).

Apparently consumers are more likely to listen to dietitians and organisations like NHF rather than government and industry (Bakewell Foods).

Cadbury Schweppes stated that consumers would perceive that endorsement programs provide an additional level of truth about the product, and that they would consider it to be an independent assessment and acknowledgement of the product and therefore above reproach.

CHC stated that consumers might interpret endorsements as implied claims.

CSIRO – HS&N pointed out that endorsements tend to be symbols not statements. Lazarus Scientific Research said that symbols could be misleading to consumers as products carrying the symbol could be perceived as being 'healthier' than similar products in the same category. They added that generally there are minimum criteria that a product must meet in order to be eligible for endorsement or trademark use but these can only be used on products where the manufacturer is willing (and financially able) to pay the licensing fees (Lazarus Scientific Research).

National Foods are aware that consumers do look for endorsements as a 'category entry point' at point of sale and a positive reassurance of nutrition information provided on the pack.

Dr R Stanton was not aware of any published evidence but finds that many people think that these endorsements imply that the products must be healthy. FSA research shows that consumers do not distinguish between types of claims but made their decisions based on whether the claim sounded convincing (Dr R Stanton).

In the experience of Nutrition Aust. there will always be some consumers that will see the relationship between a non-government organisation and the food industry as some form of endorsement regardless of the care taken to maintain independence and credibility. They added that it is quite a difficult issue.

The Coeliac Society of Aust. indicated that they currently endorse product with their logo but no words. This is well accepted by members and manufacturers. Addition of the words 'Endorsed by The Coeliac Society of Australia' would enhance the use of this endorsement.

Consumers take it at face value (Griffins Foods) and don't go into the complicated implications. If the Osteoporosis Society supports a calcium product, then that could be taken by the consumer to be a claim for osteoporosis (ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, Cadbury Confectionery, NZ Magazines).

Naturo Pharm added that consumer choice of products carrying the NHF Tick may be at the expense of potentially (and significantly) healthier products not carrying the endorsement, and as a result some consumers are miss-interpreting the messages they are being given.

Nutra-Life H&F stated that the general view is that some products are obviously not related to the condition concerned and represent an unencumbered charity action by the manufacturer but other products definitely are, and there does appear to be a link with others.

CML recommended referring to FSANZ or ACA research.

NCWA noted that they have not researched how consumers interpret endorsement statements therefore are unable to provide evidence.

Many endorsements make use of health care professionals or those perceived as being in such as state of authority, which is why there is a specific controls within the advertising regime for therapeutic goods (ASMI, TGACC).

Some submitters recommended that there is a more independent consumer research on endorsement statements (Tas DoH&HS, Lazarus Scientific Research, TCCA, ASMI, TGACC). NZFSA indicated that they were not aware of any research but recommend FSANZ should consider/explore this in their ongoing monitoring and evaluation of health claims.

Responses to question 32 that relate to question 35

The NHF NZ believed that consumers consider an 'endorsement' as coming from an appropriate and reputable third party or based on their recommendations.

The ASA (supported by Cadbury Confectionery, Naturo Pharm, NPANZ, Assoc. of NZ Advertisers, NZTBC, NZ Magazines) believed that consumers should be able to decide if the endorsement is merely a paid for acknowledgement or if it is genuine.

The NHF Aust and NHF NZ believed that there is potential consumer confusion between endorsements and cause-related marketing. They considered that the term 'endorsement program' implies a systematic approval system, with a set of processes and rules by which decisions are made as to the provision of such approval or endorsement to particular goods and services – in this case foods. Cause-related marketing was thought to include the description in Section 5.6.6 of the IAR but also where companies sponsor activities of charitable organisations, either as a corporate sponsorship or a brand-related sponsorship.

The NHF NZ proposed:

- A more appropriate definition of 'endorsement' than is currently in the Policy Guidelines is developed for the new Standard;

- Endorsements should be distinguished from cause-related marketing by clear definitions in the Standard; and

- In order to reduce the potential for misleading consumers, the definition of, and provisions for, endorsements should not permit logos, 'seals of approval', testimonials or endorsing/approving statements unless they are from a qualified and reputable third party.

The provisions should also provide clear guidelines as to how the qualification or competence of an endorsing organisation can be verified.

1.6 CAUSE-RELATED MARKETING

Question 36

What are the impacts on consumers, public health professionals and industry of permitting cause-related marketing statements?

Out of 147 submitters, 46.9% (69 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	23	18	4	2	47
Government	5	2	-	-	7
Public health	8	2	-	-	10
Consumers	2	-	-	-	2
Other	3	-	-	-	3
Total	**41**	**22**	**4**	**2**	**69**

Overview

The permission of cause-related marketing (CRM) statements were believed to impact in the following ways: consumers might interpret a CRM statement as a health claim or an endorsement, opportunities are provided for industry to support organisations which results in benefits for all stakeholders, a significant negative economic impact would occur if CRM includes individual sponsorship arrangements (e.g. Kieran Perkins) and CRM regulation would provide a level playing field for health agencies.

Impacts of cause-related marketing

Submitters who commented described the following impacts:

- Consumers could interpret a cause-related marketing statement as a health claim unless properly regulated (NCWA, Tas DoH&HS, NSW DoH – N&PA Branch, SA DoH, WA DoH, Queensland Health - PHS, TCCA, Kidney Health Aust., NHF Aust., NSF, ACDPA, Dr R Stanton, Nutrition Aust., PHAA, CSIRO, Monash Uni – N & D Unit, Aussie Bodies, CHC, Griffins Foods, NZ Dairy Foods, NZ MoH, NHF NZ, Auckland Reg. PHS, ANA).

This was supported by ASMI and TGACC in that they expressed concern about the potential for inappropriate use or over consumption of particular food products endorsed by groups associated with disease or conditions. WA DoH stated that unless cause-related marketing statements are properly regulated, the consequences would be reduced protection of public health and safety and prevention of misleading and deceptive conduct.

- The agency responsible for the cause being marketed may not have a formal relationship with the manufacturer or importer and therefore may not have control over the types of foods used in the cause marketing (Tas. DoH&HS,

SA DoH, WA DoH, Monash Uni – N & D Unit, PHAA). Cause-related marketing was therefore seen as potentially more problematic than endorsement programmes, as it could lead consumers to believe that a product is related to health.

- Consumers could perceive that the cause organisation would not apply their cause to a food product unless it met the organizations criteria, and could therefore interpret the statement as an endorsement (Cadbury Confectionery).

- Food manufactures will use cause-related marketing statements to avoid the pre-approval process for health claims. A product could therefore potentially carry a pre-approved health claim and a cause-related marketing statement and a disclaimer, which could be very confusing for consumers and may result in less confidence in the integrity of the nutrition message. Disclaimers will not lessen consumer confusion (NHF Aust., NHF NZ).

- Opportunities are provided for industry to support organizations (DAFF, AFGC, MasterFoods Aust. NZ, Dairy Aust, F&B Importers Assoc., Goodman Fielder, National Foods, National Starch, Solae Comp., Parmalat Aust., Sanitarium Health Food Comp., ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZ Magazines, NZTBC, Fonterra, Mainland Products, NZFGC, CMA supported by Mandurah Aust., Palatinit GmbH, Kingford Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch and CM of SA; Unilever Australasia), thereby:

1. Assisting organizations to achieve their goals (AFGC, MasterFoods Aust. NZ, Dairy Aust, Goodman Fielder, National Foods, Parmalat Aust., NZFGC, CMA supported by Mandurah Aust., Palatinit GmbH, Kingford Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch and CM of SA);

2. Providing benefits for consumer by increasing research into the cause and treatment of diseases and conditions as well as providing funds for education (DAA, NZDA, Dairy Aust, FBIA, Parmalat Aust., Sanitarium, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury, Naturo Pharm, NZ Magazines, NZBTC);

3. Enhancing a food manufacturer or importer's profile as a supporter of a worthwhile cause (Dairy Aust, National Starch, Solae Comp, Parmalat Aust.);

4. Raising the profile and revenue of charities (DAFF, National Starch, Solae Comp, Fonterra, Mainland Products);

5. Increasing consumer awareness and/or understanding of health issues (National Foods, National Starch, Solae Comp);

6. Increasing sales for manufacturers and importers (Sanitarium, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZ Magazines, NZTBC);

7. Providing an opportunity for consumers to support a cause (National Starch, Solae Comp, CMA supported by Mandurah Aust., Palatinit GmbH, Kingford Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch and CM of SA);

8. Decreasing the burden on government spending (Sanitarium Health Food Comp, Diabetes Aust., GI Ltd);

9. Providing an incentive for food manufacturers to research particular causes such as breast cancer (Fonterra, Mainland Products);

10. Providing benefits for all stakeholders (Unilever Australasia, F&B Importers Assoc.).

- There would be a significant negative economic impact if cause-related marketing regulations include sponsorship arrangements, such as Kieran Perkins signature on the label of Pura Light Start modified milk (National Foods);

- Regulation of cause-related marketing statements would provide a level playing field for agencies that are associated with the prevention or management of a serious disease, thereby increasing the choice for both industry and consumers and decreasing confusion in the market place (Diabetes Aust., GI Ltd); and
- There would be very little impact (Nutra NZ).

One submitter was unsure of the impact (Bakewell Foods), while four others had no evidence of the impacts (Dr C Halais, NZJBA, Frucor, NZFSA). NZFSA indicated that while there is potential to increase awareness of causes, there might also be consumer confusion with pre-approved health claims. Finally Mainland Foods believed that if the Policy Guidelines were followed there would be no major impact.

Regulation of cause-related marketing statements

Only three submitters explicitly stated that they did not believe cause-related marketing statements should be permitted (Auckland Reg. PHS, NHF Aust., NHF NZ). Sixteen industry submitters (F&B Importers Assoc., Goodman Fielder, Horticulture Aust., Nutra NZ, Kellogg's Aust, CMA (supported by Mandurah Aust., Palatinit GmbH, Kingford Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch and CM of SA) and DAFF), however, specifically expressed their support.

Many submitters commented on how cause-related marketing statements should be regulated. Four public health agencies believed that public benevolent organizations should not be disadvantaged by restrictions on cause-related marketing campaigns and that any restrictions that do apply, should be equal for both organ related and disease

related charities (ACDPA, Kidney Health Aust, TCCA, NSF). TCCA also recommended a clear distinction between cause-related marketing that is associated with service delivery (for example, funding for transport systems for cancer patients and help-lines) and those associated with health promotion activities. The NSF and ACDPA further reported that health charities should not be disadvantaged by regulation of cause-related marketing campaigns in favour of broader NGO sectors.

The NHF Aust. and NHF NZ proposed that cause-related marketing statements be prohibited; they believed food companies should however, be allowed to sponsor cause-related marketing strategies provided they meet the following conditions:

- No mention of the support on food packages;
- Promotion of an event/activity should clearly communicate that the sponsorship or partnership does not imply any endorsement of the food company's product;
- Some criteria should be applied by the health organization (such as consistency with dietary guidelines) to the food products it permits to sponsor the event/activity to ensure healthier food choices are promoted; and
- Communication about the sponsorship should relate to the specific activity/event, not the health organization as a whole.

The NHF Aust. and NHF NZ also believed that regulation should clearly distinguish between endorsement and cause-related marketing as there is potential confusion. Endorsement was seen as implying a systematic approval system with a set of processes and rules. Cause-related marketing was seen as including the description in section 5.6.6 of the P293 IAR but also where companies sponsor activities of charitable organizations, either as a corporate sponsorship or a brand-related sponsorship.

To avoid consumer confusion in cause-related marketing statement, Nutra-Life H&F suggested that manufacturers could avoid any reference to a product and use only the company name.

New Zealand industry submitters reflected that where a cause-related marketing statement is perceived as an implied health claim, then either the claims classification framework would apply (Fonterra, Mainland Products) or fair trading law would prevail (NZFGC, NZJBA, Frucor). Cadbury Schweppes and CMA (supported by Mandurah Aust., Palatinit GmbH, Kingford Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch and CM of SA) believed that it was the responsibility of the cause organisation to ensure that consumers are not misled. In addition six industry submitters stated that it was the manufacturer's responsibility to ensure labels on their products don't mislead cause-organisations and/or consumers (Cadbury Schweppes, Dairy Aust., Parmalat Aust., Fonterra, Mainland Products, NZFGC).

Some submitters who represented nutrition and health interests expressed stronger views on the permissions for cause-related marketing statements. Monash Uni – N&D

Unit, SA DoH, WA DoH and PHAA believed that if there is a risk of misinterpretation then cause-related marketing statements should be regulated under the claims classification framework. Several submitters also recommended that where a health charity features on a food label or in promotions, the cause-related marketing statement should be deemed to have a halo effect equivalent to a health claim (Horticulture Aust., Monash Uni – N&D Unit, PHAA, ACA, SA DoH, WA DoH) and therefore be classified within the claims framework (ACA, SA DoH, WA DoH).

The ACA thought the classification should be in accordance with the level of health benefit that is referred to, while SA DoH and WA DoH recommended it should be based on the halo-effect implied by the endorsement logo and by claims implied by the name of the endorser. SA DoH also stated in their submission that cause-related marketing claims should be regulated as high level claims because of the way they are perceived by consumers.
National Foods believed that sponsorship arrangements should be outside the scope of the regulation of cause-related marketing activities.

ASMI and TGACC pointed out that the Australian food industry should consider the relevancy of key principles in Quality Use of Medicines (QUM) as endorsed by the Australia Department of Health and Ageing.

Several submitters, whose primary interest is nutrition and health, recommended a complaint mechanism for cause-related marketing campaigns (TCCA, ACDPA, Kidney Health Aust., NSF, ANA).

The majority of submitters supported the requirement for a disclaimer (NSW DoH – N&PA Branch, AFGC, MasterFoods Aust. NZ, Dairy Aust., F&B Importers Assoc., Goodman Fielder, GW Foods, Horticulture Aust., Kellogg's Aust., Parmalat Aust., Diabetes Aust., GI Ltd, NZFGC, NZDA, Nestle, Unilever Australasia). DAFF also reflected this notion, adding that use of a disclaimer should be the only conditions placed on cause-related marketing statements. However, Nutra-Life H&F believed that manufacturers would avoid making cause-related marketing statements if they had to make a disclaimer, while Fonterra (supported by Mainland Products) indicated that if flexibility were permitted around the wording of cause-related marketing statements then a disclaimer might not be necessary. GW Foods noted that if cause-related marketing statements were to be approved as high level claims, then no disclaimer should apply.

TCCA, Dr R. Stanton and NZDA stated if cause-related marketing statements are permitted, then regulation around a mandatory disclaimer must include criteria on its font and its positioning. The preferred criteria were that the disclaimer should be in the same font as the cause-related marketing statement and that it should be positioned adjacent to the statement or to the symbol used by the organization linked to the cause.

Several submitters considered that a disclaimer may or may not be sufficient to reduce the risk of misleading or deceptive action, depending on how consumers reacted to the cause-related marketing statement (Tas DoH&HS, SA DoH, Monash Uni – N&D Unit, Nutrition Aust., PHAA). Although Nutrition Aust. suggested supporting

education as a solution, the others proposed more prescriptive regulation as described above.

Other comments provided but not in direct response to the question

Some of these have been incorporated into the information above.

Cancer Society NZ Inc. stated that the onus is on health charities to manage any risk associated with cause related marketing, in order to maintain the integrity of each organisation. Mechanisms to deal with complaints should be established. Food industry groups are known to support a number of nutrition related organisations. Important that such organisations do not enter into cause related marketing with particular products. Any restriction on cause related marketing should apply equally to all health promoting charities, regardless of whether the organisation make references a disease of a body organ. Public benevolent organisation should not be disadvantaged by restrictions to cause related marketing.

Question 37

Is there any evidence to indicate how consumers interpret cause-related marketing statements?

Out of 147 submitters, 29.9% (44 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	Total
Industry	13	12	2	27
Government	6	2	-	8
Public health	4	1	-	5
Consumers	2	-	-	2
Other	2	-	-	2
Total	**27**	**15**	**2**	**44**

Overview

Forty per cent of submitters (18) were not aware of any evidence on how consumers interpret cause-related marketing, so many (from all stakeholder groups) suggested the need for consumer research to assist in the development of risk management strategies for cause-related marketing statements. Only one submitter provided new information.

No evidence

The majority of submitters who responded to this question stated that they were not aware of any evidence that indicated how consumers interpret cause-related marketing statements (NSW DoH - N&PA Branch, Aussie Bodies, AFGC, MasterFoods Aust. NZ, Dairy Aust., Goodman Fielder, Parmalat Aust., Sanitarium Health Food Comp.,

Diabetes Aust., Dr C Halais, Dr R Stanton, GI Ltd, NZ MoH, NZFSA, NZ Dairy Foods, Nutra NZ, NZFGC, Nestle).

Submitters from all stakeholder groups therefore indicated that consumer research studies were required to assist in the development of risk management strategies for cause-related marketing statements (ACA, Tas DoH&HS, NSW DoH - N&PA Branch, SA DoH, WA DoH, CHC, Dairy Aust., Monash Uni – N&D Unit, TGAAC, Nutrition Aust, NZFSA). ASMI did not, however, believe that there is any need for consumer research while Fonterra stated that FSANZ's question about evidence was unnecessary because cause-related marketing statements that were perceived by consumers as implying a health benefit would come within the claims classification framework.

Evidence

A small number of submitters either provided evidence or indicated where evidence might be sought:

- Tas DoH&HS referred to a 2002 UK FSA study which suggested that consumers do not classify claims according to the proposed EU regulatory system;

- Naturo Pharm provided two articles on cause-related marketing and noted that there is significant research in the area;

- Mainland Foods stated that consumer support for the yellow-eyed penguin via Mainland butter sales is perceived as being environmentally friendly;

- Dr R. Stanton pointed out that the food industry might have evidence as the use of cause-related marketing statements is of benefit to them;

- TCCA referred to FSANZ research as did CML, who also referred to ACA research; and

- NCWA stated that evidence to indicate cause-related marketing statements misinformed consumers was anecdotal.

Two submitters believed that the proliferation of cause-related marketing campaigns strongly indicate that the overall impact on consumers is positive (National Starch and Solae). PB Foods noted that some cause-related marketing campaigns in Western Australia have been well received by consumers while National Foods believed that consumers are commercially savvy and are able to recognize the economic good-will arrangement in such campaigns. Seven New Zealand submitters stated that some consumers see it as donating to a worthy cause (ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, NZ Magazines, Naturo Pharm, NZTBC).

Question 38

What words could be used in a disclaiming statement to ensure cause-related marketing is not interpreted as a nutrition, health or related claim?

Out of 147 submitters, 41.5% (61 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	21	13	4	2	40
Government	5	1	-	-	6
Public health	8	2	-	-	10
Consumers	2	-	-	-	2
Other	3	-	-	-	3
Total	**39**	**16**	**4**	**2**	**61**

Overview

One-third of submitters (20), all of whom were from the food industry, did not support mandatory wording for a disclaimer. However in general, they supported cause related marketing and the use of a disclaimer. Seventeen submitters proposed wording for mandatory disclaimers, with most being to the effect that the product will not help in the reduction of risk of disease nor in the enhancement of health.

Do not support mandatory wording for a disclaimer

Twenty submitters, all of whom were from the food industry did not support mandatory wording for a disclaimer (AFGC, MasterFoods Aust. NZ, Dairy Aust., Parmalat Aust., F&B Importers Assoc., National Foods, Fonterra, NZFGC, CMA supported by Mandurah Aust., Palatinit GmbH, Kingford Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch and CM of SA; Nestle, Unilever Australasia). Of these, three submitters believed that it should be the manufacturer's responsibility to ensure that consumers do not misinterpret a cause-related marketing statement as a nutrition, health or related claim (Dairy Aust., Parmalat Aust., Fonterra).

Two other submitters also reflected this notion in that they stated that the specific wording would depend on the type of cause-related marketing statement being made (Goodman Fielder, PB Foods).

NSW Food Authority did not explicitly state it opposed prescriptive wording, but it did indicate that the words should be adequate to ensure that consumers understand that there is no connection between consumption of the food and 'the cause'. Finally three industry submitters suggested that guidance on the use of non-mandatory wording could be provided in a user-guide (Dairy Aust., National Foods and Parmalat Aust.). One element of the guidance could be that the wording should be as simple as possible (e.g. "This is not a health claim") (AFGC, MasterFoods Aust. NZ and Parmalat Aust.).

ASA (supported by NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZ Magazines and NZTBC) did not think that the mention of a condition in a cause-related marketing statement would be disclaimable.

Several submitters believed that the need for and/or the wording of a disclaimer should be determined by consumer research (CHC, Sanitarium Health Food Comp, TGACC, TCCA, NZFSA).

Proposed wording for disclaimers

Finally 16 Australian submitters and one New Zealand submitter, who mostly represented nutrition and health interests, proposed specific wordings for a disclaimer as illustrated in the following table:

Submitter	Disclaimer
Tas DoH&HS, NSW DoH – N&PA Branch, SA DoH, Monash Uni – N&D Unit, PHAA	The [organization linked to the cause] does not endorse this food product and it will not help in the reduction of risk of disease nor in the enhancement of health.
DAFF	Unless otherwise stated
Diabetes Aust.	X gratefully acknowledges the sponsorship of Y. This does not infer an explicit or implied health benefit.
GI Ltd	X gratefully acknowledges the sponsorship of Y. This association does not infer an explicit or implied health benefit of any nature to the user.
DAA	X gratefully acknowledges the support of Y but makes no claims in relation to Y's product and Z disease.
Nutrition Aust.	X does not endorse this food product and no relationship between this food and any effect on health is implied.
CSIRO – HS&N	Association with this cause does not imply this food is beneficial for this disease
Dr R Stanton	B% of the sales of this product are donated to X, but the product itself has no health connection with X.
ACA	A proportion of the sale of this product will be donated to X. This product will not treat, prevent or reduce the risk of developing Z disease.
NCWA	This is not a nutrition, health or related claim; it is scientifically unsubstantiated.
National Starch, Solae Comp.	The involvement of company Y in promoting issue Z does not mean that product A is in any way associated with the prevention or treatment of issue Z.
Nutra NZ	"Supporting" (i.e. the word "supporting" should be used in the cause-related marketing statement.

1.7 IMPLIED CLAIMS

Question 39

Are you able to provide any evidence that indicates how consumers may interpret various types of representations of claims?

Out of 147 submitters, 29.3% (43 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	14	8	1	-	23
Government	4	2	-	-	6
Public health	7	2	-	-	9
Consumers	2	-	-	-	2
Other	3	-	-	-	3
Total	**30**	**12**	**1**	**-**	**43**

Overview

Evidence that was provided included the outcome evaluation of the folate neural tube defect health claims pilot, the UK Joint Health Claims Initiative, Fullmer, Geiger and Parent (1991), and Chan, Patch and Williams (2004). Some submitters noted their concerns in relation to implied claims. Some food manufacturers noted from their own experience in the market, or indicated that they carry out their own research. Sixteen submitters stated that they were unable to provide evidence that indicates how consumers may interpret various types of representations of claims. Another six submitters stated that they were not aware of any research on implied claims

No evidence

Of the 40 submitters that answered this question directly, 16 submitters stated that they were unable to provide evidence that indicates how consumers may interpret various types of representations of claims (NCWA, Diabetes Aust., GI Ltd, F&B Importers, Solae Comp, Auckland Reg. PHS, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZTBC, Nutra NZ, NZ MoH, NZFSA).

Another six submitters stated that they were not aware of any research on implied claims (DAA, NZDA, AFGC supported by MasterFoods Aust. NZ and Parmalat Aust., National Starch).

Evidence

The report of the outcome evaluation of the Folate-Neural Tube Defect Health Claims Pilot notes that at baseline (before the pilot had commenced) a significant number of women claimed to have seen information on food packaging relating to the folate health claim. The authors interpret this as consumers not making a distinction about the content of nutrition related messages on labels, but perceiving a variety of

nutrition messages as health claims. (Watson 2000) (PHAA (supported by ACA), Monash Uni – N&D Unit, WA DoH, Tas DoH&HS, SA DoH).

The UK Joint Health Claims Initiative (2001, p9) suggests that an overriding principle of any health claims system is "that the likely consumer perception is paramount. In other words, what the consumer thinks the health claim means. It is not enough that there is one interpretation of a health claim that complies with this Code; all likely interpretations must comply." (PHAA (supported by ACA), Monash Uni – N&D Unit, SA DoH, WA DoH).

Evidence provided in the IAR, in particular the Food Standards Agency (FSA) Qualitative report suggests that consumers do not distinguish claims according to how the regulatory system classifies them. This report also points to the importance of distinguishing between what is objectively true about the claim and what impression it makes on the consumer (NSW DoH – N&PA Branch, PHAA (supported by ACA), Monash Uni – N&D Unit, WA DoH, SA DoH). This impression "is related to 'feeling and is influenced by the way in which the claim is presented." (FSA 2002, p32) The authors argue that this 'impression' is at least as important, if not more so, than what is objectively claimed (PHAA (supported by ACA), Monash Uni – N&D Unit, WA DoH, SA DoH).

The report also notes that consumer understanding of nutrition and health claims is not necessarily consistent or logical and that they "…drew on a variety of perceptions, assumptions and prejudices to make their own sense of what was being offered… and they look at claims in a wider and often 'fuzzy' context." (PHAA (supported by ACA), Monash Uni – N&D Unit, NSW DoH – N&PA Branch, WA DoH, SA DoH, Horticulture Aust.). NSW DoH – N&PA Branch added that this is a very important area. Consumers are likely to apply prior knowledge to their understanding and interpretation of a claim and there is a danger that they will read into claims that are not qualified, implications for health that are not warranted. Dr R Stanton also referred to research conducted by the FSA.

TCCA provided references to two research studies:

- Fullmer, Geiger and Parent (1991) conducted a study to assess consumer's knowledge of current fibre recommendations and in relation to claims on breakfast cereal labels. They found that overall attitudes were positive, consumer knowledge of fibre was low and understanding of health messages was low.

- Chan, Patch and Williams (2004) conducted research into the beliefs and attitudes of Australian consumers to fat claims on packaged foods. They found that awareness of claims about fat was high and they influenced their purchase decisions. Most preferred claim was 'X% fat free' and claims were considered most useful on foods that were high in fat. Considerable scepticism about all nutrient claims was noted and consumers preferred to check the claim against the nutrition information panel. Many claims were seen as advertising that could be misleading, deceptive or confusing. Some consumers believe low fat claims encourage over-consumption of foods. It was concluded that changes to

regulations should be made to enhance the credibility of claims and support their role in assisting consumers to make healthier food choices.

Regarding this last point, NCEFF has conducted this research (Chan C, Patch C, Williams P. Australian consumers are sceptical about but influenced by claims about fat on food labels. Eur J Clin Nutr (in press)) and they attached a full text version in Appendix 1 of their submission, for the information of FSANZ staff (in confidence).

A reference was provided for some US research that shows that consumers do not always value scientific proof. In a study of consumer attitudes, many users said that they would continue to take some products even if they were shown to be ineffective in scientific studies (Blendon RJ et al., (2001). Americans' views on the use and regulation of dietary supplements. Arch Intern Med, 26; 161(6): 805-10) (Dr R Stanton).

The Heart Foundation's Tick is a well recognised symbol amongst consumers, with 86% of consumers reporting to have heard or seen the Tick program, 85% of consumers saying the Tick can be trusted and relied upon, 78% of consumers understood the Tick on foods to mean it is good for your health generally, 87% understood a Tick-approved food must meet the Heart Foundation's guidelines, and 97% of consumers realised that foods with the Tick do not 'cure' heart disease, 93% of consumers also understood that foods without the Tick are not bad for you. Ninety two percent of consumers recalled seeing the 'Dairy Good' logo (Bergent Market Intelligence 2004). Such results highlight consumers' competence in interpreting information correctly, but also a need for government and non-government organisations and the food industry to be able to provide all of that information to better assist with their food selection (Dairy Aust. supported by Parmalat Aust.).

Food industry research

It was reported that GW Foods find that consumers see their current claims as being related to 'maintaining food health' rather than preventing disease.

Goodman Fielder reported that research information around consumer claim interpretation is conducted within in a very targeted way specific to a particular brand.

Companies conduct market research or consumer insight testing into certain claims that they might like to use on product. This research is conducted to ensure that the message that is used on product is relevant to the consumers for whom the product is intended (Nestle).

National Foods stated that the food industry is legally, ethically and economically self-interested to ensure all claims are useable, well understood and easy to interpret so consumers are able to act on the information provided to choose food. They added that the food industry also has to comply with false and misleading provisions in the Trade Practices legislation and they believe this is done in a self-regulatory manner already, as confused consumers will contact the company for clarification of claims, either their own claims or their competitors. They noted that consumer research to determine the meaning consumers ascribe the claim as proposed on page 47 of P293 is very expensive for a general level claim or for a small food company to invest in

and the food industry already conducts consumer market research to ensure messages are clear and represent the substantiated health benefit (National Foods).

Concerns relating to implied claims

Some submitters noted their concerns regarding implied claims, and DAA and NZDA were concerned because this is an area where consumers are most likely to be misled. NZFSA also believed implied claims are problematic and they added that at FSANZ workshops the different interpretations and implications taken from a selection of claims is indicative of the problem. They do not support FSANZ (or enforcement agencies) trying to interpret the claim for the consumer and stated their position that interpretation should not be made and a very black and white process should be used, e.g. a reference to cardiovascular disease is a high level claim. For some, a reference to a healthy heart may mean the same but to others it may just mean a healthy heart. They supported that reference to the disease has to be stated and not implied and therefore recommended that FSANZ remove reference throughout the document to the words 'implicit' or 'implied' (NZFSA).

TCCA also noted their concern about implied claims arising from:

1) Food names, e.g. Kellogg's Body Smart cereal.

2) Other prominent words on the front panel of the label, e.g. Lowan Oat & Wheat Honey O's feature the words 'Let's eat healthy', and Kellogg's Coco Pops feature the words 'Tasty Nutrition', both in large font on the front panel.

3) Images on the food label (e.g. Milo features images of Olympic swimmers – implying enhanced function/sports performance, Coco Pops feature a cartoon image of the mascot, dressed as a child, standing at a height chart – implying function/enhanced function with respect to vertical growth).

In relation to points 1 and 2 above, they recommended that FSANZ prohibit the use of certain words (e.g. 'health', 'nutrition', 'body' and variations of these words, and any words describing a body part [e.g. 'heart']) on the front panel of food products high in energy, fat, sugar or sodium as these may imply a health claim. In relation to point 3 above, they recommended that FSANZ prohibit the use of images that imply illness or improved health/development. They also recommended that FSANZ conduct research into consumer interpretation of the implied claims listed above (TCCA).

Griffins Foods suggested that consideration should be given to brand names and their interpretation, including whether or not a standard will encompass this. They gave the example of the use of the word 'health' in conjunction with a food which is prohibited in the current standard whereas brand names are not covered by this Standard.

Other submitters also recommended that the issue of implied claims is covered by further consumer research (Nutrition Aust. Tas DoH&HS, TGACC) by FSANZ

(CML, National Starch, Solae Comp.). Pre-testing of any permitted claims is also required (Tas DoH&HS).

Examples of implied claims

An example is the term 'low fat' is often regarded as implying an association with reducing body fat (Aussie Bodies).

CHC noted that a photograph of an extremely thin person within an advertisement or in a label might lead the consumer to believe that a particular food was beneficial to weight management. They added that it might not be necessary to include any claim other than the image.

General comments

It was submitted by AFGC that experience in the market place during the first 2 years of claims use will provide consumer feedback (via product failure/success) as to the effectiveness of various substantiated claims representations (this was supported by Masterfoods Aust. NZ and Parmalat Aust.).

The AFGC also noted that ASMI has collaborated with the Communications Research Institute of Australia to develop a code of practice for consumer focussed labelling. Purpose of this is to ensure that consumers interpret and are able to act on the information provided on a label (supported by Masterfoods Aust. NZ and Parmalat Aust.).

It was thought that consumers would believe that even inferred claims have been approved or endorsed and that the manufacturer can support the claims. However, claims should be fully substantiated by either pre-approved application process (high level claims) or dossiers of supporting evidence (general level claims) otherwise the claim should not be made. This situation lends even more credence to having all aspects of health and nutrition claims in a Standard rather than guidelines (Cadbury Schweppes).

Other comments provided but not in direct response to the question

Queensland Health – PHS commented about the legal advice in the A2 milk prosecution which indicated that unless the definition of 'claim' extends to information sources provided through website linkage by the manufacturer and is specifically regulated or prohibited in the Standard it will continue to the a loophole. They added that in the ruling on A2 milk, the magistrate indicated that inference made in advertising or reflected websites were clearly implied health claims.

Question 40

Does FSANZ need to establish criteria to enable industry and enforcement agencies to determine whether the representation of a claim conveys a greater perceived health benefit to the consumer? If so, what might these criteria be?

Out of 147 submitters, 49.7% (73 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	26	15	4	2	47
Government	5	2	-	-	7
Public health	9	4	-	-	13
Consumers	2	-	-	-	2
Other	4	-	-	-	4
Total	**46**	**21**	**4**	**2**	**73**

Overview

Forty-one per cent submitters (30) stated or implied that they did not support FSANZ establishing criteria to enable industry and enforcement agencies to determine whether the representation of a claim conveys a greater perceived health benefit to the consumer. Another 27 submitters (37 per cent) stated or implied agreement that FSANZ establishes criteria to enable industry and enforcement agencies to determine whether the representation of a claim conveys a greater perceived health benefit to the consumer. Two submitters supported this latter approach for images only.

Supported criteria

There were 22 submitters that clearly stated that they agreed that FSANZ establishes criteria to enable industry and enforcement agencies to determine whether the representation of a claim conveys a greater perceived health benefit to the consumer (NCWA, Diabetes Aust., DAA, NZDA, GI Ltd, PHAA (supported by ACA), Bakewell Foods, CML, CHC, DSM Nut. Prod, Hort. Aust., Sanitarium Health Food Comp, ACCC, NSW DoH – N&PA Branch, NSW Food Authority, SA DoH, WA DoH, Monash Uni – N&D Unit, Auckland Reg. PHS, Canterbury DHB, Nutra-Life H&F).

Another six submitters implied that they agreed that FSANZ should establish these criteria (TCCA, Dr R Stanton, Nutrition Aust., Cadbury Schweppes, NZ MoH).

In addition, NHF Aust., supported by NHF NZ submitted that criteria might be necessary only for images (as opposed to words) that may imply nutrition, health and related claims.

NSW DoH – N&PA Branch commented that although they agreed in principle, in practice this may prove difficult to do as each claim will need to be looked at on an individual basis. The general impression will be a result of the choice of words used within the claim, the artwork on the package, additional information provided, and the

type of product etc (NSW DoH – N&PA Branch). Sanitarium Health Food Comp also noted that they realise this could be difficult in practice, for example graphic designs or images on TV ads.

Although agreeing that these criteria need to be established, Nutra-Life H&F added that this is already handled by Medsafe and TGA.

Reasons provided by submitters for supporting the establishment of criteria for implied claims were that:

- It would recognise that consumers react to words/images etc in different ways (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit); and

- Guidance in the form of criteria to substantiate general level claims would assist the ACCC in responding to consumer enquiries and complaints that may arise from the use of implied claims. Implied claims can target any group or sub-group of consumers (ACCC).

Nutrition Aust. considered that it is important to regulate these implied claims to avoid the many types of logos that have appeared on food packages, which may imply health benefits.

Suggested criteria

A number of submitters recommended that further research on consumer perceptions of claims as well as pre-testing of any permitted claims would be required (SA DoH, WA DoH, Monash Uni – N&D Unit, PHAA (supported by ACA)). Similar comments to this were that:

- Enforcement agencies should request and consider any research undertaken by the food manufacturer relating to consumer interpretation of artwork, which may represent a nutrition or health claim (NHF Aust., NHF NZ);

- The criteria would need to be based on consumer research to ensure that both the criteria and the conditions are appropriate and meaningful to the consumer (NSW Food Authority);

- Research needs to be undertaken with Australian consumers to establish what they think a claim means. Criteria should include consumers' perceptions of the claim (Dr R Stanton);

- Consumer research would be important in determining consumer perceptions of likely words/images (Nutrition Aust.);

- It is necessary for research to be undertaken in this area to formulate advice and criteria for all stakeholders in relation to the representation of a claim; and

- Perception of consumers needs to be tested to determine the effect of representations of claims. If there was clear guidance for how claims might be

worded based on consumer testing this might ensure less confusion (NZ MoH).

This approach was supported by TCCA, which suggested mechanisms for avoiding such problems include establishing a set of pre-approved claims with associated criteria. Pre-approved claims and criteria should be based on good quality research and communicated in a way that is consistent with the evidence supporting the claim.

Other submitters also considered that prescribed wording of claims is required (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit).

In relation to the above recommendations, the following quote was provided: "The goal of the claim should be proper and effective communication of the scientific facts between industry or government, and consumers. Consumers, however, are not specialists who can independently interpret technical wording. Therefore, along with the scientific truth, consumers' perceptions should be considered in making health claims" (Kwak and Jukes, 2002) (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit).

Hort. Aust. went on to say that consumer perception of nutrition health and related claims will help inform classification in general. The UK Food Standards Authority research shows that consumers rarely, if ever, grouped health claims as either functional, health enhanced function, or health reduction of disease (the EC's proposals).

Other suggestions were that:

- Criteria need to substantiate risk or cause (NCWA);
- Criteria, including qualifying & disqualifying types, need to be scientifically substantiated (CML);
- There needs to be clear qualifying and disqualifying criteria, and then substantiation that is scientific, soundly based and does not mislead the consumer (Canterbury DHB);
- It must be decided whether they are general level or high level claims and the prescribed Standard and criteria follow (Auckland Reg. PHS);
- Consideration must be given to a post-market surveillance mechanism for general level claims. The market place may be flooded with presentation that convey a greater perceived health benefit and be unmanageable by the enforcement agencies due to the lack of resources and funds (CHC);
- A definition for perceived health benefit should be established because otherwise it would require legal advice on possible interpretations of the claim (Bakewell Foods);

- There is one criterion that ensures the use of symbols, drawings or models are commensurate with the expected benefits and not beyond what can be reasonably achieved. (DSM Nut. Prod.); and

- Criteria applying to implied claims should be the same criteria as that established for the general level and high level claims, captured within the Standard (Cadbury Schweppes).

Opposed criteria

There were 28 submitters that clearly stated that they opposed the establishment by FSANZ of criteria to enable industry and enforcement agencies to determine whether the representation of a claim conveys a greater perceived health benefit to the consumer (AFGC, MasterFoods Aust. NZ, Dairy Aust., F&B Importers Assoc., Food Tech. Assoc. of Vic., GW Foods, Goodman Fielder, National Foods, Parmalat Aust., PB Foods, CSIRO – HS&N, Griffins Foods, NZ Dairy Foods, Nutra NZ, NZFGC, NZFSA, Nestle, Unilever Australasia, CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, and CM of SA).

Two submitters also implied that they did not support the establishment of such criteria (Fonterra, supported by Mainland Products).

In addition, NHF Aust. (supported by NHF NZ) felt that criteria were not necessary for word claims if the Standard lists all approved general level claims and high level claims.

Some of the reasons provided by these submitters for not supporting the establishment of these criteria related to existing legislation covering false and misleading statements, including that:

- There are adequate powers under State Food Acts and ACCC regarding false and misleading statement to address this issue (National Foods, AFGC, MasterFoods Aust. NZ, Goodman Fielder, Parmalat Aust., Dairy Aust., F&B Importers Assoc. GW Foods);

- This is already covered by Fair Trading requirements (Griffins Foods);

- Both the Food and Fair Trading Acts can address whether or not a claim is false or misleading and thus there is an appropriate means of dealing with implied claims. (NZFGC); and

- There is legislation already available to enforcement agencies to ensure that consumers are not deceived or misled by claims and enforcement agencies will also be able to ensure that the substantiation is sufficient and appropriate for the claim that is made about the product (Nestle, CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, and CM of SA).

Other more general reasons for provided by these submitters for not supporting the establishment of these criteria were that:

- It was not considered to be FSANZ's role to establish these criteria (Dairy Aust., Parmalat Aust.);

- It was considered inappropriate (NZFGC) and unnecessary for FSANZ to establish these criteria (GW Foods);

- These should not be regulated and a review in several years time will show difficulties (PB Foods);

- It is too complicated and expensive to determine a criterion that would suit all product classes (NZ Dairy Foods);

- This suggests FSANZ or the enforcement bodies can interpret, for the consumer, any implications associated with the claim (NZFSA). NZFSA does not support this; and

- A claim must be substantiated before it can be used (Unilever Australasia).

It was further outlined that the food industry conducts targeted market research regarding messages to consumers to ensure messages are clear and represent the substantiated health benefit to the consumer (AFGC, MasterFoods Aust. NZ, Goodman Fielder, Parmalat Aust.).

Nestlé agreed that claim prerequisites should apply to general level claims and high level claims and that the prerequisites should be the same for both types of claims. Nestlé noted their support of the AFGC comments regarding claims criteria particularly comments regarding biologically active substances and the example quoted 'this food contains lycopene'. This is a content claim and is permitted by way of standard 1.2.8 i.e. inclusion in the nutrition information panel (Nestle).

It was also stated by CSIRO - HS&N that criteria don't need to be established and an example outlined that if the Tick program makes consumers believe that eating those foods will prevent heart disease then it should be regulated as a high level claim. They went on to suggests the NHF (and any other endorsing agency) may need to explain to the consumer exactly what the symbol is saying.

It was felt that FSANZ should not attempt to come up with rigid criteria and it should not include criteria that is inconsistent with general fair trading law. Fair Trading law views consumers as "people who may be gullible, of less than average intelligence and poorly educated". Beyond this it is not useful to attempt to pre-determine what may be perceived as a representation (Fonterra, supported by Mainland Products).

General comments

There were 14 submitters that did not clearly state whether they supported the establishment of these criteria or not, but made the comments below (Dr C Halais, NCEFF, Aussie Bodies, MLA, National Starch, Solae Comp, TGACC, ASA, Cadbury

Confectionery, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, NZTBC, NZ Magazines).

NCEFF considered it unlikely that it would be possible to establish definitive requirements since there is little established consensus on methodologies to use. They noted that ILSI-Europe has established a Consumer Science Task Force, with the aim of assembling methodologies to assess consumer understanding of health claims. They are using 5 types of approaches: marketing; quantitative social psychology; heuristics (methods of processing information; anthropology and econometry). The draft paper was developed in June 2004, with publication aimed for October 2005. ILSI hopes to present a toolbox of methods and case studies using unpublished company data showcasing different approaches to assessing consumer reaction to claims (NCEFF).

Aussie Bodies were also not sure how FSANZ could overcome the problem of implied claims, particularly in situations like the example of 'low fat' being regarded as reducing body fat. They added that there is clearly a role for education.

Further difficulties were noted, in that consumer reaction to messages will vary, and an attempt for consumers to interpret health claims in only one acceptable manner is problematic. Attempts to pre-establish criteria presumes to know how consumers will respond to messages. It was therefore suggested that enforcement agencies should monitor market claims, which may represent greater perceived consumer benefits and request independent consumer research to verify that the claim does not over-represent its benefit (National Starch, Solae Comp.).

MLA stated that they constantly conduct market research regarding messages to consumers to ensure such messages are clear and represent the substantiated health benefits to the consumer.

TGACC also believed that there is a great need for more consumer research in this area, and they noted that this would be important in terms of compliance activities.

Another recommendation to cover off implied claims was to include this in an Advertising Code, so that the honesty of the advertising is covered by self-regulation. It was explained that in New Zealand the ASA Complaints Board would be able to handle complaints of this nature speedily and efficiently. It was also recommended that it would be a good idea to cover this in advertising rules in the legislation so that claims by implication are included, and it was noted that this works very well for therapeutic advertising. A legislative backing is required, which discourages companies from avoiding the appropriate level of substantiation by making claims by implied means, which is ultimately misleading for the consumer. If pre approval of advertisements is required, then the approvals officers could act as a further check to make sure that implied claims are not made (ASA supported by Cadbury Confectionery, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, NZTBC, NZ Magazines).

Dr C Halais submitted that this question was not applicable if claims are not allowed.

Other comments provided but not in direct response to the question

ASMI expressed concern that a condition could be viewed as 'non-serious' but may imply a much more serious condition, i.e. compromised immune system. They stated that therefore, claims of "strengthens immune system" is potentially a promise greater than "enhanced function" – particularly depending on the context of how a weakened immune system is presented, i.e. as part of a self-limiting respiratory infection versus an immunodeficiency syndrome. They questioned what an absence of the context conveys to the consumer.

ASMI noted that Consumer Focussed Labelling as implemented in the Complementary and OTC medicines industry, and testing to these criteria, can overcome concerns regarding implied claims, and can serve as a source of evidence for industry to use with regulators and consumer groups. This is a strategy being adopted to ensure consumer comprehension of required health messages and quality use of a product. They provided a link to the Labelling Code of Practice on the ASMI website.

NZFSA believed the impact of claims on the 'general consumer' could not be easily stated. This is similar to their concerns about 'implied' in that most consumers come with preconceived ideas and these will not be uniform. They noted that although FSANZ is undertaking consumer research, it is problematic, as it will be discussing hypothetical situations.

ACA believed that implied claims must be tested and subject to the relevant level of health claim to which they imply a health benefit. If not strictly regulated, manufacturers may use implied claims to avoid the requirements for making explicit health claims. ACA supported prescribed wording in order to prevent the use of implied claims. They added that this would ensure that consumers receive consistent messages about individual food products and their associated health benefits.

CHAPTER 2: FSANZ REGULATORY MODEL

2.1 SETTING CRITERIA AND CONDITIONS FOR CLAIMS

Question 41

Can the criteria and conditions that apply to content claims establish the minimum criteria and conditions for other general level claims?

Out of 147 submitters, 55.8% (82 in total) directly responded to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	30	14	5	2	51
Government	6	2	-	-	8
Public health	11	4	-	-	15
Consumers	2	-	-	-	2
Other	5	1	-	-	6
Total	**54**	**21**	**5**	**2**	**82**

Overview

Sixty-three percent of submitters (52) agreed that the criteria and conditions applying to content claims provided a starting point for establishing the minimum criteria and conditions for other general level claims. There was discussion about various aspects e.g. minimum criteria, biologically active substances, risk increasing nutrients, socially responsible claims, and vulnerable groups. However, 30 per cent of submitters (24) opposed the notion that criteria and conditions that apply to content claims should be used to establish minimum criteria and conditions for other general level claims. Some suggested case-by-case assessment. Others believed there was no need for criteria and conditions that took into account other compositional attribute. The only requirement was that the claim was fully substantiated and could deliver the benefit.

Discussion

The majority of submitters (52) generally agreed that the criteria and conditions applying to content claims provide a useful starting point in terms of working up regulation for other general level claims (NCWA, TCCA, Diabetes Aust, DAA, Dr R. Stanton, GI Ltd, NCEFF, NHF Aust, Nutrition Aust., PHAA (supported by ACA), Tomox, Aussie Bodies, ANIC, Bakewell Foods, CML, CHC, Dairy Aust, DSM Nut. Prod, Food Tech. Assoc. of Vic., Horticulture Aust, MLA, National Foods, National Starch, PB Foods, Sanitarium Health Food Comp, Solae Comp, Tas DoH&HS, NSW DoH – N&PA Branch, NSW Food Authority, SA DoH, WA DoH, DAFF, CSIRO-HS&N, Monash Uni – N&D Unit, Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp, Auckland Reg. PHS, NHF NZ, NZDA, OAC NZ, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Fonterra, Mainland Products, Naturo Pharm Ltd, NZ Dairy Foods, NZ Magazines, Nutra NZ, NZTBC, Heinz Aust./Heinz Watties NZ).

Some of these submitters highlighted that the content claim criteria should be seen as minimum criteria only and the establishment of additional disqualifying criteria and/or conditions for other general level claims is probably necessary (Dr R. Stanton, Nutrition Aust., PHAA (supported by ACA), Cadbury Schweppes, Tas DoH&HS, NSW DoH – N&PA Branch, SA DoH, WA DoH; Monash Uni. – N&D Unit, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm Ltd, NZTBC, NZ Magazines).

Two Industry submitters (Heinz Aust/ Heinz Watties NZ, Nestle Trans Tasman) noted that biologically active substances do not have daily intake reference values, as is the case for nutrients that have established Recommended Daily Intake (RDI) values. This must be taken into account when establishing criteria and conditions. Three submitters (Cadbury Schweppes, Dairy Aust, Nestle) also noted that the criteria for content claims would not be appropriate for setting criteria for whole food claims.

Four submitters (Diabetes Aust, Dr R Stanton, GI Ltd, Auckland Reg. PHS) noted the need to establish criteria [disqualifying] in relation to other nutritional aspects of the claimed foods (i.e. risk increasing nutrients). Five submitters (Diabetes Aust, GI Ltd, DAA, NZDA, OAC NZ) also noted that criteria and conditions needed to vary according to food group categories, in order to achieve the best range of healthy foods eligible to make claims.

Some submitters related the use of criteria and conditions to ensuring that the claim pre-requisite outlined in the policy guideline, which states that a claim can be made providing it is *socially responsible* and does not promote *irresponsible food consumption patterns,* is met. Submitters have indicated that it is not socially responsible to market general level claims on non-core foods to children and it is irresponsible to put any health claim on foods that are high in fat, saturates, added sugar, or salt or (non-core foods) high in energy density (Horticulture Aust, PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit). Three submitters also recommended, with the exception of whole foods (fruits, vegetables, milk, meat, nuts etc), that claims should not be permitted on foods marketed to vulnerable groups such as infants and children (Dr R. Stanton, PHAA (supported by ACA)).

NSW DoH – N&PA Branch indicated that the establishment of criteria and conditions for general level claims is appropriate to ensure no misleading statements are made. Three submitters (Tas DoH&HS, NSW Food Authority, ANIC) said that criteria and conditions based on content claims criteria ensures that there is consistency in the application of criteria across the general level claims spectrum. Bakewell Foods stated that having the same minimum requirements would minimise complexity in relation to compliance.

Cadbury Schweppes raised the issue that while content claims may refer to the specific presence of a nutrient within a food, other general level claims refer to that food as part of the total diet and therefore content claim criteria may not be appropriate in order to establish minimum criteria for other general level claims.

24 submitters (Mandurah Aust, Kingfood Aust, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, CM of SA, ABC, AFGC, Cadbury Schweppes, F & B

Importers Assoc, GW Foods, Goodman Fielder, Parmalat Aust, CMA – NZ Branch, Griffins Foods, NZFGC, NZFSA, NZ MoH, Hort & Food Research Instit. of NZ, CMA, Unilever Australasia, Masterfoods Aust NZ, Palatinit GmbH, ICA, opposed the notion that criteria and conditions that apply to content claims should be used to establish minimum criteria and conditions for other general level claims.

Some submitters considered that criteria and conditions should be assessed on a case-by-case basis whilst others believe there is no need for criteria and conditions that take into account other compositional attributes. The only requirement should be that the claim is fully substantiated and can deliver the benefit; this is irrespective of the nutritional make-up of the food (Dairy Aust, ABC, AFGC, Goodman Fielder, F & B Importers Assoc, National Foods, Parmalat Aust, Fonterra, Griffins Foods, Masterfoods Aust. NZ, Unilever Australasia).

Three submitters (Dairy Aust, National Foods, Fonterra) noted that despite being in amounts lower than that for a nutrition content claim (i.e. source of), it is possible that a small amount of a nutrient could be beneficial. If there is sufficient evidence to support this, then there should not be criteria in place to prevent a claim being made in relation to that product. This view was also supported by NZFSA.

Other comments provided but not in direct response to the question

Claim prerequisites and claim criteria require further clarification. Vulnerable sectors of the population, such as pregnant women, lactating mothers, children and the elderly may have specific nutritional requirements. Claim prerequisites should ensure that claims do not mislead these sectors and claims directed at specific sub-groups do not mislead the general population. Claim criteria are need to ensure that consumers are not mislead by claims on foods with low nutritional value. These criteria should include qualifying and disqualifying nutrition criteria across all claim classifications (Tas DoH&HS, SA DoH).

Claims relating to fortified foods are currently not included for discussion as part of the criteria and conditions for content claims. There is concern that the fortification of food (standards not completed yet) will enable health claims to be made on foods of limited nutritional value which may mislead consumers and change food consumption patterns away from what is recommended in the Australian Dietary Guidelines (Tas DoH&HS).

Kellogg's Aust. suggested that the FSANZ Regulatory Model define parameters in the form of claim prerequisites, claims criteria and conditions. They believed that any claim prerequisites, criteria or conditions should be based on the evidence for the health benefits of the particular nutrient, ingredient or biologically active substance. They stated that additional disqualifying or qualifying criteria should not be warranted unless there is significant scientific evidence to support their inclusion. All foods should be able to describe their substantiated claimed benefits either in relation to the whole food itself (whether processed or non-processed) or it's ingredients or nutrients.

Lazarus Scientific Research considered that for content claims the level of the claimed component present in the food should be based on the proportion that the food contributes to the RDI levels for nutrients. In the absence of an established RDI (e.g.

biologically active components), then this should be based on the proportion of the component that the food contributes to the estimated average dietary intake levels. The quantity of the component should be 'significant' and the term 'significant' should be defined (e.g. 10%, 25% etc). For health claims they recommended that the level of the claimed component present in the food should be based on the total daily intake required to achieve the claimed outcome in a reasonable serve of the food. The quantity of the component should be 'significant' and the term 'significant' should be defined (e.g. 10%, 25% etc).

Sanitarium Health Food Comp supported the use of disqualifying and qualifying criteria for all claims, but recognised it will be difficult to develop and implement a set of criteria and conditions that will cover all foods in a manner that is not complex or convoluted. They suggested specific consultation with relevant stakeholders around how the proposed criteria and conditions would be developed in order to develop a workable set of criteria and conditions.

Adelaide Hills Comm. HS were concerned that a claim may appear on a food without looking at other aspects of that food (not related to the claim) that make it an unhealthy choice, and therefore confuse consumers, e.g. a product low in saturated fat having a claim relating to this and cholesterol levels/heart disease, but the product is high in sodium which can raise blood pressure and increase risk of heart disease. They thought that this will confuse consumers and they may think a product is 'healthy' purely because of the claim; or alternatively they may look further into the claim and see that it is only looking at one aspect of the food and therefore ignore food claims.

ACDPA and Kidney Health Aust. recommended that to protect consumer health there must be qualifying and disqualifying eligibility criteria for foods allowed to make claims. They were concerned that foods making claims may be able to detract from the negative nutritional attributes of the product, which has potential to mislead consumers. They recommended the balance between any claimed benefit and potential negative impacts of foods must be considered when determining qualifying and disqualifying eligibility criteria. In addition, disqualifying criteria should be category-specific (e.g. based on core food groups) in order to take account of the differing nutritional attributes of different food types. ANA supported these recommendations.

The NHF Aust. recommended that there should not be a single set of criteria to determine which foods carry health claims and/pr nutrition claims, but that claim-specific and category specific criteria are set. They noted there appears to be no real difference between disqualifying and qualifying criteria as they both represent nutritional maximums or minimums that need to be met, so should simply be considered ‘criteria’.

They suggested that approved claims that are listed in the standard would each include their own criteria (e.g. ‘must contain at least 1.5g fibre per serve, and no more than 300mg of sodium per 100g’) as is done for health claims in Canada and there would not be an overall set of nutritional criteria that also need to be adhered to. They recommended category-specific criteria be set, to allow for the different nutritional attributes of difference types of foods. Broad food categories such as dairy and cereal based foods etc could be used, for example:- high level claim ‘saturated fat and

reduced risk of heart disease', maximum content of saturated and trans fats, plus a maximum limit of sodium (key nutrients relevant to the diet-health relationship). Two further factors need to be considered – the type of food and the actual numerical level to be set. For determining the actual level, it may be reasonable for some food groups to set levels relevant to 'low' or 'reduced' definition in CoPoNC but this may not be appropriate for all food groups.

NHF Aust. added that to set a criterion that is too stringent for a particular food type may unnecessarily exclude some healthier food options from carrying the claim and does not encourage the reformulation of foods in a healthier direction, e.g. current CoPoNC definition of 'low saturated fat' (1.5g/100g or less) is used as a criterion in the tick program for breakfast cereals, but is not appropriate for use with oils of salad dressings (in which an alternative criterion of a maximum of 20% of total fats as saturated fats is also included) Some nutrients are not relevant for some foods and should not be in the criteria e.g. 'a low saturated fat' criterion may be applicable to savoury biscuits but relevant to canned fruit.

NHF Aust. believed relevant criteria should also be set for nutrition function and enhanced function claims. These should most likely relate to the nutrient in question, e.g. a claim about the function of zinc might need to have a minimum of 10% RDI for zinc. Category specific criteria are not needed for these types of claims, unless over-arching disqualifying criteria are introduced (e.g. food must not contain more than 500mg/100g sodium).

The NHF Aust. proposes:

- Basic criteria are established for nutrition function and enhanced function claims addressing the nutrient of relevance – e.g. minimum of 10% of the RDI for the relevant nutrient; and

- Criteria for high level claim are claim-specific (nutrients relevant to the diet-health relationship) as well as category specific in order to address the difference in nutritional profiles between foods of different types.

To protect consumer health, there must be qualifying and disqualifying eligibility criteria for foods allowed to make claims, e.g. foods high in (saturated) fat, sugar, and energy should not be permitted to make either general level or high level claims. Foods making claims from one nutritional perspective, e.g. low in fat, should not be considered as eligible if other nutritional components, e.g. high in sugar or energy, are considered harmful as this has the potential to harm consumers. Balance between any claimed benefits and harms of foods must be considered when determining qualifying and disqualifying eligibility criteria (NSF).

Cancer Society NZ agreed that there must be qualifying and disqualifying eligibility criteria for foods. Foods high in (saturated) fat, sugar and energy should not be permitted to make high level claims. Evidence shows that making claims about such foods detract from the negative attributes of the product. Consumers believe these foods are healthier than they actually are. They recommended that qualifying and disqualifying criteria are generated by food groupings rather than blanket level applied to all foods (e.g. some fruits are naturally high in sugar) (also Auckland

Cancer Society; Cancer Society - Waikato/Bay of Plenty Div, Cancer Society – Rotorua Branch).

Canterbury DHB believed there needs to be a strong set of disqualifying/qualifying criteria that dictates if a product is allowed any level of health claims e.g. sugar/fat and sodium content per 100g and per serving.

The OAC NZ recommended both general and high level claims should only be made on foods that offer significant nutritional value, given the poor nutritional knowledge and understanding of many consumers. Evidence suggests consumers assume a health claim made for one nutrient means the food is healthy in every way, however this is frequently not the case e.g. "fat-free" marshmallows that are very high in sugar and energy and contribute no useful nutrients. They recommended there are separate criteria for different categories of food so health claims can usefully be used to compare and identify the best foods within a food type, as it is unlikely that having a universal qualifying or disqualifying criteria will work. The qualifying and disqualifying criteria must ensure foods like Confectionery, alcohol, high fat (especially saturated) and/or high sugar foods, very high energy foods, very high salt foods, soft drinks and infant foods do not bear either general or high level claims.

Question 42

In addition, do these criteria and conditions need to be taken into account in pre-market assessment and approval of high-level claims?

Out of 147 submitters, 48.3% (71 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	25	13	5	2	45
Government	6	2	-	-	8
Public health	9	2	-	-	11
Consumers	2	-	-	-	2
Other	5	-	-	-	5
Total	**47**	**17**	**5**	**2**	**71**

Overview

A third of submitters (24) supported the view that 'these criteria and conditions' need to be taken into account in pre-market assessment and approval of high-level claims. Another 17 submitters gave conditional support. A further 28 opposed the view. One submitter considered that it would depend on the claim and the risk or benefit.

Support criteria and conditions being taken into account

Twenty-four submitters considered that criteria and conditions for claims should be taken into account in pre-market assessment and approval of high-level claims

(Auckland Reg. PHS, NZ Dairy Foods, TCCA, Tomox, DSM Nut. Prod, DAFF, CSIRO HS&N, TGACC, Mainland Products, NCWA, Diabetes Aust, Dr R. Stanton, GI Ltd, NCEFF, Aussie Bodies, ANIC, CML, CHC, National Starch, Sanitarium Health Food Comp, Solae Comp, NSW DoH – N&PA Branch, NSW Food Authority, Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp).

Reasons for support:

- It seems logical: an appropriate and consistent application for the same criteria and conditions to be applied in relation to pre-market assessment and approval of high level claims (NCEFF, National Starch, Solae Comp, ANIC, NSW DoH – NP&A Branch);

- Consistency of basic criteria across all the claims is essential for the simplification of the Standard for both industry and enforcement agencies (NSW Food Authority);

- high level claims would need some nutrition criteria, that should be considered with general level claim criteria (Sanitarium Health Food Comp); and

- Criteria and conditions help define what a "healthy" food is, and nutrition, health and related claims should appear on healthy foods only (Diabetes Aust, GI Ltd).

Seventeen submitters provided support (NZ MoH, Nutrition Aust.., Horticulture Aust, Tas DoH&HS, SA DoH, WA DoH, Monash Uni- N&D Unit, PHAA (supported by ACA), Dairy Aust, ASA, Cadbury Confectionery, Naturo Pharm Ltd, NZTBC, NPANZ, Assoc. of NZ Advertisers, NZ Magazines), with the following exceptions and conditions:

- If there were any concerns expressed about the public health impact of the pre-approved claims (NZ MoH);

- Although these prerequisites, criteria and conditions could form the basis of minimum requirements for all high level claims, they should not preclude additional criteria and/or conditions being applied as deemed appropriate (Tas DoH&HS, SA DoH, WA DoH, Monash Uni- N&D Unit, PHAA (supported by ACA), Nutrition Aust.), and necessary to maintain the integrity of the process and consumer confidence in the claims that are made (Horticulture Aust);

- There should be flexibility. The totality of the evidence will determine whether a food delivers a claimed benefit. High level claims should be permitted if manufacturers should be able to demonstrate convincingly that a small amount of nutrient is beneficial, despite being in amounts lower that that for a nutrition content claim (Dairy Aust); and

- There is a need to establish that the criteria and conditions are correct, as they are the basis from which the high level claim criteria and conditions are extrapolated from. If content claim criteria and conditions are not accurate then the high level claims could be at fault (ASA, Cadbury Confectionery, Naturo Pharm, NZTBC, NPANZ, Assoc. of NZ Advertisers, NZ Magazines).

Oppose criteria and conditions being taken into account

Twenty-eight submitters opposed these criteria and conditions being taken into account in pre-market assessment and approval of high level claims (F & B Importers Assoc, Fonterra, Griffins Foods, NZFSA, CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, ICA, CM of SA, Heinz Aust./Heinz Watties NZ, Nestle, Unilever Australasia, NHF Aust, NHF NZ, AFGC, Masterfoods Aust. NZ, ABC, National Foods, NZFGC, GW Foods, Goodman Fielder, Parmalat Aust, ASMI).

Reasons for opposition

- High level claims will undergo substantiation, which should determine:
  - If particular criteria or conditions need to be met for approval (CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, ICA, CM of SA, Nestle, Unilever Australasia, Parmalat Aust, National Foods, Griffins Foods, NHF Aust, NHF NZ);
  - Whether or not the food delivers the claimed benefit in the context of the total diet. Claims which are approved should not require any further criteria or conditions to be taken into account (AFGC, Masterfoods Aust. NZ, ABC, National Foods, GW Foods, NZFGC, Goodman Fielder);

- If the claimed benefit is substantiated then it does not matter about the compositional properties of the food (Goodman Fielder);

- Unnecessary if there are criteria for each particular claim (Heinz Aust./Heinz Watties NZ);

- The totality of the evidence should be looked at and there should be no set limitation according to criteria or conditions for separate claims. If evidence supports a particular claim, criteria for completely separate claims should not be used as a reason for restricting claims (Fonterra);

- Each claim should be assessed independently (NZFSA);

- A food undergoing pre-market evaluation for a high level claim might involve a circumstance where 'total diet' could not be used as criteria (i.e. a food for a special population and the claim takes a 'dose' format (ASMI); and

- Products would not fit the nutrient content criteria (Nestle).

General comments and recommendations

Five submitters recommended that claim prerequisites do not permit health claims on foods marketed to vulnerable groups such as infants and children, apart from whole foods. They stated that claim criteria are needed for all claims, and should be applied to all claims across the claims classification framework. These criteria should include qualifying and disqualifying nutrition criteria (O'Neil 2004; Rayner 2004) and food

group and ingredient criteria (SA DoH, WA DoH, Monash Uni – N&D Unit, PHAA (supported by ACA)).

NZ MoH believed that all high level claims should have independently assessed substantiation.

CHC noted that pre-market assessment of claims would need to take into account not only the presence of a nutritive substance, but also that the vehicle allows the substance to be uniformly present at the end of the shelf life, as well as being bioavailable in that form. They noted that test methods utilised by companies in order to verify this also need to be relevant to the food tested as scientifically validated.

ASMI believed that the high level claim system should take into consideration the Novel Foods evaluation procedure. ASMI noted that it is also not clear whether a Novel Food will need to undergo a separate evaluation from the Novel Food process for high level claims.

PB Foods stated that taking criteria and conditions into account in pre-market assessment and approval of high level claims would depend on the claim and the risk or benefit. They noted that high level claims might require a higher content of certain nutrients to substantiate connection to a disease or condition.

Although Nestle believed that products would not fit the nutrient content criteria, they noted that evidence regarding the claim would be sufficient to enable the use of the claim.

Aussie Bodies stated that they were unsure that high level claim criteria and conditions would have universal applications.

Other comments provided but not in direct response to the question

Dr C. Halais noted that this question would not be applicable if claims are not allowed.

Question 43

What factors need to be taken into account when establishing criteria that apply to general level claims that describe a relationship between a whole food and a specific health benefit? For instance, claims in relation to the whole food could only be made where that food is a primary food (that is, fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish). Otherwise the claim would need to specify the component within the food (that is, nutrient, energy or biologically active substance) that is linked to the claim benefit.

Out of 147 submitters, 49.7% (73 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	25	13	5	2	45
Government	6	2	-	-	8
Public health	10	3	-	-	14
Consumers	2	-	-	-	2
Other	4	1	-	-	5
Total	**47**	**19**	**5**	**2**	**73**

Overview

There were varying responses to the task of identifying factors needed to be taken into account when establishing criteria which apply to general level claims that describe a relationship between a whole food and a specific health benefit. The overall responses were in relation to whole foods, all foods and 'primary food'; substantiation and/or regulation around nutrition health and related claims; qualifying and disqualifying criteria, and exclusion of certain categories/types of food.

Submitters considered whether the health claim (general level or high level) is expressed in relation to the whole food or a particular component (i.e. nutrient, energy or biologically active substance) of the food.

Whole foods

Some submitters provided responses in relation to whole foods as follows:

- Agreed that only whole foods should carry the claim (Dr. R. Stanton);
- Agreed that whole foods should be allowed and not limited to a pre-determined list (Fonterra);
- Agreed with the example provided by FSANZ (DAFF, Mainland Products, NCWA);
- Stated that there should be provision for claims about whole foods, otherwise consumers might assume that they are less healthy than foods with added vitamins or minerals (Dairy Aust., PB Foods).

National Foods believed that the worth of a 'whole' food should be considered, as opposed to the presence of a single nutrient e.g. fat or saturated fat. (Reference was made to scientific explanation regarding dairy fat and CHD).

Parmalat Aust. stated that further guidelines on what constitutes a whole food were warranted. Fonterra stated that the proposal was inconsistent with the suggestion that claims typical of the whole food group must stipulate the whole food group. Some submitters queried the definition of 'whole food' and 'processed food'. For example:

- Bread is made from grains and ingredients such as yeast, water and salt. If whole grain bread is considered to be a 'whole food' then so too should cheese, which is made of milk, rennet, starter culture and salt, and yogurt which is milk and starter culture (Dairy Aust., PB Foods);

- Is milk still a 'whole food' once the cream has been removed? (Dairy Aust, PB Foods, Fonterra). Does this mean claims would not be permitted about yoghurt? (Fonterra);

- What about other core foods in the Australian Guide to Healthy Eating?

- Would they all be banned, even if not considered a whole food? (Fonterra);

- What about mixtures of primary foods? Flour and milk can be combined to make white sauce (Fonterra).

Naturo Pharm queried whether general level claim criteria would include primary foods that have been fortified, e.g. milk with added calcium.

It was also recommended that, for general level claim criteria, there should be consideration concerning the amount of the whole food in the product (e.g. amount of wholegrain in bread), and the amount of salt, sugar or saturated fat added (Sanitarium Health Food Comp.).

Four submitters considered that 'whole food' claims should be permitted on foods that are consistent with the recommendations of national dietary guidelines in Australia and New Zealand (NHF Aust., NHF NZ, DAA, NZDA). It was also suggested by NHF Aust. and NHF NZ that these claims are relevant to both primary foods and processed foods that meet criteria reflecting that they are 'healthier choices'.

Nutra NZ noted that whole foods are subject to natural variation in composition, influenced by seasonal changes and where they are grown. Therefore, a general level claim would need to allow for this - which is beyond the manufacturers control

With regard to processed food it was stated that FSANZ, in the development of certain standards, e.g. the vitamins and minerals standard, used the primary food designation for regulatory purposes as an artifice to place non-science based constraints on processed foods (National Foods, AFGC, Masterfoods Aust. NZ). These submitters also highlighted that all foods are part of the Australian Guide to Healthy Eating and that the Australian Dietary Guidelines state "eat a wide variety of nutritious foods".
GW Foods also stated that the example provided by FSANZ (for this question) assumed that processed foods were 'less healthy' than fruits and vegetables. However they believed that many processed foods were the nutritional equivalent of fresh foods and in some cases represented a safer alternative.

All foods

Many submitters noted that they would like to see substantiated claims permitted on 'all foods':

- Not just primary foods (Bakewell Foods);

- Either in relation to the whole food itself or a compound (its ingredients or nutrients) contained within the food product (GW Foods, Heinz Aust./Heinz Watties NZ, NZFGC, National Foods, as well as CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA, CMA-Vic Branch and CM of SA);

- CMA and their supporters also mentioned that, in addition to substantiation, the product should meet the prerequisites, conditions and criteria for making a claim.

However, Food Tech. Assoc. of Vic expressed caution (in relation to whole food versus an active known or claimed component/constituent), noting that current science is not always sound or exact.

Primary foods

Some submitters stated that claims should take into account primary food i.e. fruit, vegetables, grains, legumes, meat, milk, eggs, nuts, seeds and fish (PHAA (supported by ACA), SA DoH).

Other suggestions were that:

- Claims should take into account primary food or food product with significant levels of the primary food (Tomox);
- Claims in relation to the whole food should only be made where the food is a 'primary food' and credible research shows that the food is a good source of a nutrient, or consumption of the food assists with the prevention of disease (TCCA); and
- Consumers more easily understand whole foods where they relate to primary foods. Where they do not relate there is a strong need to clearly specify the component of the food that is linked to the claim benefit (Horticulture Aust.).

However a number of submitters queried the definition for a primary food. It was described as being very limiting and that some whole foods would not fit the given definition (Nestle). Heinz Aust./Heinz Watties NZ also disagreed with the example provided in the question. Bakewell Foods recommended that the definition be reviewed and Parmalat Aust. suggested deleting the reference to 'primary food' as this would restrict a whole food claim to just milk, thus preventing similar claims for fat reduced or fortified milks.

National Foods queried as to whether yogurt, and also, yoghurt with biscuit pieces, are primary foods. They stated that although water was essential to life, it was not listed as a primary food. In addition, they believed that an indicative list was akin to

regulation by vertical standards and would never keep pace with food product innovations.

FSANZ noted that some submitters misinterpreted the proposed application of the definition of 'primary foods' assuming that all foods, other than 'primary foods' would not be permitted to make any type of general level claim.

Twelve submitters stated that they did not agree that whole food claims should only be made in relation to primary foods (CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA, CMA-Vic Branch and CM of SA, Nestle, Heinz Aust./Heinz Watties NZ). Examples were given to illustrate this point:

- Canned flavoured tuna (e.g. tuna with onions, tomatoes and sauce) may not necessarily be a primary food, yet will provide the same nutritional benefits as canned tuna (unflavoured). Some consumers who choose to avoid unflavoured tuna may be disadvantaged if the same claims cannot be made on flavoured tuna (Heinz Aust./Heinz Watties NZ);

- Whole food claims can also be made in relation to foods that are a mixture of primary foods e.g. a vegetable cannelloni meal manufactured from a mixture of vegetables and grain products made from wholemeal pasta with added soluble fibre and containing olive oil might be able to carry a claim relating to coronary heart disease (Nestle); and

- Whole of food claims should not be limited to just one primary food. Provided the claim is substantiated and the product meets the prerequisites for making a claim, then it should be able to make a claim, whether it is a whole of food claim, or a claim about its ingredients or nutrients within the food product (Nestle).

Twenty-three submitters made reference to substantiation as a factor that needed to be taken into account when establishing criteria which apply to general level claims that describe a relationship between a whole food and a specific health benefit (Unilever Australasia, Griffins Foods, ABC, Dairy Aust., PB Foods, AFGC, Masterfoods Aust. NZ, Goodman Fielder, CHC, F& B Importers Assoc., ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery, Fonterra, NZ MoH, Hort & Food Research Instit. of NZ, Auckland Reg. PHS, National Foods, GW Foods).

Five submitters stated that all foods should be able to describe their substantiated claimed benefits either in relation to the whole food itself, or its ingredients or nutrients contained within (ABC, AFGC, Masterfoods Aust. NZ, Goodman Fielder, F& B Importers Assoc.).

It was also noted that:

- The only factor that needs to be taken into account is that the food delivers the specific benefit that will be met by the substantiation requirements (Unilever Australasia);

- Provided that a claim can be substantiated, then its health benefit for that food should be able to be communicated to the consumer (Dairy Aust., PB Foods, AFGC, Masterfoods Aust. NZ, Goodman Fielder);

- There would have to be scientific evidence that supported the claim for a whole food. This could then be treated as a general level or high level claim for substantiation (ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery);

- The claim must be substantiated and cannot be misleading, e.g. prohibited to say a food provides X benefit where a typical food of that type does not (Fonterra);

- Claims should be based on evidence about the food to ensure consumer protection (NZ MoH);

- Factors included the level of strength and quality of the evidence for the association (Auckland Reg. PHS).

In terms of general regulation, it was expressed that there was support for using CoPoNC and Standard 1.2.8 criteria as the foundation for general level claim criteria (Mainland Products).

Many submitters referred to qualifying criteria in relation to the concentration of nutrients as a factor that needed to be taken into account when establishing criteria which apply to general level claims that describe a relationship between a whole food and a specific health benefit.

It was stated that there should be general qualifications about nutritional criteria for foods making claims (NZ MoH). NZFSA emphasised that the regulations needed to be simple and realistic and that concepts such as 'claimable foods' becomes over complicated. Tas DoH & HS indicated that the criteria should reflect dietary guidelines. National Foods suggested that the criteria for food should be determined on a case-by-case basis, considering the entire nutritional package of a food. Mainland Products suggested that both 'qualifying' and 'disqualifying' criteria will be required in different circumstances on a 'claim-by-claim' basis.

A few submitters referred to specific components within the food (i.e. nutrient, energy or biologically active substance) that is linked to the claim itself (TCCA, Dr. R. Stanton, Diabetes Aust.). Dr. R. Stanton suggested that nutrients and biologically active components should be included, along with the amount present and its relevance to overall health.

Other submitters mentioned key nutrients such as calcium, iron, and dietary fibre, to be included in specific primary food categories (Diabetes Aust., GI Ltd).
NSW Food Authority suggested that all claims should be expressed in terms of the specific nutrient or biologically active substance that brings about the claimed benefit e.g. calcium in milk, fibre in grains.

Six submitters (Monash Uni. – N&D Unit, Tas DoH&HS, WA DoH, SA DoH, PHAA (supported by ACA)) suggested that the qualifying criteria should include:

- Nutrient composition, i.e. x% of the RDI before a claim can be made;
- Concentration of biologically active substance, i.e. x% in the serve size;
- Composition and concentration should relate to substantiation requirements in that the amount present has the efficacy claimed;
- Presence of at least one other nutrient other than the claimed nutrient/biologically active substance.

Nutrition Aust. supported the above views but did not comment on the latter point. NSW DoH - N&PA Branch expressed the qualifying criteria as "a minimal nutritional value – which could be defined as a product containing a certain % of the RDI for one or more nutrients before a claim can be made". Additional points were that:

- It is important to consider realistic serve size (PHAA (supported by ACA), Monash Uni. – N&D Unit);
- Claims meet a defined nutrient profile for 'healthy' foods (O'Neil 2004; Rayner 2004) (WA DoH);
- There should be appropriate total energy and nutrient density (Nut Aust.).

Some submitters made reference to quantities of the food eaten /dose rate required to achieve a beneficial effect (Auckland Reg. PHS, Hort & Food Research Instit. of NZ, Aussie Bodies). Hort & Food Research Instit. of NZ specifically referred to function/risk reduction claims. Aussie Bodies suggested that another consideration should be respective balance or ratio of component nutrients, e.g. protein to carbohydrate ratio.

Hort & Food Research Instit. of NZ stated that since general level content claims provide information to the consumer, the label needs to include the concentration, e.g. in NIP. In addition, they did not believe that there should be any other criteria for a content claim.

It was noted that if claims are made for a food containing a specific nutrient or food component, the suitability of the food must be considered before a claim can be made. For example, under CoPoNC, Coco Pops are fortified with calcium, iron, zinc, B vitamins and vitamin C and make claims about these added nutrients. However, they contain 36.5g sugar per 100g (high), 564mg of sodium per 100g (high) and 0.4g dietary fibre per average serve (low). In addition iron and calcium compete for absorption, so the effectiveness of fortifying this cereal with iron is questionable given that it is consumed with milk and the claims made may give parents the impression that their children are consuming more iron than they actually are (TCCA).

It was also noted that nutrient levels were being determined through dietary modelling e.g. the Glycemic Index Tested program and the NHF 'Tick' program (GI Ltd, Diabetes Aust.).

TCCA stated that a food must naturally contain at least 10% of a vitamin or mineral before it could be fortified – as previously suggested by FSANZ when it was called ANZFA. It was also noted that in the United States, any food bearing a health claim should contain, prior to fortification, at least 10% of the daily value of at least one of six FDA-specified nutrients - vitamins A and C, iron, calcium, protein, or fibre. This approach, also called the 'jelly bean rule', was devised to preserve a balance of nutrients in the diet (Kwak and Jukes 2002) (WA DoH, PHAA (supported by ACA), SA DoH).

Submitters also referred to, or implied, disqualifying criteria in relation to the composition of the food, other than qualifying criteria, as a factor that needed to be taken into account when establishing criteria which apply to general level claims that describe a relationship between a whole food and a specific health benefit.

Thirteen submitters recommended that disqualifying criteria, or implied disqualifying criteria should be established (TCCA, Dr. R. Stanton, GI Ltd, Diabetes Aust., Auckland Reg. PHS, Nutrition Aust., PHAA (supported by ACA), Tas DoH&HS, NSW DoH – N&PA Branch, SA DoH, WA DoH, Monash Uni. – N&D Unit).

The latter eight submitters, suggested disqualifying criteria in terms of:

- Concentration of fat (especially saturated fat), sugar and sodium that are the subject of dietary guidelines (Australian Dietary Guideline and New Zealand Food and Nutrition Guidelines) which aim to reduce or moderate intake; and

- Presence of nutrients or non-nutrients that are known to adversely affect bioavailability of claimed nutrient.

Additional suggestions were that:

- There must be enough of the nutrient present and available to achieve the claimed benefit (NSW DoH – N&PA Branch);

- Disqualifying criteria are important to avoid e.g. vitamin-enriched confectionery (Dr. R. Stanton);

- Nutrient criteria should be set for each primary food based on the optimal amount of kilojoules, energy density, total fat, saturated fat and sodium (GI Ltd, Diabetes Aust.).

Other comments noted:

- nutrient profiling of 'unhealthy' foods (O'Neil 2004; Rayner 2004) (WA DoH);

- The importance of claim substantiation as well as involving the setting of nutrient criteria for each type of primary food based on optimal characteristics (such as energy, fat) and key nutrient content (TGACC).

It was noted that in the United States, food bearing a health claim must not contain certain levels of total fat, saturated fat, cholesterol, or sodium. (These disqualifying levels are set at 20% of the daily reference values of these four nutrients). Along with the provisions on disqualifying levels, any food bearing a health claim must meet another requirement for 'minimum nutrients levels' in the United States and Japan (PHAA (supported by ACA), WA DoH, SA DoH, Monash Uni. – N&D Unit).

Some submitters suggested that certain types of food be prohibited from making claims as a factor that needed to be taken into account when establishing criteria which apply to general level claims that describe a relationship between a whole food and a specific health benefit.

Eight submitters identified the exclusion of alcohol and baby foods. In addition there were formulated supplementary foods, foods targeted at vulnerable groups such as children and foods of poor nutritional value e.g. foods that are high in saturated fat, sugar or salt – which would need to be defined (Nutrition Aust., PHAA (supported by ACA), WA DoH, Tas DoH&HS, NSW DoH – N&PA Branch, SA DoH, Monash Uni.- N&D Unit). Additional comments were that:

- Some judgement should be made on the suitability of a food as a vehicle for addition of components. This issue has been raised in the fortification debate - not necessarily covered under disqualifying criteria (Nutrition Aust);

- Standard 1.3.2 Addition of Vitamins and Minerals sets a precedent on allowing only certain foods to make claims (WA DoH, NSW DoH – N&PA Branch, PHAA, SA DoH, Monash Uni. – N&D Unit). PHAA (supported by ACA) and Tas DoH&HS also specified that it defines claimable foods as: a food which consists of at least 90% by weight of – (i) primary foods; or (ii) foods listed in the Table to clause 3; or (i) a mixture of primary foods; and/or (ii) water; and/or; (iii) foods listed in the Table to clause 3 excluding butter, cream and cream products, edible oils, edible oil spreads and margarine; and

- The inference of this question is that Standard 1.3.2. (regarding a food having to be a primary food before any claims can be made in the first place) will be retained in a Standard for health and nutrition claims (Cadbury Schweppes).

There were other factors that needed to be taken into account when establishing criteria, which applied to general level claims that describe a relationship between a whole food and a specific health benefit.

These suggestions included:

- Energy density (Tas DoH&HS);

- The bioavailability of the nutrient, including levels of inhibitors (the phytate: zinc molar ratio was noted) (MLA);

- The nutrient density of the food and it's role in the Australian diet. With increasing interest in managing obesity/reducing energy intake care is required to ensure an adequate intake of key nutrients (reference was made to a study regarding insufficient iron and zinc intake (MLA);

- Method of processing, storage, handling and packaging of the food (CML);

- Claims should not lead to a drastic change in population consumption patterns (DSM Nut.Prod);

- The food must be available and affordable to the whole population, and exclusive to a particular segment of the population (DSM Nut. Prod);

- The food should not pose a health risk to an individual when consumed in excess (DSM Nut. Prod);

- Criteria should be decided by health experts; with separate criteria for each of the five core food groups. Whether the food is a good source of a nutrient, even if fortified, must also be considered (TCCA); and

- Although whole fish consumption may be encouraged to increase omega 3 fat intakes, this might pose a problem with farmed fish (which contain low levels of omega 3s) becoming more common (CSIRO-HS&N).

Other recommendations were that:

- The starting point should be the claim itself. It is just as possible that manufactured foods may deliver a beneficial matrix. Proving the effect of individual bioactive substances may not be the issue (NCEFF);

- The question was not applicable if no (health) claims were allowed (Dr C. Halais); and

- Criteria should be imposed for function/risk reduction claims when the concentration of other components negates the health claim or impose a substantial health issue. However, these should be applied by food category to avoid unintentional effects, e.g. fruit, although high in sugar, should not have a blanket ban (Hort & Food Research Instit. of NZ).

Other comments provided but not in direct response to the question

ASMI considered that in some instances the definition of 'primary food' might exclude certain foods that may legitimately be able to be encompassed within 'whole foods'.

CHAPTER 3: SUBSTANTIATION

Question 44

Does the Substantiation Framework clearly establish the processes FSANZ will use to assess high-level claims?

Of the 147 submitters, 47.6% (a total of 70) responded directly to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	25	12	2	-	39
Government	5	2	-	-	7
Public health	13	5	-	-	18
Consumers	2	1	-	-	3
Other	3	-	-	-	3
Total	**48**	**20**	**2**	**-**	**70**

Overview

Many submitters considered that the framework provided in the IAR clearly establishes the process that FSANZ will use to assess high-level claims. However, many submitters provided additional comments surrounding issues that they consider important. Several submitters (mostly industry) were concerned that the process was too complex for manufacturers and the delineation between FSANZ and manufacturer responsibility was unclear. Much discussion also centred on the similarities between these criteria and the criteria required for medicines.

Discussion of submitter responses

Four of seven government departments answered yes to the question (The NSW Food Authority, NSW DoH - N&PA Branch, Tas DoH&HS and NZFSA). The WA DoH answered no, and suggested that the NHMRC Dietary Guidelines should be used as the benchmark for substantiation. The Department also provided amendments to the wording in section 1.1 of the substantiation framework. Both the WA DoH and NSW DoH - N&PA Branch stated that an independent party rather than the food industry should undertake a safety assessment of foods to gauge whether a food meets the qualifying criteria.

CSIRO - HS&N and The NCWA support the proposed framework.

The DITR commented that the Australian medicine industry is concerned that the substantiation requirements for claims on food are less onerous than therapeutic goods, placing manufacturers of medicines at a disadvantage compared to food manufacturers. Similarly, the Beer, Wine & Spirits Council of NZ believe that the five step process proposed in the Framework is based on medical evidence, whereas a health benefit from food is more difficult to prove. The NZ MoH stated that section 3.1 of the substantiation framework (identifying an appropriate authoritative evidence source) should include a list of approved textbooks.

The majority of Australian Public Health organisations responded yes to the question (ACDPA, Diabetes Aust, GI Ltd., Kidney Health Aust., TCCA, DAA, Auckland Reg. PHS, J. Seal - PH Nut, NHF Aust., Nutrition Aust., PHAA (supported by ACA), Dr R. Stanton). However, the first five of these suggested that FSANZ implement a validation exercise for the substantiation process, most citing the World Cancer Research Fund's validation of its "Food, nutrition and cancer prevention" report.

Several Australian and New Zealand Public Health organisations provided specific comments. The DAA and NZDA stated information on a process to challenge FSANZ decisions was required, and that the DAA should be actively involved in the assessment process. Dr R. Stanton stated that it would be difficult although necessary to involve experts without conflicts of interest in such a process. NHF Aust and NHF NZ suggested providing guidance on how applications would be submitted to FSANZ. The Auckland Cancer Society, NZ Cancer Society and the NSF (Australia) stated that only the highest levels of rigour outlined in the Framework for high-level claims should be applied to all claims. NSF added that responsibility for assessing the link between food components and health is too burdensome for industry and should rest with FSANZ.

The NCEFF commented that greater focus on dietary methodology that addresses issues of food consumption patterns and provides evidence of actual consumption is required. Canterbury DHB supports the level of evidence grading in the Framework.

TCCA provided detailed comments, including the following: clear criteria for assessing the totality of evidence is required; section 2.2 on grading the quality of evidence confuses the level of evidence with the quality of evidence; a judgement of the completeness and appropriateness of the methodology may be subjective; clarity on how the appropriateness of the statistical methods will be judged is required; a table of excluded studies and associated reasons is required for section 2.2.12; and it would be more efficient to assess causality based on the totality of evidence rather than individual studies.

The response from industry groups was divided. Over half stated that the framework did clearly establish assessment processes (ANIC, ASMI, Aussie Bodies, Bakewell Foods, Cadbury Schweppes, CML, CHC, Dairy Aust., DSM Nut. Prod., F&B Importers Assoc., Horticulture Aust., Kellogg's Aust., Mainland Products, National Starch, NZ Dairy Foods, NZFGC, Nutra-Life H&F, Nutra NZ, NZ Magazines, Solae Comp), however the ANIC and Horticulture Aust. stated that it is unclear whether significant evidence for a particular category of food would also be considered significant evidence for individual foods within that category to use a claim.

Two respondents commented that more information is required about the submission and evaluation process (ASMI, CHC). Several stated the framework doesn't clearly delineate the role of FSANZ from the manufacturer (Dairy Aust., PB Foods, Fonterra, Goodman Fielder). Dairy Aust. suggests clarifying the roles and responsibilities of manufacturers, outlining how applications will be prioritised and limiting the role of manufacturers in substantiating a high level claim to step 1 of the framework (identifying and categorising evidence).

The Sanitarium Health Food Comp supports the requirement for approved claims to undergo review. AFGC recommends including an appeals process for the decisions of an expert panel.

Of the industry groups that answered no to this question (ABC, AFGC, Food Tech. Assn of WA, GW Foods, Goodman Fielder, National Foods, Parmalat Aust., PB Foods Ltd, Wyeth Aust), several believe the proposed substantiation process is too complex or that the 5 step process is unclear (AFGC, Beer Wine and Spirits Council of NZ, Food Tech Assn of Australia, GW Foods, Dairy Aust., F&B Importers Assn, Flour Millers Council of Aust., Goodman Fielder, National Foods, NZFGC, NZ V&PG Fed/NZFG Fed). The AFGC, PB Foods and Fonterra also recommended using a flow chart to assist industry in making their applications. Several suggested using a similar step-by-step process to the Regulatory Guideline for Medicine applications (Cadbury Schweppes, ASA, NPANZ, NZ Magazines). Both Nestle and Unilever Australasia support the comments made by the AFGC.

Wyeth Aust. commented that information is lacking about using reviews that are not peer reviewed and textbooks that are considered to be suitable. The submission also said that clinical as well as statistical significance should be taken into account.

Parmalat Aust. stated international systems for assessing high-level claims need to be evaluated and Food Tech. Assn. of Vic. suggested looking at the system used in the UK.

The Consumers Instit. of NZ noted the cost a rigorous substantiation process would be expensive and may result in an increase to the cost of food.

Question 45

Have the different study types and evidence sources been described accurately and adequately for the purposes of the Substantiation Framework?

Of the 147 submitters, 42.2% (a total of 62) responded directly to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	21	10	2	-	33
Government	5	2	-	-	7
Public health	10	4	-	-	14
Consumers	2		-	-	2
Other	5	1	-	-	6
Total	**43**	**17**	**2**	**-**	**62**

Overview

Sixty-one per cent of submitters (38) responded positively, agreeing that the different study types and evidence sources have been described accurately and adequately. However, eight respondents did not feel that the different study types and evidence

sources have been accurately and adequately described. Six submitters suggested that there be a greater level of detail regarding study types and evidence sources. Road testing of the substantiation process was recommended by a number of respondents.

Discussion of submitter responses

Thirty-eight submitters responded positively, agreeing that the different study types and evidence sources have been described accurately and adequately. These responses represented 3 government submitters (NSW DoH - N&PA Branch, NZFSA, Tas DoH&HS), 25 industry submitters (CML, F&B Importers Assoc., Wyeth Aust., DSM Nut. Prod., Griffin Foods, NZ Dairy Foods, NZFGC, Nutra-Life H&F, Flour Millers Council of Aust., Sanitarium Health Food Comp, MLA, ABC, National Starch, Solae Comp, AFGC supported by Parmalat Aust. and Nestle, GW Foods, National Foods, Cadbury Schweppes, Goodman Fielder, Kellogg's Aust., ASA, NPANZ, Cadbury Schweppes, NZ Magazines), 1 consumer group (NCWA), 5 public health submitters (Diabetes Aust, Nutrition. Aust., GI Ltd, DAA and NZDA) and 4 others (Uni of Adel. and Uni of SA – Nutrition & Physiology Research Grp, CSIRO - HS&N, Horticulture & Food Research Instit. of NZ, TGACC). Of the total of 38 positive responses, 18 also made additional comments or suggestions, these are discussed further below.

The TGACC also commented that the substantiation framework should be a living document.

Six submitters suggested a greater level of detail regarding study types and evidence sources. The ASA, NPANZ, Cadbury Schweppes NZ and NZ Magazines noted that more detail may be required for educative purposes as much as anything else. They also noted that regulatory consultants, who are familiar with the process for foods and medicines would be able to guide companies through the process and assist in the collation of the data required and the conduct of studies. Similarly, Cadbury Schweppes suggested that providing greater detail as to what evidence and studies are not suitable would assist industry. Dairy Aust. supported by Parmalat Aust., commented that more information should be provided about specific study designs, such as the potential draw-backs for case control and ecological studies, versus the stronger scientific evidence derived from randomised controlled and prospective cohort studies.

Similarly, ANA commented that there needs to be clear criteria for assessing the totality of evidence, especially as individual study results (most likely from observational studies) may be difficult to apply. They noted that ideally randomised controlled trials that show an association between a dietary component and a disease should be available, but also noted that in reality it is difficult to conduct high quality randomised-controlled trials for assessing dietary components.

In contrast to the above comments, suggesting more detail around evidence and study requirements, NZFSA noted that it may be more restrictive to detail the evidence requirements further, as the nature of the available evidence for each claims assessment will be different and evaluation of the quality and quantity available will be an inherent aspect of the assessment process.

Other submitters who commented on evidence and study requirements included Aussies Bodies, who noted that the evidence type descriptions in the Substantiation Framework are broad which encourages inclusiveness, and that caution may be necessary in interpretation of the descriptions. The ASMI commented that traditional evidence, particularly for herbals, has not been included in the regime, nor should it be. TCCA commented that the difference between quality of evidence and quantity of evidence should be made clearer in the Substantiation Framework – "level of evidence" refers to study type (randomised controlled trial, cohort study etc), while "quality" refers to how well the study was designed and conducted (use of blinding, concealment of allocation, minimisation of biases including confounding)

Fonterra suggested it would be useful to use an international standard for assessing levels of evidence, such as that developed by the Centre for Evidence Based Medicine in Oxford, UK. They also noted that frameworks in other countries and particular international bodies should be recognised (such as ILSI, PASSCLAIM), and that acceptance by a credible organisation that a biomarker has a demonstrable link to a disease should be sufficient for FSANZ to accept that link to that biomarker.

The NCEFF commented that the adequacy of the description of evidence requirements and study types in the Substantiation Framework will be tested with use. They noted that it should reflect the particular nature of food-based studies, including definitions of controls and methods to control for other dietary variables.

The ACCC questioned whether the standards for science-based evidence that sits within the Substantiation Framework minimum standards, and whether they can be described as world's best practice.

Road testing of the substantiation process was recommended by a number of respondents. The AFGC, as well as GW Foods, National Foods, Dairy Aust. and Parmalat Aust., suggested road testing with an industry working group early in the standard development process, and offered their assistance with this. Parmalat Aust. and Nestle supported this suggestion. Goodman Fielder also suggested that some example health claims be taken through the process to highlight any issues before finalisation of the framework, and suggested formation of an evaluation working group consisting of both large and small industry companies, and FSANZ. Similarly, GI Ltd recommended that FSANZ institute a validation exercise to properly evaluate the substantiation process.

Eight respondents did not feel that the different study types and evidence sources have been accurately and adequately described, including WA DoH, PHAA, ACA, Horticulture Aust., Monash Uni. - N&D Unit (this group of submitters also commented on use of the NHMRC Dietary Guidelines, see paragraph below). The CHC felt that this needs more work. NZ MoH commented that 3.1 [section in the Substantiation Framework - Identifying an appropriate authoritative evidence source] is vague and could easily be misused. They also commented that if a poor quality text formed the basis of substantiation the claims should possibly not be allowed. They felt that if textbooks are to be used for substantiation these should be listed somewhere as approved texts.

NHF Aust. and NHF NZ both felt that the different study types and evidence sources have not been accurately and adequately described. These groups disagreed with the categorisation of primary and secondary sources. They felt that it is unclear whether FSANZ places greater weight on primary or secondary sources. Furthermore, they disagreed that systematic reviews and meta-analyses be described as secondary sources, as these potentially provide a more unbiased and informative view of the literature than single "pivotal" studies. They do not believe that "pivotal" studies can be objectively determined for the purposes of substantiation and see the introduction of bias into the substantiation process if manufacturers were allowed to self select these studies from a systematic process. These groups support further consideration of potential conflicts of interest when describing information sources that have not undergone a peer review process. They also noted that under "language and other requirements for applicants" the final sentence should read "abstracts or summaries are NEVER sufficient to allow detailed evaluation". Finally, they would like to see quantification of the phrase "substantial number of human studies" under convincing evidence as they felt this definition was uncertain.

A number of respondents suggested that the substantiation process should be consistent with recognised NHMRC guidelines (Kellogg's Aust.) and or Cochrane or similar review guidelines, to ensure convincing evidence according to WHO criteria for ranking of evidence (Tas DoH&HS). The DAA, supported by NZDA, commented specifically on the categorisation of meta-analyses, suggesting that these should be level 1 evidence rather than level 2, as they represent the most detailed and comprehensive evidence available, and this would be in line with NHMRC guidelines. NHF Aust and NHF NZ made a similar comment (see above paragraph). Dr R. Stanton commented that NHMRC guidelines should be the basis for all claims. The WA DoH, PHAA, ACA, Horticulture Aust. and Monash Uni.- N&D Unit all recommended that the NHMRC Dietary Guidelines be used as a benchmark for substantiation, as these have been compiled following a rigorous process of review of the scientific evidence, and give a summary of the NHMRC levels of evidence for each guideline. They also recommended that permitted serious diseases /conditions should be limited to those referenced in these documents.

Finally, Beef and Lamb Marketing Bureau commented that smaller companies should not be penalised for their potential lack of access to appropriate expertise when trying to substantiate claims, and Dr C. Halais responded by commenting that question 45 was irrelevant if claims are disallowed, which was her preference.

Question 46

Do you agree with the proposed evidence requirements for substantiating high level claims?

Of the 147 submitters, 41% (a total of 60) responded directly to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	25	10	2	-	37
Government	4	2	-	-	6
Public health	10	3	-	-	13
Consumers	1	-	-	-	1
Other	3	-	-	-	3
Total	**43**	**15**	**2**		**60**

Overview

Eighty per cent of submitters (48) agreed with the proposed evidence requirements for substantiating health claims. However, several of these submitters commented that the baseline data from the National Nutritional Survey is now nine years out of date and does not represent current consumption patterns in Australia. Several comments were made pertaining to the criteria for assessing a convincing level of evidence. It was also noted that meta-analyses should not be treated as a secondary source of data.

Discussion of submitter responses

29 of the 35 submissions from Australian and New Zealand Industry agreed with the question (ASA, Aussie Bodies, ABC, Australian Foods and Grocery Council, ASMI, Cadbury Schweppes, CML, CHC, Dairy Aust., DSM Nut. Prod, F & B Importers Assoc, Flour Millers Council of Aust., Frucor, Griffins Foods, GW Foods, Goodman Fielder, Horticulture Aust., MLA, National Foods, National Starch, NZ Dairy Foods, NZFGC, NZJ&BA, Nutra-Life H&F, NZ Magazines, Parmalat Aust, Sanitarium Health Food Comp, Solae Comp, Tomox, Wyeth Aust).

However, several of these commented that the baseline data from the National Nutritional Survey is now nine years out of date and does not represent current consumption patterns in Australia (ABC, AFGC, Dairy Aust., Flour Millers Council of Aust., National Foods, Nestle).

Dairy Aust. does not believe that high-level claims should be substantiated using only case control studies, stating experimental and prospective cohort studies are preferable. Cadbury Schweppes suggested a clearer definition of what constitutes an acceptable human study is required. GW Foods believe systematic reviews and meta-analyses should be considered primary, not secondary sources of evidence, in keeping with NHMRC guidelines on assessing evidence for study design. The NZFGC commented that the benchmark for accepted evidence might be set too high, preventing high-level claims from being used. Nestle supports this comment.

Of the industry groups that disagreed with the question, Kellogg's Aust. stated more information is needed on the level of agreement required on the evidence to allow a high level claim, noting that CODEX allows for varying levels of substantiation for claims. PB Foods and Fonterra commented that the rationale behind the level of substantiation required for high level claims compared to low level claims is unclear. Innovation and Solutions proposed five criteria for assessing high level claims, i.e. serious disease or biomarker must be strongly influenced by diet; dietary component must have substantial efficacy; benefit to society must be readily demonstrated; claims must be attractive to food companies; and consumer behaviour change must be feasible. A detailed case study was provided for a pre-approved high-level health claim for Omega-3 DGA and EPA and cardiovascular disease.
MasterFoods Aust. NZ believes the proposed assessment process offers inadequate commercial protection and that a review panel would need to operate in confidence.

Of the six responses from governments, half agree with the question (NZ MoH, NZFSA, NSW Food Authority). The NSW DoH - N&PA Branch Department supports some aspects of the Framework (requirements for well designed studies, evaluation of the totality of evidence, applicability to Australian and New Zealand populations, establishing qualifying criteria) and stated that additional requirements include clear criteria for assessing a convincing level of evidence (ideally randomised controlled trials). The Department also believes the substantiation process should include a thorough safety assessment by an independent party that would include potential adverse effects of over-consumption by the target population and consumption by the non-target population. Several Public Health organisations agree with these statements (ACDPA, Nutrition Aust., PHAA, ACA).

The other Australian and New Zealand Public Health organisations generally agree with the question (Auckland Regional PHS, Dr R. Stanton, Diabetes Aust, DAA, NZDA, GI Ltd, NCEFF, NHF Aust, NHF NZ, TCCA), with some specific exceptions. Diabetes Aust and GI Ltd stated that meta-analyses should not be treated as a secondary source of data. Both NHF Aust and NHF NZ and the Auckland Reg. PHS support a high level claim based on convincing evidence only.

Submissions from other Australian organisations (NCWA, CSIRO – HS&N, TGACC, Uni. of Adel. & Uni. of SA – Nutrition & Physiology Research Grp) agree with the question, except for Monash Uni.- N&D Unit, which recommended that the NHMRC Dietary Guidelines be used as the benchmark for substantiation.

Question 47

Does the Substantiation Framework clearly establish the processes manufacturers should use to assess general level claims?

Of the 147 submitters, 59% (a total of 86) responded directly to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	26	12	5	1	44
Government	9	1	-	-	10
Public health	18	5	-	-	23
Consumers	1	-	-	-	1
Other	7	1	-	-	8
Total	**61**	**19**	**5**	**1**	**86**

Overview

Thirty percent of submitters (26) agreed that the substantiation framework does establish the processes manufacturers should use to assess general level claims. Twenty-three submitters disagreed, mostly from industry. Many submitters made additional comments relating to clarity and the ease for industry and enforcement agencies to have a practical understanding of the process. Other issues included the level of rigour of scientific substantiation required, evidence sources and appropriateness of different types of evidence, the ability of industry to understand and undertake the substantiation process, and the provision of pre-approved claims by FSANZ.

Discussion of submitter responses

Twenty-six submitters gave a positive response, indicating that the Substantiation Framework does establish the processes manufacturers should use to assess general level claims. Seventeen were from industry, one from government, one consumer, four from public health, and three others. A number of these submitters gave additional comments with their positive responses and these are discussed further below.

Twenty-three submitters gave a negative response to this question. Nineteen of these were from industry, two from government, one from public health and one other. Many submitters made additional comments alongside their responses. The NZFSA commented that while considerable useful detail is provided, the Substantiation Framework does not provide the information in a form that allows either industry or enforcement agencies to have a practical understanding of the process they need to undertake, or the format in which supporting evidence should be retained. Dr R. Stanton felt that the Substantiation Framework is not clear enough, and Horticulture & Food Research Instit. of NZ also noted that they felt that the Substantiation Framework does not describe the process. Two other submitters commented that there was less detail provided on process than for criteria, in particular in relation to the process of evaluation or review by regulators (ASMI, TGACC). Further submitter comments are discussed below.

NCEFF noted that they have tested the proposed substantiation process and found that the most difficult part was ranking the evidence according to the evidence classification scheme. It was also difficult to determine what constitutes "enough" evidence without a reference guide in the framework and no indicators for assessing overall risk associated with the claim. They suggest a risk assessment process or scale of risk process be established to guide the substantiation process and assist in quantifying the amount of evidence required.

Some submitters commented on the scientific standard proposed under the Substantiation Framework. ACDPA and Kidney Health Aust. both commented that being based on "authoritative, current and generally accepted information sources" does not provide sufficient level of rigour of scientific substantiation. Kidney Health Aust. felt that a convincing level of evidence should be required for any health claims and that lower levels such as "probable" and "possible" are not acceptable as these would mislead consumers and would be likely to require review sooner. They felt that there is a need for clear criteria for assessing the "totality of the evidence" as individual study results such as from observational studies, could be difficult to apply. Randomised controlled trials were cited as the ideal basis, however it was noted that in reality it is difficult to conduct high quality randomised-controlled trials to assess dietary components.

There were comments on the wording and evidence sources presented in the Substantiation Framework. Cadbury Schweppes commented that better definitions of "authoritative" and "generally accepted" would be useful. WA DoH, as well as Monash Uni. - N&D Unit, PHAA and the ACA also indicated that wording such as "authoritative, current and generally accepted sources, where such sources can be identified" was vague and unhelpful.

Further specificity in what constitutes appropriate evidence was called by a number of respondents. It was noted by Nutrition Aust. that manufacturers might have difficulty deciding what are "authoritative, current and generally accepted sources". National Foods felt that there is a need to specify current authoritative substantiation resources, noting that the NHMRC Dietary Intakes from 1990 require updating. Dairy Aust. also noted that many Australian resources are out of date including the National Nutrition Survey and Recommended Dietary Intakes, and called for "current" authoritative materials, as well as further clarity about how passages of textbooks can be used. Wyeth Aust called for additional guidance, especially in the area of using textbooks to support claims. Dr R. Stanton felt that many manufacturers do not know what constitutes evidence.

NHF Aust. and NHF NZ felt that there should be a list of authoritative sources and texts included in the Substantiation Framework, with the former also commenting that this list should include evidence based policy documents of NHF Aust. and NHF NZ. The NCEFF commented on the importance of clear guidelines for manufacturers who wish to rely on appropriate authoritative statements on which to base general level claims, citing the US FDA as an example, who accepts only summary statements used in block from DRV papers, rather than all the text in the background chapters.

Further clarification of the process involved in substantiating general level claims was requested by a number of respondents, including the NZFGC. PB Foods noted they it

is unclear as to who would undertake assessment of the evidence. Similarly, the TGA Advertising Code Council felt that there is insufficient detail on the process of evaluation and review by the regulator, in contrast to the criteria for assessment, which is clearly provided.

A lack of knowledge and expertise by manufacturers was felt to be a potential problem in meeting substantiation requirements for general level claims. NSW DoH - N&PA Branch felt that this may hamper genuine attempts to meet substantiation requirements, and that manufacturers who do not seek expert assistance in development of a dossier of evidence would mistakenly make a claim based on incomplete or inaccurately interpreted evidence. Nutrition Aust. also questioned whether manufacturers could ably carry out the substantiation process particularly in relation to more complex claims. PB Foods indicated that most companies would not have easy access to current scientific text and reports of health claims assessed by overseas governments, and would not have the expertise to undertake scientific literature reviews and assess the evidence. They suggested that the most likely source of reference for manufacturers would be the Dietary Guidelines and Recommended Dietary Intakes, and that no further evaluation of these sources should be expected from manufacturers.

Three submitters suggested that industry, particularly small manufacturers, may require assistance in meeting Substantiation requirements (NSW DoH - N&PA Branch, NSW Food Authority, NZFSA).

A number of submitters commented that substantiation requirements for general level claims would place a burden on the food industry, and may disadvantage smaller manufacturers compared to larger manufacturers (Horticulture Aust., WA DoH, NSW DoH - N&PA Branch, Monash Uni.- N&D Unit, ACDPA, Diabetes Aust, GI Ltd, Nutrition Aust. PHAA, ACA, NZ Cancer Society including Rotorua and Waikato branches). It is perceived that larger companies would have an advantage over smaller as they could afford to employ the services of suitably qualified personnel to undertake substantiation (NSW DoH - N&PA Branch, Nutrition Aust.). Other submitters (TCCA, Diabetes Aust, GI Ltd) also noted that larger manufacturers, who would be able to dedicate resources to substantiating general level claims, should not be able to gain a market advantage over smaller manufacturers. These groups suggested that FSANZ should substantiate all general level claims so that no manufacturers could gain a monopoly over particular claims. The NZ Cancer Society, and Rotorua and Waikato branches, also suggested that responsibility for substantiation should rest with FSANZ, as the industry would be unlikely to have the skills to gather, analyse and assess the information linking food components to health.

Enforcement issues were raised in some responses this question. NSW DoH - N&PA Branch, as well as WA DoH, Monash Uni – N&D Unit, ACA, and PHAA noted that requiring individual manufacturer substantiation meant that assessing compliance and enforcing breaches, which could be unintentionally misleading, would be an additional burden for enforcement agencies. Nutrition Aust noted that the states and territories, which are responsible for enforcement, are not well resourced to do so.

Six submitters suggested the development of guidelines (AFGC, National Foods, the Flour Millers Council of Aust., NZFGC, NZ Magazines, Unilever Australasia).

Assistance from industry during development was suggested, and in particular the AFGC offered their services in assisting FSANZ with their development.

A number of submitters indicated their preferred substantiation process in response to this question. Many of these included preference for a pre-approved list of acceptable claims. NSW DoH - N&PA Branch commented that all general level claims, except content claims, as well as associated qualifying and disqualifying criteria could be pre-approved and listed in the standard. Other submitters presented a model in which a list of pre-approved general level claims would be listed in either the standard or in an interpretive guideline (WA DoH, Monash Uni.- N&D Unit, ACA, PHAA). Prerequisites and criteria would be stated in the standard. Manufacturers would be responsible for demonstrating compliance with the prerequisites and criteria, including substantiating the presence of the nutrient or food component in the food, and its biological activity, with information describing analytical methods available in the standard. Under this model one central body would hold the substantiation evidence and make it available to all parties, providing they meet specified criteria. A number of advantages were seen in using this model. A similar suggestion was made by a number of Australian public health groups (The ACDPA, supported by Kidney Health Aust., as well as Diabetes Aust and GI Ltd) who believe that FSANZ should pre-approve all function and enhanced function claims, thereby providing industry with a list of acceptable claims, and that the food industry be responsible for substantiating the presence of that nutrient or food component in the relevant food. GI Ltd also commented that the exception to regarding FSANZ as a more authoritative substantiator than the food industry is endorsement programs like the Glycaemic Index Tested program which uses a certification trademark vetted by the ACCC to ensure it is not misleading to consumers.

Nutrition Aust also sees a number of advantages in a process by which FSANZ pre-approves general level claims, other than content claims. They also noted that the framework should be flexible to respond quickly to new evidence. The NZ Cancer Society, as well as the Rotorua and Waikato branches of the Cancer Society, believe FSANZ should be responsible for the scientific substantiation of any claims with food manufacturers retaining responsibility for demonstrating the nutrient is present in the correct amount and that the food meets the qualifying and disqualifying criteria. Similarly TCCA believes responsibility for substantiating function and enhanced function claims to the necessary level should rest with FSANZ, through provision of a list of acceptable claims to industry. They also noted that even if pre-approval is not required for general level claims, manufacturers should have to lodge the information on which they rely with FSANZ.

NCEFF commented that it would be useful for FSANZ to consider developing a list of authoritative statements, such as the Canadian National Health Products Directorate (regulates dietary supplements) Monographs, which manufacturers could rely on. The NZFGC suggested FSANZ maintain an up-to-date reference library, particularly to assist smaller companies with accessing relevant and credible sources. Dr R. Stanton recommended that all evidence for all claims should be held by FSANZ and be made available to anyone who searches for them. GI Ltd. indicated that the framework does establish the necessary processes manufacturers need to follow, but also proposed that FSANZ pre-approves function and enhanced function claims, as it

is too burdensome for food manufacturers and/or suppliers to perform substantiation to the required standard.

Finally, MasterFoods Australia NZ believe there is no necessity for further substantiation in addition to the science that is the basis for prudent dietary advice, for general level claims, except to demonstrate that the product contains the ingredient at the required levels accepted as providing the benefit. They comment that all claims should be made permitted and available to all products that meet the required nutrient content level.

Question 48

What practical issues do you envisage will arise when attempting to follow the Substantiation Framework to substantiate a general level claim?

Of the 147 submitters, 52% (a total of 77) responded directly to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	27	14	4	2	46
Government	6	2	-	-	8
Public health	12	3	-	-	15
Consumers	2	1	-	-	3
Other	3	1	-	-	4
Total	**50**	**21**	**4**	**2**	**77**

Overview

Submitters envisaged that many practical issues would arise when attempting to follow the Substantiation Framework to substantiate a general level claim. These issues included: difficulties and issues faced by enforcement agencies, requirement for who holds the substantiation evidence, sources of evidence, cost and resources required to substantiate a claim, inequity between large and small manufacturers, consumer confidence and consumer confusion, and the pre-approval of general level claims.

Discussion of submitter responses

One submitter responded yes to this question (DSM Nut. Products), one other responded that they don't know (NZ MoH), and one responded that there were no practical issues currently envisaged (Tegel Foods). Dr C. Halais commented that this question was not applicable if claims are disallowed. The other respondents raised a range of issues; these are discussed below.

Three submitters raised enforcement issues. NSW DoH - N&PA Branch questioned whether enforcement agencies would be required to scan the literature to ensure all negative results were included in the dossier, noting that manufacturers may be reluctant to include all studies that don't support their claims. NSW DoH - N&PA Branch also felt that there could be difficulties for enforcement agencies trying to

access the evidence held by manufacturers. Similarly Queensland Health - PHS noted that the Standard must clearly indicate that substantiation information must be provided to an enforcement officer on request. Queensland Health - PHS also feels that the process may be time consuming for enforcement officers, and holds concerns with the evaluation of the substantiation evidence by enforcement officers who may not have the necessary expertise without clear guidance and direction. This was also noted by the AFGC, who noted that the priority of enforcement agencies, which must focus on public safety, means it is unlikely that action will be taken with any speed on technical breaches of general level claims.

Queensland Health - PHS also raised the issues of who was to hold substantiation evidence for general level claims. They noted that it must be clear who is required to hold the substantiation evidence as for example, a manufacturer may produce food under licence for another entity that is making the claims, and may not necessarily be involved in the marketing of the food they produce. They also noted that it may not be feasible for each manufacturer to hold evidence.

Two submitters commented on issues around the presence of the nutrient that is the subject of a claim. The Food Tech. Assn. of Vic. suggested that all measurements for the presence of nominated nutrients, particularly "actives" or individual substances, be established by methodology that is available to Australian analytical laboratories. They also noted that measurements of analytes should be what are actually present rather than just what is added. Nutra - Life H&F commented that manufacturers will have to ensure they can provide analytical results by batch to confirm the nutrients that form the basis of the claim are present and in the claims amount, in the same way that manufacturers of complementary medicines do.

Naturo Pharm raised the issue of bioavailability of nutrients and wording used in claims. They noted that the words "contains" and "provides" could have different meanings, such that the statement "this food *contains* x amount of added calcium" means the food contains x amount of calcium irrelevant of whether it is bioavailability, however the statement "this food *provides* x amount of calcium" means that x amount of calcium is bio available. Naturo Pharm comments that consumers may not understand the subtle difference in the language used, and may simply assume that a product that has added calcium is better for them than a product with no calcium added.

A considerable number of submitters raised issues around sources of evidence. This included comments that source documents require further definition. Nutrition Aust noted that deciding what is "authoritative, current and generally accepted sources" could be open to interpretation, as did the PHAA, ACA, Monash Uni. - N&D Unit, the Tas DoH&HS, WA DoH and NSW DoH - N&PA Branch. Similarly, Northland Health Dietitians felt that what constitutes an authoritative, current and generally accepted information source is unclear, and Aussie Bodies felt there could be problems around interpretation of "generally accepted sources", and who accepts the sources. NHF Aust. and NHF NZ commented that defining "other relevant national, diet-related policy documents released by authoritative bodies" could prove to be problematic. National Foods suggested that an indicative list of suitable reference materials be made available to manufacturers in a user-guide, and the NZFGC suggested that FSANZ maintain an up-to-date reference library to allow relevant and

credible sources to be available, and that this resource may also possibly contain examples of approved general level claims.

The ASMI commented that there is a need to identify the source data being utilised by an "authoritative" journal or reference source and ensuring the data is still valid. Similarly CML felt there would be difficulties in maintaining currency of information or data, and that prescribed texts may be needed. CSIRO – HS&N foresees a probable lack of data around general level claims, as these conditions do not have a serious health impact. The NCEFF commented that the first practical test of the substantiation framework for general level claims would be determining the extent of information required. Cadbury Schweppes noted that issues will arise when manufacturers do not use appropriate sources of information or cannot relate evidence regarding a component of a food to the entire food.

PB Foods and Fonterra commented that the Dietary Guidelines and reviews of Recommended Dietary Intakes (Recommended Dietary Intakes) are the best sources of evidence.

There were a number of comments that current resources are out of date, for example: the national dietary surveys are old and may not reflect current consumption patterns, and the Recommended Dietary Intakes (or Nutrient reference Values) are out of date and as they are currently under review claims may need revising once they are updated (National Starch, Solae Comp, Sanitarium Health Food Comp, Tas DoH&HS, Diabetes Aust, GI Ltd, DAA, NZDA, Tomox). Defining serving sizes was also identified as an area, which could be problematic (Tomox, Diabetes Aust, GI Ltd, DAA, NZDA). A number of submitters with this concern recommended that FSANZ highlight the Australian Guide to Health Eating as a valuable source in defining serving sizes across the different food groups, or alternately that a new system prescribing the standard serves of food would be need to be implemented along the lines of that used in the USA (Diabetes Aust, GI Ltd, DAA, NZDA). The Tas DoH&HS commented that there is a lack of current food composition and dietary intake data to draw on for dietary modelling when making a risk assessment of the safety of health claims.

A number of submitters recommended an indicative list of suitable reference material be compiled and made available to manufacturers (ABC, Goodman Fielder, Parmalat Aust.). Similarly, Northland Health Dietitians questioned whether there will be a list of appropriate texts that will be updated on a regular basis. Dairy Aust. noted that there are potential resource implications for FSANZ relating to maintenance (by FSANZ) of an indicative list of appropriate materials in a guideline.

The issue of access to evidential sources and texts was also raised. Dairy Aust. noted there would be resource implications relating to accessing the appropriate resources such as recent National Nutrition Surveys, Dietary Guidelines, Recommended Dietary Intakes and a list of appropriate textbooks. Fonterra and PB Foods noted that industry would need access to evidence from current texts and reports of claims assessed overseas.

Wyeth Aust, who commented that access to databases like Embase and Medline, as well as access to people with the expertise to carry out thorough searches would be a

consideration, also noted industry access to source information as a practical resource consideration. NZ Dairy Foods commented that access to and cost of literature studies would be considerations, and that these factors could disadvantage smaller companies.

ACA commented on the situation where companies may engage in their own research studies, noting that where companies are going to develop studies in order to support claims they would be wise to seek the advice of FSANZ during study design to ensure it is of the highest quality and will therefore support use of a claim.

Other industry resource considerations raised were: time required to compile evidence, personnel and staffing issues, money and costs and skills and expertise. The ASA, NPANZ, Cadbury Schweppes and NZ Magazines all noted that companies may have limited experience in substantiation. The Tas DoH&HS, and the DAA commented that industry might not have the skills and knowledge to assess nutrition texts for quality in relation to the criteria set out in the substantiation framework. Similarly, National Starch and Solae Comp. commented that food companies vary in terms of their level of sophistication regarding nutrition and as such some companies may have difficulty assessing the quality of nutrition texts when meeting the criteria set. Specific expertise within the industry was a concern commented on by ACA, who also noted that some manufacturers may not know the difference between various types of studies and levels of evidence. The NCWA noted that knowledge and time were considerations. Dairy Aust. and NZ Dairy Foods noted that manufacturer's time would be required to collate substantiation documents. The Consumers Institute of NZ noted that if substantiation is carried out with sufficient rigour it will be time intensive and expensive, and noted that this may add to the cost of health food. Time and money were resource considerations commented on by Wyeth Aust. Dairy Aust. also commented on resource implications that manufacturers would require competent staff capable of assessing the suitability of evidence for a general level claim. NZ Dairy Foods noted that is would be necessary to determine the credibility of different sources, and to know how much information is required to make a general level claim. The NCEFF also noted that the extent of information required to be stored by industry may also turn out to be a practical issue, and the cost and the capability of research providers to deliver requirements has yet to be tested.

Cadbury Schweppes (Australia) commented that many manufacturers may not necessarily have the resources, such as funds, personnel and contacts, in order to substantiate their claims as fully as is required. Six industry submitters (CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA NSW Branch, CMA Qld Branch, ICA, CMA Vic Branch, CM of SA) felt that it is likely that scarce financial and human resources would not be channelled in the direction of claims, due to the hurdle of the substantiation process. Griffin Foods noted that the substantiation requirements would require comprehensive literature searches in order to enable provision of evidence for some commonly known facts. Frucor and NZJ&BA noted that the cost and time required for substantiation may limit any potential market advantage, thereby restricting the role of developing substantiation to specialty ingredient manufacturers. Similarly CML noted there was an issue with costs of substantiation versus return on investment. The CHC noted that marketers will attempt to absolutely minimise their substantiation through argument rather than

fact. Finally, NCEFF noted that there is no formal quality assurance system in place to protect industry in building the scientific dossiers they will require.

ACA is concerned that the onerous requirements for manufacturers to substantiate general level claims could also result in "me too" claims where a manufacturer will see a competitor making a claim and assume their own similar product will be eligible to carry the same claim. The manufacturer may then make this claim without collecting the relevant substantiation information and wait until they are called to present the evidence before they collect it.

A considerable number of submitters felt that the substantiation requirements for general level claims would give a market advantage to larger manufacturers over smaller manufacturers, due to the greater capacity of larger manufacturers to meet the costs and resources involved in substantiating general level claims (NSW DoH - N&PA Branch, Tas DoH&HS, WA DoH, Palatinit GmbH, CMA NSW Branch, CMA Qld Branch, CMA Vic Branch, CM of SA, Mandurah Aust., Kingfood Australia, MLA, CMA - NZ Branch, ICA, CMA, the ACDPA, PHAA, ACA, Monash Uni.- N&D Unit, as well as the specific comments listed below) Similarly, Dr R. Stanton commented that the general level substantiation requirements will be difficult for small manufacturers and many will not understand what is required, the NZFGC noted that it may be difficult for smaller companies to access relevant and credible authorities, NZ Dairy Foods noted that access and costs of literature studies would disadvantage smaller companies, and the NCEFF commented that the ability of small and medium enterprises to participate in the exercise may be limited. Nutrition Aust. noted that smaller manufacturers would need to seek appropriate external expertise, as they may not have the appropriate technical expertise themselves. The ASA, NPANZ Cadbury Schweppes and NZ Magazines noted that small to medium manufacturers may need to establish regulatory affairs consultants or use consultants to handle substantiation requirements for them. NZFSA and the NSW Food Authority commented that smaller industries may require additional assistance in meeting substantiation requirements, with the later suggesting this should be provided by either FSANZ or the "expert committee". Finally, while not directly relevant to this question focussing on general level claims, the Horticulture and Food Research Institute of NZ commented that the cost and effort involved in substantiating high level claims will be too great for most New Zealand food businesses, except for the very largest companies, and noted that a substantial amount of innovation occurs in small companies therefore there will not be support for increasing levels of innovation.

The issue of interpretation, particularly in respect of the literature, was also raised. A number of submitters commented that there may be differing interpretations of the literature by difference manufacturers and enforcement agencies, as well as between manufacturers and enforcement agencies (Tas DoH&HS, WA DoH, Nutrition Aust., PHAA, ACA, Monash Uni.- N&D Unit). Similarly NSW DoH - N&PA Branch commented that there may be different interpretations of he level and quality of evidence, and the ACCC was concerned that the substantiation framework for general level claims may give rise to interpretive bias. Coles Myer was concerned that there may be inconsistencies in approaches taken towards substantiating general level claims, and differences in expert opinions.

Issues around consumer confidence and consumer confusion were also raised by a number of submitters. The ACCC felt that the proposed substantiation framework for general level claims might give rise to consumer confusion when making buying decisions. NSW DoH - N&PA Branch commented that there could be a loss of confidence by consumers in general level claims due to the apparent differing levels of credibility. Kidney Health Aust. believes it is likely that consumers would regard general level claims as more authoritative if substantiated by FSANZ. The WA DoH, PHAA, ACA, and Monash Uni.- N&D Unit all commented that there may be a loss in consumer confidence in general levels claims, and that consumers may judge the validity of the claims differently depending on the body substantiating the claim and whether they are perceived to have a vested interest or not. The AFGC felt that the presence of unsubstantiated claims in the market might reduce consumer confidence in the system to the detriment of all concerned. The ACA also commented on potential consumer confusion, as consumers may be led to believe that only those products carrying a claim will provide the stated benefit when a product from a smaller manufacturer that doesn't make a claim may also provide the same benefit. There they believe that is there is a significant health concern that warrants the permission of a health claim then consumers must have access to equal information. Finally, the Northland Health Dietitians believe there needs to be consistency in wording of general level claims as public confusion will increase if many foods have claims regarding a particular issue all with different wording.

Other issues that were raised included a process of review for general level claims. Dairy Aust. noted that there was a resource issue for FSANZ around how frequently these claims would be reviewed. They also noted that there should be a recommendation about how often a dossier of evidence needs updating, and are in support of 5-year reviews.

NZFSA raised the scope of the general level claims substantiation framework – noting that industry will be seeking to make claims around non-traditional dietary issues and health benefits associated with functional ingredients and food formats, and therefore the framework should be broadened to readily encompass this broader scope.

The ASA, NPANZ, Cadbury Schweppes and NZ Magazines all commented that an education programme would be needed around substantiation requirements for general level claims, which could be carried out by industry.

The NCEFF noted that they would be prepared to pass on to FSANZ staff the findings of a research study, which identified some difficulties food companies, would have with the proposed FSANZ Substantiation Framework.

Finally, a number of submitters commented on the proposed substantiation process, particularly in relation to guidelines and a possible indicative list of claims. ACA commented that the substantiation process for general level claims is particularly complex and onerous. The AFGC also believe that the substantiation process is overly complex for claims that are, in general, simple in nature. AFGC recommended that an indicative list of suitable reference materials would be of assistance, and that a guideline document includes a list of well established nutrition function claims. Unilever Australasia and Nestle supported these suggestions. Similarly Goodman Fielder, National Foods, and MLA all commented that well established nutrition

function statements should be made available in a guideline to assist manufacturers in complying with the substantiation requirements for general level claims. MLA also believes that the framework should additionally allow freedom in developing new general level claims.

Pre-approval of general level claims was also raised. Horticulture Aust. recommends that the onus for pre-approving general level claims should sit with FSANZ, or an expert committee similar to the Joint Health Claims Initiative in the UK. Similarly, Kidney Health Aust. and the ACDPA proposed that FSANZ pre-approve all function and enhanced function claims, as for high level claims, as it is too burdensome to require manufacturers and/or food suppliers to perform substantiation to the required standard. The ACDPA noted that an advantage of FSANZ taking responsibility for substantiation of general level claims would be that there is no monopoly gained by certain food manufacturers on any particular general level claim. The NCEFF noted that there may be a need for pre-approval of general level claims of the substantiation framework cannot be implemented in the Australian context. TCCA strongly believes that it is essential that any claim justification as a minimum be lodged with FSANZ prior to the claim being used, as this mechanism would at least ensure that substantiations have been completed and are available to the regulatory in circumstances where a complaint is lodged. Furthermore, this substantiation information would then be available to potential complaints or members of the public.

Question 49

Are there authoritative evidence sources that could be included in the appropriate evidence sources for general level claims?

Of the 147 submitters, 42% (a total of 63) responded directly to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	27	7	3	2	39
Government	3	2	-	-	5
Public health	8	5	-	-	13
Consumers	2	-	-	-	2
Other	4	-	-	-	4
Total	**44**	**14**	**3**	**2**	**63**

Overview

Most submitters named sources of evidence that they considered appropriate for substantiating general level health claims. These sources included: documents from reputable government organisations (e.g. the National Health and Medical Research Council), non-government organisations and professional associations (e.g. Dietitians Association of Australia and the National Heart Foundation), international groups (including the World Health Organisation and the Food and Agriculture Organisation), and textbooks from relevant university courses. Several respondents suggested that textbooks were not appropriate.

Discussion of submitter responses

One submitter responded by saying "no" (WA DoH). Four submitters responded with a positive "yes" – including the NZ MoH, and the Uni of Adel. & Uni of SA - Nutrition & Physiology Research Grp (combined). The CHC said that yes, many authoritative evidence sources exist, and CSIRO- HS&N said content claims – yes.

The majority of respondents answered by naming sources of evidence that they considered appropriate for substantiating general level claims. Some submitters responded with a general recommendation that sources include documents from reputable government organisations such as NHMRC (Dairy Aust., Goodman Fielder, MLA, National Foods, Nestle, NCEFF, Unilever Australasia).

In many cases specific government documents were identified by respondents, including the Australian/NZ Dietary Guidelines (Tas DoH&HS, Goodman Fielder, Palatinit GmbH, CMA NSW Branch, CMA Qld Branch, CMA Vic Branch, CMA NZ Branch, CM of SA, CMA, Mandurah Aust., ICA, Parmalat Aust., Kingfood Australia, MLA, National Foods, Nestle, Unilever Australasia, Fonterra), and their background documents (BRI Australia Ltd), and the Nutrient Reference Values (also called the Recommended Dietary Intakes) (Tas DoH&HS, Goodman Fielder, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA NSW Branch, CMA Qld Branch, ICA, CMA Vic Branch, CM of SA, MLA, National Foods, Nestle, Unilever Australasia). MLA also identified the Australian Guide to Health Eating as suitable evidence source.

Documents, position papers and scientific reviews from non-government sources, professional associations and independent health associations were also specified by a large contingent of respondents (Dairy Aust., Goodman Fielder, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA NSW Branch, CMA Qld Branch, ICA, CMA Vic Branch, CM of SA, National Foods, Nestle, National Starch, Parmalat Aust., PB Foods, Sanitarium Health Food Comp, Solae Comp, Diabetes Aust, the DAA supported by the NZDA, the GI Ltd, Fonterra, Unilever Australasia, Lazarus Scientific Research). Specific non-government organisations suggested by one of more of the above respondents as sources of suitable evidence documents were: the NHF, Diabetes Aust, the National Asthma Council, the DAA, the Dental Federation, the Coeliac Society, the Cancer Council, the Nutrition Society, the Institute of Food Science and Technology, and the Cochrane Collaboration Library.

International groups nominated as suitable sources of evidence were the WHO and FAO (Tas DoH&HS, MLA, National Starch, Solae Comp, Diabetes Aust, the DAA supported by the NZDA, GI Ltd, NCEFF).

Many respondents also nominated university texts from relevant courses, such as recognised nutrition, food science, food technology or dietetics courses, as suitable sources of evidence (the ABC, AFGC supported by GW Foods, F & B Importers Assoc, Goodman Fielder, National Foods, Nestle, NHF Aust, NHF NZ, NZFGC). Nutra-Life H&F suggested that texts including epidemiological studies would form the basis for the evidence. Wyeth Aust. suggested that FSANZ should provide a list of textbooks that are currently used by universities around the country that could be

used as a guide by companies. They also noted that the list should not be exhaustive, and should be updated by FSANZ every year. NZFGC noted that in addition to texts from recognised courses, they believe Massey University in NZ would be an important source of authoritative evidence. In addition to supporting university texts the AFGC, supported by GW Foods, recommended that documents where the method of scrutiny of the evidence base from which the information is sourced is clearly described, and included and excluded studies are detailed, be included as appropriate evidence sources.

Dairy Aust. also commented that where possible, materials should represent the views of a group of experts in a particular area (as opposed to one author), and be peer-reviewed, and noted that universities with accredited nutrition course may be able to play a role in this process.

Three respondents suggested that textbooks would not be sufficient as authoritative evidence sources. Fonterra noted that a textbook could provide useful even presumptive evidence but that other evidence may rebut this. Griffin Foods do not consider a "Nutrition text" to be appropriate, instead recommending peer reviewed scientific literature. Dairy Aust. noted that permitting textbooks could create problems, as textbooks do not always contain systematically reviewed evidence.

Two respondents noted that a list of pre-approved general level claims would avoid the necessity for identifying appropriate evidence sources for manufacturers (Tas DoH&HS, Monash Uni. - N&D Unit).

Three other respondents were of the opinion that the onus for pre-approved general level claims should sit with FSANZ (the PHAA, supported by ACA) or an Expert Committee similar to the framework used by the Joint Health Claims Initiative in the United Kingdom (WA DoH).

Two submitters suggested FSANZ should be responsible for evidence requirements - Dr R. Stanton suggested that FSANZ should be responsible for all evidence after viewing by an external expert. Similarly, CML recommended that FSANZ conduct literature searches.

Other submitters, including the NCWA, suggested that evidence requirements for general level claims should be the same as for high level claims. The NZ Cancer Society, as well as the Rotorua and Waikato branches of the organisation commented that only the highest levels of rigour, as outlined in the current proposal for high level claims, be applied to all claims. They commented further that any notion that claims can be based on "authoritative, current and generally accepted information sources" belittles the complexity and skills required to come to agreement on health claims and is derogatory to the field of nutritional science. TCCA expressed similar feelings - that "being based on authoritative, current and generally accepted information sources" does not provide a sufficient level of scientific rigour. The latter also commented that while there would be come authoritative evidence sources that exist which could be included as appropriate evidence sources for general level claims, it may not be appropriate to expect the food industry to carry out the substantiation process described.

A few respondents pointed out potential difficulties relating to authoritative evidence sources for general level claims. Nutrition Aust. commented that the issue of interpretation still remains. NSW DoH - N&PA Branch commented that defining and ensuring that appropriate evidence sources are used in fraught with difficulties, providing the example that information in the Dietary Guidelines could be misused to make a claim. Aussie Bodies noted that sources of authority differ according to the area of nutrition – some organisations that are widely regarded as "authorities" do have an entrenched approach to their position on certain nutritional matters and this may limit their ability to maintain currency with new findings.

Other more general comments by respondents included a request for guidance from FSANZ regarding appropriate expertise for substantiation, including a list of acceptable evidence sources (Beef & Lamb Marketing Bureau). Tegel foods also requested a non-exclusive list of authoritative evidence sources. Lazarus Scientific Research suggested that an indicative list of acceptable authoritative sources be included in a guideline. NZFSA recommended that FSANZ considers substantiation to include more than one reputable text or source. Cadbury Schweppes commented that authoritative evidence sources may comprise an extensive list, which may change very quickly. They suggested that FSANZ consider having a listing of personnel or facilities, and their corresponding capabilities, on their website as this would then be updated easily.

Question 50

Would you support FSANZ producing an indicative list of acceptable authoritative evidence sources?

Of the 147 submitters, 62% (a total of 92) responded directly to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	30	16	2	2	50
Government	7	2	-	-	9
Public health	15	10	-	-	25
Consumers	2	1	-	-	3
Other	4	1	-	-	5
Total	**58**	**30**	**2**	**2**	**92**

Overview

Over three-quarters of submitters (71), mostly industry, agreed that an indicative list of authoritative texts should be provided. Fifteen submitters (mostly from public health and government) did not agree that an indicative list should be provided. Those in favour of a list suggested that it would have to be regularly reviewed. The DAA suggested that they have the skills and expertise to provide FSANZ with a list and that they be held responsible for establishing and maintaining a list. Several submitters, however, did not think a list was required as they considered the onus should be on FSANZ to pre-approve general level health claims.

Discussion of submitter responses

Seventy-one submitters agreed that a an indicative list of authoritative texts should be provided (ACA, NCWA, ACCC, Tas DoH&HS, NSW Food Authority, DAFF, Sanitarium Health Food Comp, Solae Comp, Lazarus Scientific Research, Dairy Aust., Flour Millers Council of Aust., ABC, AFGC, ASMI, GW Foods, National Starch, Wyeth Aust., Cadbury Schweppes, Goodman Fielder, Nestle, F&B Importers Assoc., DSM Nut. Prod, CML, PB Foods, Parmalat Aust., CHC, National Foods, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA NSW Branch, CMA Qld Branch, ICA, CMA Vic Branch, CM of SA, MLA, TGACC, CSIRO - HS&N, Uni of Adel. & Uni. of SA – Nutrition & Physiology Research Grp, GI Ltd, DAA, Tomox, Dr R. Stanton, Diabetes Aust, TCCA Aust., Nutrition Aust., Aussie Bodies, NZ MoH, NZFSA, NZTBC, Tegel Foods, Griffins Foods, Nutra-Life H&F, ASA, NPANZ, Cadbury Confectionery, NZ Magazines, NZ Dairy Foods, Beef & Lamb Marketing Bureau, NZFGC, NZJBA, NZ V&PG Fed/NZFG Fed, Fonterra, NZDA, NHF NZ, Northland Health Dietitians, Auckland Reg. PHS, NZDA, Unilever Australasia)

Fifteen submitters did not agree that a an indicative list of authoritative texts should be provided (SA DoH, WA DoH, Monash Uni - N&D Unit, Kidney Health Aust., Dr C. Halais, PHAA, NSF, ACDPA, The Coeliac Society of Aust., Mainland Products, Horticulture & Food Research Instit. of NZ, Cancer Society NZ - Waikato/Bay of Plenty Division, Cancer Society NZ, Cancer Society NZ – Rotorua Branch, Heinz Aust./ Heinz Watties NZ)

NZ Dairy foods believe that a list is necessary to ensure a level playing field amongst industry.

Several submitters said that they would like to see the list in a guideline document (Lazarus Scientific Research, ABC, GW Foods, Wyeth Aust., Goodman Fielder, Nestle, PB Foods, Parmalat Aust., National Foods, CMA, Unilever Australasia), with some giving the preface that that list should be devised in consultation with Industry (ABC, AFGC, GW Foods, Nestle, National Foods, Aussie Bodies, Nutra-Life H&F, Unilever Australasia). Aussie Bodies commented that industry involvement would provide them with some ownership and in turn improve their support.

Some of those in favour of a list suggested it would have to be regularly reviewed to be kept up to date (ASMI, TGACC, GI Ltd, Dr R. Stanton, Diabetes Aust) and would have to comparable in nature to a Cochrane Collaboration analysis (ASMI). The suggestion was made by several submitters to use the FSANZ website to disseminate up to date information (GI Ltd, DAA, Diabetes Aust). Tegel foods made the point that they do not think that the list should be exclusive.

Dr R. Stanton also noted that experts with conflicts of interest would have to be identified including conflicts of interest that may apply to colleagues in their university.

Recommend expanding the list of authoritative bodies to include any technically based foundation/organisation generally recognised to be an authority in the claimed disease or condition, particularly when those bodies issue position statements and/or

guidelines related to nutrition. For example, Cancer Research Council (Lazarus Scientific Research).

The DAA consider that they have the skills and expertise to provide FSANZ with a list and that they be responsible for establishing and maintaining a list. The NZDA supports their view.

Reasons for supporting a list included:

- A list is necessary to ensure a level playing field amongst industry (NZ Dairy Foods);

- If FSANZ does not approve general level claims than they should provide a list of authoritative texts and databases of reputable sources (ACA);

- An authoritative list would provide greater confidence in the claims made, particularly were there is a low level of regulatory control (ACCC); and

- Very few organisations/individuals posses the skills to gather analyse and assess information linking food components and health. Consider that such a process is too burdensome for industry and so the responsibility should rest with FSANZ (Auckland Cancer Society).

Tas DoH&HS thought that a technical advisory group could assist FSANZ in prescribing a list.

Canterbury DHB support the Levels of Evidence grading as developed by the Canadian Health Department.

NHF Aust (supported by NHF NZ) suggest that there should be a list of texts and authoritative sources that includes the evidence-based policy documents of the NHF of Australia and NZ.

Many submitters gave reasons for not agreeing with a list or highlighting implications that need to be considered if a list is developed:

SA DoH, WA DoH and the PHAA did not think that a list is required as they consider that onus for pre approval of general level claims should sit with FSANZ or expert committee. The suggestion was made that the food industry is highly fragmented with many farmers, growers, wholesalers, packers, manufacturers and retailers responsible for product. Requesting that the food industry substantiate general level claims individually puts unnecessary burden on all stakeholders to repeat the same work. The process of enforcement would also be extremely difficult. One central body should hold the substantiated evidence and make it available to all parties provided they meet specified criteria (SA DoH, WA DoH, PHAA, NSF)

Dr C. Halais is not in favour of a list as she is not in favour of clams of any type.

SA DoH and the PHAA consider that providing a list may not overcome the main problems, which are:

- Sourcing of appropriate authoritative, current and generally accepted information (this will be open to broad interpretation);
- Differing interpretations of the literature by different manufacturers;
- Differing interpretations of the literature amongst enforcement agencies and between enforcement agencies and manufacturers;
- Advantage given to larger manufacturers over smaller manufacturers who cannot necessarily afford to resource the substantiation process; and
- Loss of confidence by consumers in general level claims in that consumers may judge the validity of claims differently depending on the body substantiating the claim (i.e. perceived to have a vested interest or not).

The NSW DoH - N&PA Branch commented that whilst a list may be preferable it does not solve the problem of misusing information contained with in these sources. Tas DoH&HS also comment on the problems surrounding individual interpretation of evidence.

Several submitters believe that the proposed substantiation for general level claims 'being based on authoritative, current and generally accepted information sources' does not provide a sufficient level of rigour of scientific substantiation (Kidney Health Aust., NSF, ACDPA)

Cancer Society NZ - Waikato/Bay of Plenty Div., Cancer Society NZ, Cancer Society NZ – Rotorua Branch all state that the notion that claims be based on "authoritative, current, and generally acceptable information sources' belittles the complexity and skills required to come to agreement on health claims and is derogatory to the field of nutritional science.

Problems with lists becoming out dated were citied as reasons for not having a list by Mainland Foods, The Horticulture & Food Research Instit. of NZ and Heinz Aust./ Heinz Watties NZ.

Question 51

Do you support FSANZ developing a list of model general level claims and associated qualifying criteria, to help manufacturers/suppliers stream line the substantiation of claims? These model general level claims may be included in interpretive user guides.

Out of 147 submitters, 57.8 % (85 in total) directly responded to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	26	15	3	2	46
Government	8	2	-	-	10
Public health	13	-	-	-	13
Consumers	2	-	-	-	2
Other	5	9	-	-	14
Total	**54**	**26**	**3**	**2**	**85**

Overview

All submitters agreed that FSANZ should provide a list of model claims. (None disagreed). In addition, many suggested that the list (of general level function, enhanced function and risk reduction claims as well as high level claims) be included in the standard. Others recommended inclusion in a guideline document.

Discussion of submitter responses

All those that gave a direct reply (yes/no) to this question stated yes, they agreed with the inclusion of a model list of claims (NCWA, ACCC, DAFF, ACA, Queensland Health - PHS, NSW Food Authority, NSW DoH - N&PA Branch, SA DoH, Tas DoH&HS, WA DoH, Solae Comp, National Starch, Sanitarium Health Food Comp, Horticulture Aust., Flour Millers Council of Aust., Goodman Fielder, GW Foods, ABC, Dairy Aust., AFGC, ASMI, Wyeth Aust., CML, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA NSW Branch, CMA Qld Branch, ICA, CMA Vic Branch, CM of SA, CHC, F&B Importers Assoc., DSM Nut. Prod., Parmalat Aust., PB Foods, National Foods, MLA, Nestle, Cadbury Schweppes, TGACC, Uni of Adel. & Uni. of SA – Nutrition & Research Physiology Grp, CSIRO - HS&N, Monash University - N&D unit, GI Ltd, Tomox, DAA, PHAA, Dr R. Stanton, ACDPA, Nutrition Aust., NSF, Diabetes Aust, TCCA Australia, NCEFF, Aussie Bodies, NZ MoH, NZFSA, NZTBC, Tegel Foods, Nutra-Life H&F, Mainland Products, Griffins Foods, ASA, NPANZ, Cadbury Confectionery, NZ Magazines, NZJBA, NZ V&PG Fed/NZFG Fed, NZ Dairy Foods, NZFGC, Fonterra, Horticulture &Food Research Instit. of NZ, NZDA, OAC NZ, ANA, Auckland Reg. PHS, Northland Health Dietitians, NHF NZ, Heinz Aust./ Heinz Watties NZ, Unilever Australasia, Masterfoods Australia New Zealand).

No submitter disagreed with a list of model claims being provided by FSANZ.

Many submitters suggested the inclusion of a list of general level function, enhanced function and risk reduction claims as well as high level claims in the standard was the best option and preferable to a model list (ACA, Queensland Health - PHS, NSW

Food Authority, NSW DoH - N&PA Branch, SA DoH, Tas DoH&HS, WA DoH, Horticulture Aust., ASMI, CHC, TGACC, DAA, NSF, ACDPA, NZ MoH, Cancer Society - Waikato/Bay of Plenty Div, Cancer Society NZ – Rotorua Branch, Cancer Society NZ, NHF NZ). Reasons for this opinion included:

- Many manufacturers may choose to make general level claims rather than a high level claim if the FSANZ approval process is too long and onerous (ACA);

- Manufacturers may make a general level claim while they are waiting for approval of a high level claim (ACA);

- Pre-approving these general level claims is particularly important while there is insufficient evidence to determine whether consumers make a distinction between similar general and high-level claims (ACA);

- Create a more level playing field for all manufacturers (ACA, ACDPA, Cancer Society NZ - Waikato/Bay of Plenty Div, Cancer Society NZ – Rotorua Branch, Cancer Society NZ);

- Pre-approved general level claims will be of benefit to large manufacturers, as they will not have to outlay money to gain approval of claims that are then used by their competitors (ACA);

- Minimise the risk possibility of misinterpretation (Horticulture Aust., NHF NZ);

- Industry and enforcement officers would be allowed a consistent framework for substantiation of general level claim (Queensland Health - PHS, Cancer Society NZ – Rotorua Branch, Cancer Society NZ - Waikato/Bay of Plenty Div, Cancer Society NZ);

- Industry could to assess accurate information on which to base decisions (Queensland Health - PHS, Tas DoH&HS);

- Industry would be assisted by reducing the burden of substantiation (Tas DoH&HS, WA DoH);

- Consumers would be provided increased confidence in the process (Tas DoH&HS, NSW DoH - N&PA Branch, NSF, ACDPA, Cancer Society NZ – Rotorua Branch, Cancer Society NZ - Waikato/Bay of Plenty Div., Cancer Society NZ, NHF NZ);

- There is no monopoly gained by certain food manufacturers on any particular general level claim. The larger and more well resourced food manufacturers who are able to dedicate resources to substantiating general level claim should not be able to gain an unfair market advantage (NSF, Cancer Society NZ – Rotorua Branch, Cancer Society NZ - Waikato/Bay of Plenty Div., Cancer Society NZ);

- Believes general level claim be required to have the same level of substantiation as high level claims (OAC NZ);

- Prefers that FSANZ prescribe the exact wording of all claims, including general level claim to reduce consumer confusion (OAC NZ, ANA); and

- Believes using standard wording in claims would mean only claims which have been pre-tested with consumers and known to be the least likely to cause confusion would be used (OAC NZ, ANA).

OAC NZ believes standard wording would prevent manufacturers trying to outdo each other and give consumers consistent messages; consistency that would help consumers to understand claims and make education easier too. ASMI disagrees and suggested that the wording of listed claims should be indicative and not be prescriptive

Several suggestions were made for consideration in determine a list of general level claim for use in a guideline:

- The ACA suggested that claims currently being made by manufacturers could be used as a starting point for pre-approval of general level function, enhanced function and risk reduction claims, but they must be substantiated by scientific evidence;

- Many submitters thought that consultation with industry in determining a guideline list was important (GW Foods, ABC, Dairy Aust., AFGC, CML, F & B Importers Assoc., Parmalat Aust., National Foods, MLA, Nestle, NZFGC, Unilever Australasia);

- Cadbury Schweppes note that guidelines will only be able to advise manufacturers as to claims in a generic sense only. Manufacturers will have to interpret user guides in order to 'create' the claim that they may want to make regarding their product. The user guides must be able to provide meaningful examples and direction;

- Several submitters suggested using the Joint Health Claims Initiative list of claims as a starting point (AFGC, WA DoH, Horticulture Aust., MasterFoods Aust. NZ);

- The list of general level claim is road tested (CMA, Parmalat Aust., Dairy Aust.);

- GW Foods comments on the resource issues facing FSANZ and suggested that emphasis should be given to high level claim in the first instance;

- Recommend regular review (Tomox); and

- DAA state that their members are experts in all matters regarding food and nutrition and they therefore believe it would be an advantage to FSANZ if they were actively involved in the consultative process for developing and reviewing general-level health claims and associated evidence sources. The NZDA supports the DAA in their submission.

Flour Millers Council of Aust. considers that list would be most useful and would assist uniformity in interpretation and understanding, providing for more credible performance across the industry.

Some several comments were made pertaining to qualifying/disqualifying criteria. Goodman Fielder oppose the development of qualifying/disqualifying criteria, they are of the opinion that it is unnecessary. They believe that if a claim can be substantiated then manufacturers should be able to use the claim irrespective of the compositional properties of the food. Other submitters also oppose the development of qualifying/disqualifying criteria (ABC, GW Foods, Dairy Aust., AFGC, PB Foods, National Foods, Fonterra). Some submitters highlighted the importance and necessity of qualifying/disqualifying criteria (J. Seal - PH Nut, TCCA). The suggestion was made that criteria be based on food groupings rather then across all groups (Cancer Society NZ – Rotorua Branch, Cancer Society NZ - Waikato/Bay of Plenty Division, Cancer Society NZ).

CHAPTER 4: ISSUES REGARDING HIGH LEVEL CLAIMS

4.1 PRELIMINARY ADVICE ON THE PRIORITY LIST FOR PRE-APPROVED CLAIMS

Question 52

Which of the public health claims approved overseas do you believe would have the most public health impact?

Out of 147 submitters, 64% (94 in total) directly responded to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	30	18	3	2	53
Government	2	2	-	-	4
Public health	17	3	-	-	20
Consumers	12	-	-	-	12
Other	4	1	-	-	5
Total	**65**	**24**	**3**	**2**	**94**

Overview

Many submitters supported the use of all claims substantiated overseas for use in New Zealand. No claim was favoured above others for permission by submitters. In addition, there were comments made about testing claims that are permitted overseas in the context of the New Zealand and Australian situation, before being allowed in these countries.

Discussion of submitter responses

DAFF acknowledged the importance of using pre-approved claims given the extensive assessment process. A number food industry groups stated that overseas claims that have been rigorously assessed should be approved in Australia and New Zealand (ABC, AFGC, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA NSW Branch, CMA Qld Branch, CMA Vic Branch, CM of SA, Nestle, Unilever Australasia, Heinz Aust./ Heinz Watties NZ, ICA).

CMA (supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA NSW Branch, CMA Qld Branch, ICA, CMA Vic Branch and CM of SA) cited Canada's claims in particular should be used.

NSW DoH - N&PA Branch stated the extent of the impact of the claims would depend upon consumer's response. Dairy Aust. supports this statement, and believes consumer perceptions of their diet and willingness to change in response to health claims would be of influence.

Aust. Egg Corp. does not support cholesterol as a heart health and *trans*-fat/saturated fat claim given a lack of evidence showing a link between cholesterol and a reduction

in heart disease. However, other Australian industry groups specified that claims relating to lowering cholesterol, the risk of heart disease would have the most impact (Aussie Bodies, CHC, CMA - NSW Branch). Some industry groups suggested targeting diseases of greatest prevalence first (CML, Cadbury Schweppes) or those identified as national health priorities (ASMI). CMA – NSW Branch supported this, and also noted stroke, cataracts and muscular degeneration of the eye. Aussie Bodies also included dental caries and osteoporosis. The ANIC supports a claim specifically in relation to nuts and heart disease.

Several Australian Public Health organisations believed there is a conflict between the level of convincing evidence in the substantiation framework and some of the proposed health claims awaiting assessment. (ACDPA, Diabetes Aust, GI Ltd) Three organisations stated that health claims should not be permitted for all of the 'serious diseases or conditions' provided by FSANZ in the IAR, given the level of scientific evidence may not be sufficient to justify health claims linking specific nutrients/foods to disease prevention e.g. cancer.

Nutrition Aust. and the PHAA (supported by ACA) stated that claims in keeping with Australia/NZ dietary guidelines and nutrition frameworks should be developed first. Monash Uni.- N&D Unit supported this. Several groups stated that claims relating to fruit and vegetables should be given priority (Dr R. Stanton, GI Ltd, Kidney Health Aust., Horticulture & Food Research Instit. of NZ). The PHAA (supported by ACA) supported this, in addition to support for *trans*-fat/saturated fat and sodium related claims, supported this.

Other public health groups listed the following specific claims:

- DAA (supported by NZDA) stated that claims associated with obesity and cardiovascular disease would have the greatest public health impact;

- NZFSA suggested claims that consumers are least knowledgeable about and also cited Omega-3 fatty acids as an example;

- NZFSA also noted fatty acids; and

- Northland Health Dietitians listed wholegrain/cancer and *trans*-fats & saturated fat/heart disease.

The NCEFF supports using a working model where nutritional science developments occur alongside the food supply to answer the question informatively. Dr R. Stanton commented that the process to establish health claims should involve consultation with health professionals. Griffins Foods supported this view.

NHF Aust. and NHF NZ stated that nutritionally vulnerable population groups should be able access foods carrying health claims. It also believes health claims need to be attractive for use by manufacturers in terms of ease of communication and consumer interest. Conversely, the ACA and NHF NZ, commented that prioritisation of health claims should not be based on the priorities of food manufacturers.

The ACA also stated that Australia and New Zealand's health claims should not be prioritised according to claims used overseas, given FSANZ assessment processes will differ. However, Many industry groups believe that overseas claims have been substantiated through vigorous government process and therefore should be approved (NZJBA, CMA - NZ Branch and NZFGC, Frucor).

Other New Zealand industry groups listed coronary heart disease, high blood pressure and stroke, and cholesterol as priority claims (ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Schweppes, NZ Magazines). NZ Dairy Foods commented that claims relating to obesity, cancer, coronary heart disease and osteoporosis would have the most public health impact. The obesity and osteoporosis claims were supported by Nutra-Life H&F and Fonterra, respectively. Mainland Products also cited fruit and vegetables/heart disease, sodium/stroke and probiotics/immunity. In addition to Omega-3 fats/blood cholesterol and calcium/osteoporosis, Nutra NZ also noted probiotics/immunity, soluble fibre and soy protein/CHD/cholesterol.

Other Australian groups also listed specific claims. The NCWA listed *trans*-fat/saturated fats/cholesterol, calcium, vitamin and folate as priorities. CSIRO - HS&N stated calcium and osteoporosis, "Especially if calcium fortification is liberalised". The Uni of Adel. & Uni of SA – Nutrition & Physiology Research Grp. suggested Omega-3 fatty acids and cardiovascular health.

Question 53

Which of the health claims approved overseas would industry wish to make?

Of the 147 submitters, 48% (a total of 70) directly responded to the question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	26	15	5	2	50
Government	5	1	-	-	6
Public health	9	4	-	-	13
Consumers	1	-	-	-	1
Other	2	-	-	-	2
Total	**43**	**20**	**5**	**2**	**70**

Overview

The majority of submissions from both Australian and New Zealand industry recommended that all health claims used overseas that been subject to a rigorous assessment process or at least an approval process would be appropriate for use. Public health and government submitters were of the opinion that no overseas claims should be accepted without a process to ensure they are based on valid and up to date evidence. The most popular claims from industry submitters were those pertaining to fruit and vegetables and those relating to coronary heart disease.

Discussion of submitter responses

The majority of submissions from both Australian and New Zealand Industry recommended that all health claims used overseas that been subject to a rigorous assessment process or at least an approval process would be appropriate for use in Australia (ABC, AFGC, Dairy Aust., CML, F&B Importers Assoc., Goodman Fielder, CM of SA, Heinz Aust./ Heinz Watties NZ, Kingfood Australia, MasterFoods Aust. NZ, Mandurah Aust., National Foods, Nestle, Frucor, NZFGC, Griffins Foods, NZJBA, Unilever Australasia, CMA - NZ Branch). This was supported by both submissions from International Industry (ICA, William Wrigley Junior).

Aussie Bodies, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA NSW Branch, CMA Qld Branch, ICA, CMA Vic Branch, CM of SA, suggested all overseas approved claims should be used. Both Solae Comp and National Starch stated that all of the approved U.S. claims should be used.

However, WA DoH and Tas DoH&HS stated that claims approved overseas may be either out of date or not subject to the kind of rigorous substantiation process required by FSANZ. NSW DoH - N&PA Branch agreed, noting that no overseas claims should be accepted without a process to ensure they are based on valid and up-to-date evidence. All of the Australian Public Health organisations (ACDPA, Diabetes Aust, Dr R. Stanton, GI Ltd, Kidney Health Aust., NHF Aust., NSF, Nutrition Aust., PHAA (supported by ACA)) and almost all of the NZ Public Health organisations concurred, (ANA, Auckland Cancer Society, Cancer Society NZ) as did the Monash University - N&D Unit.

WA DoH also suggested that the NHMRC Dietary Guidelines should be the benchmark used for an approval process, given there is global agreement by health authorities that increased fruit and vegetable consumption is a priority. DAFF believe that the current FSANZ health claims could be used as a guide for approving overseas claims. NSW Food Authority stated that responses from industry on this question would be more appropriate than comments from governments. Similarly, NHF NZ stated it can't comment on behalf of industry and the NZ MoH stated it did not know in response to the question.

The ACA stated, "Prioritisation of …claims should not be based on the priorities of food manufacturers".

Dairy Aust. also stated that claims in keeping with public health objectives should be used first and that the wording of the claims should not be prescriptive. Parmalat Aust. and PB Foods supported this.

Several companies cited that claims relating to fruit and vegetables should be a priority (Horticulture Aust., Cadbury Schweppes, ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes, NZ Magazines).

A number of companies suggested claims relating to coronary heart disease (DSM Nut. Prod., Goodman Fielder, GW Foods, ANIC, Mainland Products, Nestle), while others suggested claims relating to Omega-3 fatty acids (Cadbury Schweppes, ANIC, Griffins Foods, Nestle, NZ Dairy Foods) and calcium (Cadbury Schweppes, Nestle,

Fonterra, NZ Dairy Foods, Sanitarium Health Food Comp, Griffins Foods). In addition the following were suggested:

- Blood cholesterol and obesity (CHC);
- Wholegrains, saturated fat, soy protein and energy (Sanitarium Health Food Comp);
- Several for nuts/heart disease, saturated fat/cholesterol, soluble fibre/blood cholesterol, sodium/blood pressure, and folate/neural tube defects (ANIC);
- Folate/neural tube defects, pre-approved overseas claim for wholegrain/heart disease, the recently approved Food and Drug Administration claim for Omega-3 fatty acids and cardiovascular disease (GW Foods);
- Resistant starch/colorectal cancer, soluble fibre/colorectal cancer, iodine/thyroid dysfunction, selenium/cancer, probiotics/immunity, cheese/dental caries, glycaemic index/diabetes, Omega-6 fatty acids/cholesterol, Omega-9 fatty acids/cholesterol (Griffins Foods);
- Saturated fat, *trans* fat/cholesterol, dietary sugar alcohol/dental caries (Nestle); and
- Fibre, plant sterols (NZ Dairy Foods).

Goodman Fielder also supports claims relating to plant sterol/stanol esters and a reduction in cholesterol levels, noting applications are now in the FSANZ final assessment stage for the addition of plan sterols to breakfast cereals, low fat milk and yoghurts. The submission also stated that incorporating plan sterol containing products in the diet is part of the overall management of cholesterol levels, noting a health claim for plant sterol/stanol esters in reducing the risk of heart disease is permitted in the United States.

Goodman Fielder also stated a claim relating to soluble fibre and coronary heart disease should be used, noting scientific evidence that diets high in oat products can reduce cholesterol levels, and that there is a high level claim permitted in the United States for soluble fibre in certain foods and the risk of coronary heart disease.

Question 54

What factors do you consider in prioritising the list of health claims in terms of scientific validation?

Of the 147 submitters, 49% (a total of 68) responded directly to what factors are considered in prioritising the list of health claims.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	26	11	3	2	42
Government	4	1	-	-	5
Public health	10	5	-	-	15
Consumers	2	-	-	-	2
Other	4	-	-	-	4
Total	**46**	**17**	**3**	**2**	**68**

Overview

There were many factors listed as being important when prioritising the list of health claims. The two most commonly citied factors were public health significance and strength of evidence. Many submitters made comment in relation to the adoption of overseas claims substantiated through a rigorous scientific framework. Several submitters suggested that scientific validation must conform to the substantiation framework/requirements and that if the claim cannot be appropriately substantiated it should not be considered.

Discussion of submitter responses

There were many factors listed as being relevant when prioritising the list of health claims:

- Strength of evidence (CSIRO - HS&N, Diabetes Aust, GI Ltd, NCEFF, ACA, NCWA, ANIC, CML, CHC, GW Foods, Goodman Fielder, National Foods, Sanitarium Health Food Comp);

- Size of effect (CSIRO - HS&N, ACA, NCWA, PB Foods, NSW Food Authority);

- Prevalence of the disease being considered in New Zealand and Australia (CMA, CMA - NZ Branch, ACA, ICA, CM of SA, Kingfood Australia, Mandurah Aust., Palatinit GmbH, CMA NSW Branch, CMA Qld Branch, CMA Vic Branch, Solae Comp);

- Public health concern and public understanding of the disease (NZ Dairy Foods, ACA, ASMI, National Starch, PB Foods);

- Lack of negative impact on other conditions (CSIRO - HS&N);

- Age of evidence (Diabetes Aust, GI Ltd);

- Public health significance/need and potential extent of benefit (Diabetes Aust, Dr R. Stanton, GI Ltd, NCEFF, Uni of Adel. and Uni of SA – Nutrition & Physiology Research Grp, NCWA, Cadbury Schweppes, GW Foods, DAFF, DAA, NZDA);

- Quality of the scientific evidence of health benefit (Uni of Adel. and Uni of SA – Nutrition & Physiology Research Grp, NCWA);

- Willingness of manufacturers to put the claim on the pack (GW Foods, DAFF);

- Feasibility of delivery in food and likelihood of adoption (Uni of Adel. and Uni of SA – Nutrition & Physiology Research Grp);

- Ability of food to be easily incorporated into the diet (Aussie Bodies); and

- How well the food targets the population with the particular condition (Aussie Bodies).

Many submitters made comment in relation to the adoption of overseas claims substantiated through a rigorous scientific framework should be permitted as this would save FSANZ re doing already completed work (Fonterra, Nestlé, Unilever Australasia, Frucor, NZJBA, CMA - NZ Branch, ICA, ABC, AFGC, CML, F&B Importers Assoc., GW Foods, Goodman Fielder, CM of SA, Kingfood Australia, Mandurah Aust., National Foods, Parmalat Aust, Sanitarium Health Food Comp).

Several submitters suggested that scientific validation must conform to the substantiation framework/requirements and that if the claim cannot be appropriately substantiated it should not be considered (Monash Uni - N&D Unit, Nutrition Aust., PHAA, TCCA, CHC, WA DoH, Tas DoH&HS).

Dr C. Halais made the comment that scientific validation is difficult, if not impossible, since only research in support of a claim is published. Equivocal or negative effects tend to be disregarded and remain unpublished.

NHF Aust and NHF NZ thought that there should be an emphasis on those groups that display a greater relative prevalence of the disease burden, specifically Aboriginals, Maori, Pacific Island people and those in lower socio-economic groups.

Nutra-Life H&F were of the opinion that first priority for health claims should be the obesity epidemic.

Question 55

Are there any other health claims that you believe should be considered for pre market assessment?

Out of 147 submitters, 39 % (58 in total) directly responded to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	19	11	4	2	36
Government	4	2	-	-	6
Public health	9	3	-	-	12
Consumers	1	-	-	-	1
Other	2	1	-	-	3
Total	**35**	**17**	**4**	**2**	**58**

Overview

Over 30 health claims were suggested as being worthy of consideration of pre-market assessment. The most popular were those about fruit and vegetables, phytosterols and cholesterol, and sodium potassium and blood pressure/heart health. Three submitters did not believe there were any other claims to be considered.

Discussion of submitter responses

The following were suggested as claims that should be considered for pre approval in the future;

Fruit and vegetables	NNF&V Coalition, ACDPA
Phytosterols & Cholesterol	NZFSA, CSIRO-HS&N, Tomox, AFGC, Goodman Fielder, Nestle,
Low sodium & cardiovascular health	Uni of Adel. & Uni of SA – Nutrition & Research Physiology Grp
Sodium, potassium & blood pressure	NHF Aust., AFGC, NHF NZ
Fruit, vegetables and wholegrain & heart disease	NHF Aust., Go Grains, NHF NZ
Lycopene	Heinz Aust./ Heinz Watties NZ
Saturated/*trans* fatty acids & heart disease	NHF Aust., NHF NZ, Northland Health Dietitians
Omega-3 fatty acids & heart disease	NHF Aust., Nutrition Aust., AFGC, GW Foods, Goodman Fielder, NHF NZ
Energy balance & obesity	NHF Aust., NHF NZ

A diet rich in fruit, vegetables and low fat dairy helps reduce high blood pressure, which helps protect against heart disease and stroke	Tomox, National Foods, Parmalat Aust.
Milk and other calcium-rich dairy foods & the risk of dental caries	Tomox, Dairy Aust., National Foods, Parmalat Aust.
Regular exercise and a reduced kilojoule diet based on fruit, vegetables, low fat dairy, lean meats and wholegrain cereals can reduce the risks of obesity	Tomox, NZFCG
Phytoestrogens	NCWA
Antioxidants	NCWA, NZ Dairy Foods
Wholegrain & risk reduction of diabetes	AFCG, Go Grains, GW Foods,
Rye & risk reduction of bowel cancer	AFCG, GW Foods, Goodman Fielder, NZFCG
Glycaemic index & risk reduction of heart disease and diabetes	AFCG, NZFCG
Milk and other calcium-rich dairy foods can assist in reducing the risk of obesity	AFCG, Dairy Aust., NZ Dairy Foods, NZFCG
Folate & risk reduction for coronary heart disease	AFCG
Soy protein & risk reduction of prostate cancer	AFCG, GW Foods
Soluble fibre & lowering blood cholesterol	AFCG, GW Foods
Selenium & risk reduction of some cancers	AFCG, GW Foods
Nuts & heart disease	ANIC
Milk, other calcium-rich dairy foods and calcium can assist in reducing the risk of osteoporosis	Dairy Aust., National Foods, Parmalat Aust., Fonterra
A diet that is high in fruit, vegetables and low-fat dairy foods in controlling high blood pressure.	Dairy Aust., National Foods, Parmalat Aust.
Milk, other calcium-rich dairy foods and calcium can assist in reducing the risk of some cancers	Dairy Aust., National Foods, Parmalat Aust.
Glycaemic Index & risk reduction of heart disease and diabetes	GW Foods
Probiotics & immunity	Parmalat Aust., Fonterra, NZ Dairy Foods
Low fat dairy foods & blood pressure	Parmalat Aust.

Iodine & thyroid	NZFCG
Wholegrain & cancer	Northland Health Dietitians
Does not promote tooth decay	CMA – NZ Branch
May reduce the risk of tooth decay	CMA – NZ Branch
Sugar alcohols to reduce risk of dental caries	CMA – NZ Branch
Absorption of calcium for teeth	CMA – NZ Branch

The Tas DoH&HS, WA DoH and NSW DoH - N&PA Branch do not think that there are any other claims that should be considered.

The NZFSA suggests that new legislation should consider the impact on the "Pick the Tick" campaign.

TCCA stressed that the cancer claims listed in the Initial Assessment Report as being permitted overseas, should not be permitted in Australia and New Zealand.

AFCG recommends that claims for phytosterols and cholesterol reduction automatically be included in pre-approved claims as the efficacy has already been assessed during the Novel Foods assessment and this should not affect the number of reviews that FSANZ needs to resource. Unilever Australasia and Goodman Fielder agree with this view.

CML suggests claims linking consumption of food with improvements in mental health (i.e. Omega-3's).

Goodman Fielder states that they manufactured a margarine spread, which included Omega-3 DHA, & EPA in the formulation. The product remained on the market for approximately 12 months despite many years of research and product trials to develop a palatable product. Consumer research indicated that while consumers were aware of omega-3 DHA & EPA they couldn't really name one benefit and did not understand what it did for them from a health perspective and because of that could not justify paying a premium for the product. The research also indicated that consumers did not understand the difference between Omega-3 from Vegetable oils and Omega-3 from fish oils.

National Foods requests that FSANZ, in addition to approving approximately five high level claims for inclusion in the Standard, commits to assess five new high level claims per year, in order to update the health claims regulatory system and maximise compliance.

Mainland Products and Unilever Australasia would like to see all those claims permitted in the US, Canada and Sweden also permitted in the Code.

Allergy NZ & Anaphylaxis Aust considered that food allergy claims should be addressed. The give the example; claims on goat milk products that state "..may be suitable for those with cows milk protein allergy or sensitivity..". They suggest that similar claims have resulted in allergic reactions (anaphylaxis) in infants with cow

milk allergy whose parent did not know that cow and goat milk cross reactivity occurs in most of these patients.

4.2 REVIEW OF PRE-APPROVED HIGH LEVEL CLAIMS

Question 56

What do you consider would be an appropriate process to undertake a regular review of approved claims?

Of the 147 submitters, 49% (a total of 72) responded directly to this question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	32	11	5	3	51
Government	5	2	-	-	7
Public health	6	4	-	-	10
Consumers	1	-	-	-	1
Other	2	1	-	-	3
Total	**46**	**18**	**5**	**3**	**72**

Overview

The Australian and New Zealand governments favoured a regular review of health claims every five years in conjunction with a watching brief, as did the majority of Australian and New Zealand public health organisations. Many Australian and New Zealand industry groups stated that a review process would need to be responsive to new scientific evidence that becomes available and therefore a continuous watching brief would be appropriate. Several groups supported linking a review of health claims to the five-year review of dietary guidelines undertaken by the National Health and Medical Research Council, pending the availability of new scientific evidence.

Discussion of submitter responses

The Australian governments that responded to this question favoured a regular review of health claims every five years in conjunction with a watching brief (NSW Food Authority, NSW DoH - N&PA Branch, Tas DoH&HS, WA DoH). The NZFSA and the NZ MoH supported this. The state health departments also stated this approach would need to include a mechanism to rescind approval for claims.

The majority of Australian and New Zealand Public Health organisations were also in support of both a review and watching brief (ACDPA, Diabetes Aust, DAA, GI Ltd, NSF, NZDA, Nutrition Aust., Monash Uni – N&D Unit, TCCA, ANA, Auckland Cancer Society). Dr R. Stanton suggested that a panel of public health and consumer experts should undertake a review, on a non-altruistic basis. Monash Uni. - N&D Unit, NHF Aust. and NHF NZ agreed with using an approach using a panel of experts and a transparent process to challenge existing claims. Monash Uni. - N&D Unit also made a number of suggestions that include ensuring high quality evidence to

substantiate claims is used, that the required intake of a food is achievable for the intended population group and that the NHMRC guidelines should the benchmark for substantiation.

NCEFF stated that an evaluation plan of the process is required and Northland Health Dietitians suggested that appropriate modifications be would be made following an evaluation.

Several Australian Industry groups also supported both a regular review and watching brief (ANIC, Bakewell Foods, Dairy Aust., GW Foods, Goodman Fielder, Tomox, Unilever Australasia). However, the majority stated that a regular review on its own would be appropriate (CML, CM of SA, Horticulture Aust., Kingfood Australia, Lazarus Scientific Research, Mandurah Aust., MLA, National Foods, Parmalat Aust, PB Foods, Wyeth Aust, Sanitarium Health Food Comp). The CHC stated that a 5-10 year interval between reviews would be too long and that 12-month period is preferred. Horticulture & Food Research Instit. of NZ stated a regular five-year review would be appropriate. CSIRO - HS&N suggested reviewing claims and consumers understanding of them every 1-2 years.

Many Australian and New Zealand Industry groups stated that a review process would need to be responsive to new scientific evidence that becomes available and therefore a continuous watching brief would be appropriate (Cadbury Schweppes, CML, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA NSW Branch, CMA Qld Branch, ICA, CMA Vic Branch, CM of SA, Griffins Foods, ICA, MasterFoods Aust. NZ, Nutra-Life – H&F, NZ Dairy Foods, NZ Magazines). National Starch and Solae Comp. suggested that a regular review of all claims may be inefficient given many would not need to be changed. Similarly, DSM Nut. Prod. suggested reviewing claims on a case-by-case basis. The ASA, NPANZ and the Assoc. of NZ Advertisers stated that risks to the public of an outdated claim would be minimised using a watching brief compared to implementing change from a review process.

NCWA also supported a process based on a continuous watching brief.

Several groups supported linking a review of health claims to the five year review of dietary guidelines undertaken by the NHMRC, pending the availability of new scientific evidence (AFGC, Frucor, Fonterra, Mainland Products, Nestle, NZJBA). The NZFGC supported a regular review undertaken by the NZ MoH. Heinz Australia/Heinz Watties NZ stated that an approval process would need to incorporate stakeholder input.

Question 57

What risks would there be in maintaining a watching brief on new or contrary evidence as opposed to conducting a regular review?

Of the 147 submissions received 40% (total of 59) responded directly to the question.

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	19	13	3	-	35
Government	6	2	-	-	8
Public health	7	3	-	-	10
Consumers	1	-	-	-	1
Other	4	1	-	-	5
Total	**37**	**19**	**3**	**-**	**59**

Overview

Many submitters stated that there was no real risk from maintaining a watching brief on new or contrary evidence as opposed to conducting regular reviews. Others considered a watching brief too haphazard and unsystematic and that it might not consider the totality of evidence that a regular review would cover.

Discussion of submitter responses

Many submitters were of the opinion that there was no real risk from maintaining a watching brief as opposed to conducting regular reviews (Fonterra, Frucor, NZFGC, NZJBA, Unilever Australasia, ABC, AFGC, Nestle, DSM Nut. Prod., Goodman Fielder, MLA, National Foods, Parmalat Aust.)

There were several examples of risks provided by other submitters:

- Some may be missed and it may require working with public health nutrition authorities to enable effective watching (NCWA, NHF Aust, NHF NZ);
- Does not take in to account new pieces of key information that may be outside of the literature, such as conference presentations of new and emerging research (NHF Aust, NHF NZ);
- A watching brief is unsystematic in what is otherwise a systematic process (NHF Aust, NHF NZ);
- Low risks so long as industry was given sufficient time to remove or modify claims if required (Mainland Products);
- Watching brief is too haphazard (Dr R. Stanton);
- A formal review may never be undertaken (CML); and

- A watching brief may not consider that totality of evidence that a regular review would (Monash Uni - N&D Unit, NSW DoH - N&PA Branch, NSW Food Authority).

Several submitters suggested that the risks to public health would be minimal compared to waiting for a regular review process (ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes).

ACA supports a combination of watching brief and regular review. It is their opinion that both roles should be carried out by FSANZ with assistance from stakeholders in provision of new research of relevance. They suggest that the reviews could draw on the outcome of reviews on the NHMRC dietary guidelines and should be timed to coincided or follow on from these reviews. Diabetes Aust. suggests that the 10-year period for which the dietary guidelines are reviewed is too long and may put consumers at risk.

NCEFF suggest that the two options should not be dichotomous position and that both the watching brief and review processes are important. Nutrition Aust. and the PHAA, TCCA, NZ MoH, NZFSA, Tas DoH&HS, WA DoH, GW Foods also suggest that both are required. Horticulture Aust. suggests that a watching brief could be used to support a formal review process.

4.3 Implications of the claim-by-claim approach to pre-market assessment

Responses to questions 58 and 59 were closely linked, with considerable overlap. Accordingly, the discussion of submitter responses for these questions has been amalgamated.

Question 58

Given the claim-by-claim approach to pre-assessing claims, can you foresee any circumstance where a manufacturer can gain exclusive right to a claim?

Out of 147 submitters, 43.5% (64 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	27	13	3	2	45
Government	3	2	-	-	5
Public health	7	2	-	-	9
Consumers	2	-	-	-	2
Other	3	-	-	-	3
Total	**42**	**17**	**3**	**2**	**64**

Overview

Given the claim-by-claim approach to pre-assessing claims, the majority of submitters stated that there were circumstances where a manufacturer could gain exclusive right to a claim. These related to patentable ingredients, technologies or information and intellectual property other than patents (e.g. copyright, trademark, brand and confidential research).

Question 59

If so, does this present a problem in the context of the broader regulatory framework for nutrition health and related claims?

Out of 147 submitters, 28% (41 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	15	11	-	-	26
Government	3	2	-	-	5
Public health	5	2	-	-	7
Consumers	2	-	-	-	2
Other	2	-	-	-	2
Total	**27**	**15**	**-**	**-**	**42**

Overview

Some submitters suggested that exclusive rights to a claim by a manufacturer might present problems in the context of the broader regulatory framework for nutrition health and related claims. These problems included reducing the public health benefit of health claims and favouring larger companies. Other comments related to possible neutral or positive effects of exclusive claims.

Discussion of submitter responses to questions 58 and 59

It was suggested that consideration must be given to questions of intellectual property, patents, trademarks and copyright (CHC). In this context, it was recommended that FSANZ examine intellectual property in more detail (CML).

Possibility of exclusive claims

The majority of submitters were of the opinion that exclusive rights to a claim are possible in reference to patentable ingredients, technologies, or information (ABC, AFGC, ASA, Cadbury Confectionery, Cadbury Schweppes, CMA (supported by Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, CM of SA, ICA), Dairy Aust., DAA, Diabetes Aust., Fonterra, GW Foods, GI Ltd, Goodman Fielder, Griffins Foods, Heinz Aust./Heinz Watties NZ, Lazarus Scientific Research, Mainland Products, NCEFF, National Foods, National Starch, Naturo Pharm, Nestle, Northland Health Dieticians, Nutra-Life H&F, Monash Uni – N&D Unit, Nutrition Aust.,

NZFGC, NZ Magazines, NZ MoH, NZTBC, NZDA, NZJBA, Parmalat Aust., PB Foods, PHAA (supported by ACA), SA DoH, Sanitarium Health Food Comp, Solae Comp, WA DoH).

Some of the submissions emphasised that the claim could or should remain with the ingredient for use in whichever food is licensed to use such an ingredient (ABC, AFGC, NZJBA, GW Foods, Goodman Fielder, National Foods).

The ability of patent holders to substantiate exclusive claims was questioned by a number of submissions (Dairy Aust., Nutrition Aust., Monash Uni - N&D Unit, Mainland Products, PHAA (supported by ACA), SA DoH, WA DoH). Some submitters suggested that intellectual property other than patents (e.g. Copyright, Trademark, Brand, confidential research) might result in exclusive claims (ASMI, CHC, Heinz Aust./Heinz Watties NZ, National Starch, NCWA, Nutra-Life H&F, NZ MoH, Wyeth Aust.). There was some suggestion that exclusivity would occur without patent protection due to delays for subsequent approvals (GI Ltd).

A minority of submissions stated that exclusivity of claims was unlikely in any circumstance (NZFA, NSW DoH – N&PA Branch, Bakewell Foods, CML, F&B Importers Assoc.). A number of submitters stated that the claim-by-claim process was less likely to give individual manufacturers exclusivity (PHAA (supported by ACA), NSW DoH – N&PA Branch, SA DoH, Lazarus Scientific Research, Aussie Bodies, Monash Uni -N&D Unit).

Possible detrimental effects of exclusive claims

Some submitters suggested that exclusive claims would be broadly to the detriment of public health, or increase inequalities between socio-economic groups, or presented a problem in context of the broader framework, because it would reduce the public health benefit of health claims (Dr R. Stanton, TCCA, Northland Health Dietitians, NCWA, TCCA), and that health claims that have been widely accepted as beneficial to the public should be available for all industry to use (Sanitarium Health Food Comp, Bakewell Foods, Fonterra). It was also considered likely that exclusive claims would favour larger companies (Dr R. Stanton, Cadbury Schweppes). In this context, some acknowledgement was made that some return on research and development investment would be reasonable (TCCA, NZ Dairy Foods, Fonterra).

Possible neutral or positive effects of exclusive claims

Many submissions stated that exclusivity of claims did not present a problem in the context of the broader regulatory framework for nutrition health and related claims (ABC, AFGC, ASA, Cadbury Confectionery, CSIRO – HS&N, Dairy Aust., DAA, DSM Nut. Prods, F&B Importers Assoc., GW Foods, Goodman Fielder, NCEFF, National Foods, National Starch, Naturo Pharm, NZ Dairy Foods, NZ MoH, NZTBC, NZDA, NZFA, NZFGC, NZJBA, NZ Magazines, Parmalat Aust., Solae Comp, WA DoH). Most submitters that addressed Question 59 were of the view that exclusivity of claims was of benefit to industry and consumers; therefore they considered such claims to be free of problems.

Other submitters answered no to this question, on the basis that exclusive claims were unlikely to be possible (see above). One submission was unsure of the likely impact of exclusive claims (NSW DoH – N&PA Branch), while others gave qualified support provided that claims were sufficiently substantiated (NSW Food Authority, Griffins Food) and consumer choice would not be limited by exclusive claims (Diabetes Aust, GI Ltd).

Possible negative effects if exclusive claims were prohibited

One submission supposed problem within the framework, because a perceived lack of exclusivity would be a disincentive for investment (Fonterra). Another submission saw some problems within the framework, but also perceived some opportunities for licensing new products and technologies (Nutra-Life H&F).

A number of submissions presented the opinion that companies deserved a return from their effort of establishing claims (Heinz Aust./Heinz Watties NZ, National Starch, Solae Comp, ASMI). They stated that exclusive claims would ensure return on research and development investments; otherwise companies might be hesitant to apply for claims (Nestle, Cadbury Schweppes, CML, CSIRO - HSN) and the framework may become unworkable in this regard (PB Foods). Exclusive access to a claim could be an incentive for manufacturers to develop novel foods that improve health (National Starch, Solae Comp).

Other issues

- It was submitted that where several companies were working on the same claim, it would be unfair for a competitor to gain an advantage by getting their application approved first (Cadbury Schweppes);

- Sunset clauses and prioritisation criteria should be considered to allow investment return, as well as public health benefit and availability of claims to whole industries (Fonterra);

- It was suggested that a register of companies and corresponding claims should be available to industry (Cadbury Schweppes);

- Where an established claim is used by other organisations criteria for its use should be established (Fonterra); and

- Frequent and costly review of claims may stifle innovation (CML).

CHAPTER 5: CONSUMER RESEARCH

5.1 WORDING ISSUES

Question 60

Are you aware of any additional consumer research on nutrition, health and related claims?

Out of 147 submitters, 29.9% (44 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	15	10	3	-	28
Government	5	1	-	-	6
Public health	6	1	-	-	7
Consumers	1	-	-	-	1
Other	2	-	-	-	2
Total	**29**	**12**	**3**	**0**	**44**

Overview

A variety of references were provided from a number of submitters.

References provided by AFGC

- Calfee, JE and Pappalardo, JK (1991) Public policy issues in health claims for foods. J public Policy and marketing 10:33-53
- Ippolito, PM and Mathios, AD (1989) Health claims in Advertising and labelling, A study of the Cereal market, Bureau of Economics Staff report, Federal trade commission, Washington DC.
- Noakes, M and Crawford, DA The Nationals Heart Foundation's 'Pick the Tick' Program, consumer awareness, attitudes and interpretation. (1991) Food Australia 43:262-66
- Williams P, McHenery J, McMahon A & Anderson H, 2001. Impact evaluation of a folate education campaign with or without the use of a health claim. Australia New Zealand Journal of Public Health, 25:396-404.
- Levy AS, Derby BM and Roe BE, 1997 Consumer Impacts of Health Claims: An Experimental study. FDA CFSAN, Division of market Studies, Washington DC (AFGC)
- Garretson JA and Burton S, 2000 Effects of nutrition facts panel values, nutrition claims, and health claims on consumer attitudes, perceptions of disease related risks and trust, J Public Policy and Marketing 19: 213-17
- Levy, AS, Derby, BM, and Roe, BE, 1997 Consumer impacts of health claims: an experimental study. FDA CSFAN, Division of Market Studies, Washington DC
- www.foodstandards.gov.au/mediareleasespublications/speeches/speeches2004/robknowlesfoodsafety2590.cfm

- Murphy D, Hoppock TH and Rusk MK (1998) Generic copy test of food health claims in advertising. Federal Trade Commission, Washington DC
- Health Canada 2000. Health claims focus testing (2000), nutrition Evaluation Division, Food Directorate, Health Canada
- Kozup JC, Creyer EH and Burton S (2003). Making healthful food choices: The influence of health claims and nutrition information on consumer evaluations of packaged food products and restaurant menu items. J Marketing 67: 19-34
- National Consumer Council 92003) Bamboozled, Baffled and Bombarded, consumer views on voluntary food labelling, National Consumer Council, London

The AFGC considered that the views expressed by FSANZ authors of this section and the evidence used are interned to diminish the value of health claims as a tool for assisting consumer choice. They submitted that they authors have been: 1) selective in presenting evidence; and 2) biased in drawing conclusions from that evidence; and can only conclude that the intent is to make a case for restricting the ability of food companies to make truthful health claims about food products.

The AFGC also noted that contrary to the conclusion drawn by FSANZ concerning the limitation of health claims for consumer information and choice, the totality of the evidence points to the following conclusion: "Truthful statements which communicate the health benefit of a food to consumers need to be relevant to the target consumer and consistent with other information on the label, in order for it to maximise the return for the consumer" (supported by GW Foods, MasterFoods Aust. NZ and Nestle).

References provided by NSW DoH – N&PA Branch, SA DoH, WA DoH and Horticulture Aust:

- Wansink, Brian (2003) How do front and back package labels influence beliefs about health claims? The Journal of Consumer Affairs 37 (2)
- Garretson, Janet A et al (2000) Effects of nutrition facts panel values, nutrition claims, and health claims on consumer attitudes, perceptions of disease-related risks, and trust. Journal of Public Policy & Marketing 19 (2)
- Byrd-Bredbenner, Carol et al (2000) Consumer understanding of US and EU nutrition labels British Food Journal 102 (8)
- Roe, Brian et al (1999) The impact of health claims on consumer search and product evaluation outcomes: Results from FDA experimental data Journal of Public Policy & Marketing 18 (1)
- Rayner, Michael et al (2001) Consumer use of health-related endorsements on food labels in the United Kingdom and Australia Journal of Nutrition Education 33 (1)
- Food Standards Agency (2002) Health claims on food packaging Consumer-related qualitative research
- Rayner, Michael et al (2004) The origin of Guideline Daily Amounts and the Food Standard Agency's guidance on what counts as 'a lot' and 'a little' Public Health Nutrition 7 (4)
- Choice (2004) Health Claims: Food or medicine? Choice Magazine 2004. Accessed online from www.choice.com.au 12/10/04 (provided by WA DoH).

Research information provided by DAA (supported by NZDA):

- (1) Fulmer et al. Consumer knowledge, understanding and attitudes to health claims on food labels. JADA 1991; 91:166-171
- (2) CSIRO Information needs and concerns in relation to food choice. CSIRO/NHF
- (3) American Dietetic Association. Position Paper of the ADA: Functional Foods. JADA 2004; 104:814-826
- (4) Wansick, B. How do front and back package labels influence beliefs about health claims. J. Consumer Affairs 2003; 37:305-312
- (5) Rudd J, Glanz K. How individuals use information for health action: consumer information processing. In Health Behaviour and Health Education. Ed Glanz, Lewis and Rimer. Jossey-Bass. 1990

DAA considered there to be little evidence on consumer behaviour in relation to health claims and existing research suggested that health claims are not always regarded as a credible source of information by consumers and have not fulfilled the stated aim of education consumers. For example in the USA, Fulmer et al (1) found consumer understanding of health claims on breakfast cereals to be low, with little overall improvements in knowledge of the effects of dietary fibre. Australian research conducted by the CSIRO found that, while there was in principle support for health claims as an aid to food choice, consumers were suspicious of health claims by manufacturers (2).

DAA noted that as health claims are not statements of certainty, but rather statements of putative benefit, wording tends to be lengthy. For example, one approved US claim is two sentences long and contains nearly 60 words (3). Available published research on the effectiveness of format and wording on food packages suggests that too much information is confusing, raising questions about the effectiveness of lengthy health claims (4). The same research found US consumers supported a combination of short health claims on the front of food packages with longer, more complex information on the back. However, no similar research exists for the Australian and New Zealand context and it should not be assumed that Australians and New Zealanders would react in the same way as Americans. They added that simple and unambiguous food labelling is consistent with current understanding of consumer processing information psychology (5) (DAA supported by NZDA).

Research information provided by NCEFF

NCEFF noted that relying on research with consumers in other countries may not always be appropriate or relevant however acknowledges that there is a considerable body of research in addition to that cited in the IAR. Common findings emerging from these studies are:

Consumers believe health claims are useful:

- Tessier S, Edwards C, Morris S. Use and knowledge of food labels of shoppers in a city with a high proportion of heart disease. J Consum Stud Home Econom 2000:24; 35-40.

- Fullmer S, Geigher C, Parent C. Consumers' knowledge, understanding and attitudes toward health claims on food labels. J Am Diet Assoc 1991:91; 166-171.
- Shine A, O'Reilly S, O'Sullivan A. Consumer use of nutrition labels. Br Food J 1999b; 99: 290-296.
- Worsley A. Which information do shoppers want on food labels? Asia Pacific J Clin Nutr 1996; 5: 70-78.

Consumers are naturally sceptical about the truth of claims:

- Consommation Logement et Cadre de Vie and Union Feminine Civique et Sociale, Les Allegations Nutritionelles et les Allegations Sante. 2003, CLCV and UFCS: Paris.
- Szykman L, Bloom P, Levy A. A proposed model of the use of package claims and nutrition labels. J Pub Pol Marketing 1997; 16: 228-241.
- National Institute of Nutrition. Tracking Nutrition Trends V. Ottawa: National Institute of Nutrition; 2004.

Better-educated consumers and females are more likely to use health claims:

- Fullmer *et al*, 1991 (as above)
- Nayga R. Determinants of consumers' use of nutritional information on food packages. J Agric Appl Econ 1996; 28: 303-312.

Consumers do not like claims that are heavily qualified with words like 'may' or 'could':

- National Consumer Council, Messages on Food. Consumers' use and understanding of health claims on food packs (PD 09/D1/97). Available at http://www.ncc.org.uk/pubs/pdf/messages_on_food.pdf. 1997: London.
- Health Canada, Health claims focus testing. 2000, A report prepared by Goldfard Consultants for Nutrition Evaluation Division, Food Directorate, Health Canada: Ottawa. p. 16.

Consumers are suspicious of long claims and prefer succinct claims or split claims:

- Svederberg E, Consumers' views regarding health claims on two food packages. 2002, Department of Education, Lund University (available at www.pedagog.lu.se/forskning/skrifter/report21.pdf): Lund.
- National Consumer Council, 1997 (as above).
- Health Canada, 2000 (as above).
- National Institute of Nutrition. Nutrition labelling: perceptions and preferences of Canadians. 1999, National Institute of Nutrition: Ottawa.
- Wansink B. How do front and back package labels influence beliefs about health claims? J Consum Aff 2003; 37: 305-316.

Their submission also notes the key finding of NCEFF research to measure attitudes and intention to the consumption of omega-3 enriched foods (Patch C, Tapsell L, Williams P. Attitudes and intentions towards purchasing novel foods enriched with omega-3 fatty acids. J Nutr Ed Behav (in press)) was that belief about the likely

efficacy of the food was found to be the sole predictor of intention to eat these products. Therefore efforts to influence consumers may be significantly effected by the ability to communicate a cause and effect relationship between a specific product or ingredient and a health benefit. It was suggested that the role of health claims might be important in the promotion of these foods.

Masters students of the University of Wollongong undertook a recent study of consumer reactions to different formats of health claims in a supermarket intercept study. Appendix 4 of their submission provided a confidential summary of the preliminary findings from this research (NCEFF).

An annotated Bibliography of studies of consumer use of health claims was included as Appendix 2 of the NCEFF submission. This has the following references:

Surveys and focus group studies:

- Fullmer et al, 1991 (as above).
- Worsley A (1996). Which information do shoppers want on food labels? *Asia Pacific J Clin Nutr*. 5: 70-78.
- Nayga, 1996
- Szykman *et al*, 1997.
- Mayer JA, Maciel TL, Orlaski PL, Flynn-Polan G (1998). Misleading nutrition claims on cracker packages prior to and following implementation of the Nutrition Labeling and Education Act 1990. *Am J Prev Med* 14: 189-195.
- Shine A, O'Reilly S, and O'Sullivan A (1999). Consumer use of nutrition labels. *Br Food J*. 99: 290-296.
- National Institute of Nutrition (1999). Health Claims in Canada - Taking the Consumer Pulse. Institute of Nutrition, Ottawa.
- Tessier et al, 2000.
- National Institute of Nutrition (2000). Consumer awareness of and attitudes toward functional foods. National Institute of Nutrition, Ottawa.
- Mason M and Scammon D (2000). Health claims and disclaimers: extended boundaries and research opportunities in consumer interpretation. *J Pub Pol Marketing*. 19: 144-150.
- Brecher S, Bender M, Wilkening V, McCabe N, and Anderson E (2000). Status of nutrition labeling, health claims, and nutrient content claims for processed foods: 1997 Food Label and Package survey. *J Am Diet Assoc*. 100: 1057-1062.
- Svederberg, 2002.
- Urala N, Arvola A, and Lahteenmaki L (2003). Strength of health-related claims and their perceived advantage. *Int J Food Sci Tech*. 38: 815-826.
- Bech-Larsen T and Grunert K (2003). The perceived healthfulness of functional foods. A conjoint study of Danish, Finnish and American consumers' perceptions of functional foods. *Appetite*. 40: 9-14.
- Caswell JA, Ning T, Liu F, Mojduszka EM (2003). The impact of new labelling regulations on the use of voluntary nutrient-content and health claims by food manufacturers. J Pub Pol Marketing 22:147-158.

- Consommation Logement et Cadre de Vie (CLCV) and Union Feminine Civique et Sociale (EFCS) (2003). Les Allegations Nutritionelles et les Allegations Sante, Paris.
- LeGault L, Brandt M, McCabe N, Adler C, Brown A, and Brecher S (2004). 2000-2001 Food label and package survey: an update on prevalence of nutrition labeling and claims on processed, packaged foods. *J Am Diet Assoc*. 104: 952-958.
- National Institute of Nutrition and Canadian Food Information Council. (2004). Tracking Nutrition Trends V. National Institute of Nutrition, Ottawa.

Experimental studies:

- Ford G, Hastak M, Mitra A, and Ringold D (1996). Can consumers interpret nutrition information in the presence of a health claim? A laboratory investigation. *J Pub Pol Marketing*. 15: 16-27.
- Keller S, Landry M, Olson J, Velliquette A, Burton S, and Andrews J (1997). The effects of nutrition package claims, nutrition facts panels, and motivation to process nutrition information on consumer product evaluations. *J Pub Pol Marketing*. 16: 256-269.
- Roe B, Levy A, and Derby B (1999). The impact of health claims on consumer search and product evaluation outcomes: results from FDA experimental data. *J Pub Pol Marketing*. 18: 89-105.
- Mitra A, Hastak M, Ford G, and Ringold D (1999). Can the educationally disadvantaged interpret the FDA-mandated nutrition facts panel in the presence of an implied health claim? *J Pub Pol Marketing*. 18: 106-117.
- Andrews J, Burton S, and Netemeyer R (2000). Are some comparative nutrition claims misleading? The role of nutrition knowledge, ad claim type and disclosure conditions. *J Advert*. 29: 29-452.
- Garretson J and Burton S (2000). Effects of nutrition facts panel values, nutrition claims, and health claims on consumer attitudes, perceptions of disease-related risks, and trust. *J Pub Pol Marketing*. 19: 213-227.
- Bone P and France K (2001). Package graphics and consumer product beliefs. *J Bus Psychol*. 15: 467-489.
- Maynard L and Franklin S (2003). Functional foods as a value-added strategy: the commercial potential of "cancer-fighting" dairy products. *Rev Agr Econ*. 25: 316-331.
- Kozup J, Creyer E, and Burton S (2003). Making healthful food choices: the influence of health claims and nutrition information on consumers' evaluations of packaged food products and restaurant menu items. *J Marketing*. 67: 19-34.
- Wansink B (2003). How do front and back package labels influence beliefs about health claims? *J Consum Aff*. 37: 305-316.

Purchase behaviour outcome studies:

- Moorman C (1996). A quasi experiment to assess the consumer and informational determinants of nutrition information processing activities: the case of the Nutrition Labeling and Education Act. *J Pub Pol Marketing*. 15: 28-44.

- Rayner M, Boaz A, and Higginson C (2001). Consumer use of health-related endorsements on food labels in the United Kingdom and Australia. *J Nutr Ed*. 33: 24-30.
- Marquart L, Weimer K, and Jacob B (2001). Solid science and effective marketing of health claims. *Nutr Today*. 36: 107-111.

Health impact evaluation:

- Ippolito P, Mathios A (1991). Health claims in food marketing: evidence on knowledge and behavior in the cereal market. *J Pub Pol Marketing*. 10: 15-32.
- Watson M and Watson L (2001). An evaluation of the impact of the folate and neural tube defects health claim pilot. *Aust J Nutr Diet*. 58: 236-241.
- Williams P, McHenery J, McMahon A, and Anderson H (2001). Impact evaluation of a folate education campaign with and without the use of a health claim. *Aust N Z J Public Health*. 25: 396-404.
- Kim S-Y, Nayga R, and Capps O (2001). Food label use, self-selectivity, and diet quality. *J Consum Aff*. 35: 346-363.
- Zarkin G, Dean N, Mauskopf J, and Williams R (1993). Potential health benefits of nutrition label changes. *Am J Public Health*. 83: 717-724.
- McCullum C and Achterberg C (1997). Food shopping and label use behavior among high school-aged adolescents. *Adoles*. 32: 181-197.
- Kozup J, Burton S, and Creyer E (2001). A comparison of drinkers' and nondrinkers' responses to health-related information presented on wine beverage labels. *J Consum Policy*. 24: 209-230.

References provided by Tas DoH&HS:

- UK Food Standards Agency (2002) and FSANZ research indicated consumer confusion with nutrient and health claims (Paterson 2003a)
- MJ Watson and LF Watson (2000) Outcome Evaluation of the folate-neural tube defect health claim pilot; final report, ANZFA, Canberra
- Fulmer et al (1991). Consumer knowledge, understanding and attitudes to health claims on food labels. JADA; 91:166-171
- Paterson D. et al, 2003a, A qualitative consumer study related to nutrition content claims on food labels, FSANZ (CO3037)
- Food Standards Agency, 2002, Health claims on food packaging; consumer related qualitative research, final report, COI Communications, London (Project f016) http://www.food.gov.uk/news/newsarchive/2002/nov/98783
- (Dr R Stanton also provided this reference.)

It was considered by Tas DoH&HS that there is little evidence on consumer behaviour in relation to health claims. They recommended that more research is required in this area to ascertain how consumers regard health claims. The research available suggests that health claims are not always regarded as a credible or useful source of information by consumers and do not fulfil the stated aim of educating consumers. They noted the Folate-Neural Tube Defect Health Claim evaluation, which found that only 17% of consumers preferred health claims as a primary source of health information (Watson &Watson 2000). They also noted that Fulmer et al

(1991) found consumer understanding of health claims on breakfast cereals to be low, with little overall improvements in knowledge of the effects of dietary fibre.

Other information provided by submitters

Diabetes Aust. and Gl Ltd provided information about their research conducted through their involvement with the GI Symbol Program (News poll Market Research, Omnibus Studies of main grocery buyers 18 years and over, 2002 - 04) (average of 500 people/survey), in the five mainland capital cities. Results showed 81-85% considered the GI useful for "everyone" for general health and approximately 70% of respondents said it was either "somewhat" or "very likely" that they would use the GI symbol when shopping for food.

NSW Food Authority recommended referring to research conducted by the NHF.

CSIRO – HS&N commented on experimental evidence that such labelling does have an impact on perceptions and preferences for products, e.g. work done by CSIRO on fibre labels (Mialon et al, 2002).

Heinz Aust./Heinz Watties NZ have conducted a consumer research project regarding lycopene claims (2004) – some results were included in their submission and the full report can be provided upon request.

ASMI considered that the food industry and regulators would need to examine the principles of Consumer Focussed Labelling as implemented in the OTC and Complementary medicines industry as a way of effectively delivering health claims on labels.

National Foods agreed that consumer understanding of claim wording should be investigated, particularly for pre-approved claims and they recommended that FSANZ seek input from marketing experts for useable, understandable and clear claims. They suggested that those claims most likely to have public health impact are those that will be used by food industry. They thought that qualified claims to be lengthy and negative and unlikely to be used or fit onto small packs. They pointed out they commission consumer research on specific nutrition claims relevant to their brands but stated this research is confidential although may be available if FSANZ is interested in a specific area.

It was noted by two other submitters that there is extensive research into a range of nutrition messages but not health claims *per se*. They recommend that FSANZ should commission well-recognised researcher(s) to conduct this research and they noted Sydney-based candidates well versed in this research field - Liz Dangar and Julie Dang (National Starch, Solae Comp.).

Not aware of any additional research

Submitters who commented that they were not aware of any additional research were NCWA, TCCA, Dr C Halais, Cadbury Schweppes, CML, CHC, Dairy Aust., F&B Importers Assoc., Goodman Fielder, Parmalat Aust., ASA, NPANZ, Assoc. of NZ

Advertisers, Cadbury Confectionery, Naturo Pharm, NZTBC, NZJBA, Frucor, NZ Dairy Foods, and NZFSA.

It was recommended that consideration must be given to establishing consumer focus groups to test the interpretation of both general level and high level claims so as to avoid any ill-informed health decisions. It was also noted that consumers must not be misled into believing that their health care requirements can be solely obtained from eating specific foods (CHC).

NZFGC have asked member companies to provide evidence of any additional consumer research on nutrition health and related claims and will forward any information on that come to hand to FSANZ.

Other comments provided but not in direct response to the question

The Tas DoH&HS considered that as the introduction of health claims into Australia and NZ aims to encourage consumers to make health food choices, Australian and NZ research is required to appreciate how consumers understand health claims in terms of wording, context, length of health claim statement and where appropriate, warnings to avoid harm.

The SA DoH noted that FSANZ is undertaking consumer market research regarding consumer's perceptions of nutrition and health claims and they believe that this data is critical in informing the regulatory system and it should be released as soon as possible.

Food Technology Assoc. of Vic. recommended that any assessment of nutrition, health and related claims should be based on Australian conditions for the Australian population and not rely on overseas population studies where different and varying dietary, health, hereditary, personal habits, lifestyle and environmental factors etc could provide data that is irrelevant to Australians.

The DAA recommended that health claims be trialled on consumers representative of all socio-economic backgrounds and that they be asked open-ended questions relating to health claims which would allow them to respond subjectively.

The Consumers' Institute of NZ noted that they are pleased that FSANZ is commissioning research looking at consumer attitudes and perceptions of health claims. They considered it important that health claim messages are pre-tested with the intended target audience, independently of industry.

The ACA stated that overall, the consumer research does not provide a convincing argument to support the use of health claims for providing consumers with information to enable them to make an informed choice, let alone improving health and nutrition. They added that the evaluation of the pilot health claim on folate shows that education was more successful than the health claim in communicating information about the consumption of folate and its role in preventing neural tube defects.

SA DoH pointed out there has been one systematic review of consumer understanding of nutrition labelling (European Heart Network, 2003), and it concluded that consumers have problems understanding nutrition labels e.g. they are confused by some types of information, have difficulty placing an individual product in the context of their overall diet, and have generally poor or moderate levels of nutrition knowledge. They referred to the WHO report on nutrition labels and health claims (2004a) which discusses the complexities of consumers understanding of nutrient content and health claims and the difficulties in particular of regulating health claims.

SA DoH believed food regulation must be considered in the context that food manufacturers use nutrition and health claims in advertising their products and doesn't think this has been adequately addressed: claims are not being sought in a value-free environment. They did not believe there has been consideration of the food industries' influence on food regulation and its effect on public health principles that should support the food supply. They highlighted that the WHO report touches on this area (WHO 2004a, pvii) by quoting "commercially, the outcome of the use of health claims has been mixed. Evidence from Europe and the US suggests that such claims can increase market share, but there have been significant market failures for foods without health claims". Also highlighted was the review commissioned by the UK Food Standards Agency (Hastings, 2003) 'Does food promotion influence children: a systematic review of the evidence'.

Cancer Society NZ noted that it is not acceptable to just develop claims based on nutritional science. Consumer testing should be undertaken to ensure consumers understand claims and that understanding translates to healthy changes in behaviour. Usability testing of health claims is required rather than just assessing consumer preference of wording and understanding as evidence suggests that consumer can 'parrot back' messages without actually being able to action changes (Hunt, p., Gatenby, s., & Rayner, M. (1995)). They added that it is critical to undertake consumer testing, independently of industry, in those consumer groups most vulnerable to ensure that inequalities in health are not further widened but the use of health claims (also Auckland Cancer Society; Cancer Society NZ – Waikato/Bay of Plenty Div, Cancer Society of NZ – Rotorua Branch).

OAC NZ stated that evidence suggests some nutrition, health and related claims confuse consumers and do not lead to healthy diets, e.g. "%fat-free" claims used by many food sellers. They quoted The British Consumers' Association report "Food labels- the hidden truth", that people find the use of these claims very confusing and when shown a range of claims about fat content 53% of respondents thought that the 90%fat-free pack was lower in fat than the low-fat one which had 3% fat." Also* quoted was a study published by Fontaine et al (2004) which found "A high intake of foods with reduced-fat claims could lead to a relatively high energy-dense diet and thus promote weight gain." OAC NZ noted plans of FSANZ for consumer research and urges that fat claims such as these be included in the investigation. They recommended FSANZ disallow such claims if the research confirms consumers are confused by or misunderstand such claims. Ensuring consumers understand about total energy is essential if overweight and obesity are to be prevented. OAC NZ stated that many consumers note only the fat-free claim and fail to check the energy content on the NIP. Reduced and fat-free claims are presently found on foods that are not low sugar or energy.

CHAPTER 6: EDUCATION

Question 61

What do you consider to be the essential components of an education strategy for nutrition, health and related claims?

Out of 147 submitters, 48.3% (71 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	26	14	4	2	46
Government	6	1	-	-	7
Public health	8	4	-	-	12
Consumers	2	-	-	-	2
Other	3	1	-	-	4
Total	**45**	**20**	**4**	**2**	**71**

Overview

Essential components of an education strategy for nutrition and health claims included defining the target groups, understanding their knowledge (via quantitative survey or focus groups), developing communication campaigns, testing and modifying campaign messages for comprehension, defining relevant communication vehicles, implementing communication/education programmes, and defining evaluation methods to test the effectiveness of the messages and the campaigns. Another suggestion related to a management system that is independent of the food industry. Many of the submitters expressed recommendations relating to industry and consumer education, stakeholders and other aspects of communication (e.g. use of websites).

Steps of an education strategy

A number of submitters proposed the following steps to be essential components of an education strategy for food nutrition and health claims (DAA, NZDA, GI Ltd, Diabetes Aust., National Starch, Solae Comp.):

- Define the target groups– consumers, media, food manufacturers, retailers, health professionals (e.g. public nutritionists, dietitians, GP's);
- Understand their knowledge (via quantitative survey or focus groups);
- Develop key campaign messages;
- Test campaign messages for comprehension; modify where appropriate/necessary (National Starch, Solae Comp only);

- Define relevant communication vehicles (based on effectiveness of reach to target group, for example TV and print advertising, Internet, brochures, posters, seminars targeted to different audiences, media releases);

- Develop and implement communication/education programme; and

- Define evaluation method to test effectiveness of the messages and campaign.

NZDA added that another essential component for an education strategy is a management system that is independent of the food industry. This is necessary for 'buy-in' from stakeholder groups.

Diabetes Aust. added that to create partnerships, consistency and collaboration is needed between generators of approved health claims and key public health programmes to maximise the 'campaign' dollar.

A number of other submitters agreed that the first priority for an education strategy is to identify the target audience and develop appropriate messages for that target audience (ABC, GW Foods, National Foods, AFGC supported by MasterFoods Aust. NZ, Parmalat Aust. and Nestle).

Dairy Aust. recommended the communication campaign should:

1. Explain the purpose of health claims (to improve public health).
2. Clarify the qualifying process (substantiation) undertaken by a manufacturer or organisation to be able to communicate a claim.
3. Assure that claims have been objectively evaluated and developed by FSANZ rendering them legal and based on credible scientific evidence.
4. Explain that claims are widely accepted internationally and the adoption of this type of labelling will bring Australia in line with the global market.

They added that the focus for enhancing 'general' understanding of health claims should be through a 'communication' strategy, rather than an education strategy, targeting consumers, industry and health professionals.

Other components of an education strategy

Goodman Fielder suggested that many examples of permitted claims and formats will make the communication more effective.

Two submitters noted the Folate-Neural Tube Defect (NTD) Health Claims Pilot outcome evaluation, which states that "a folate-NTD health claim (and probably other health claims should they be implemented) would be more effective if accompanied by other consumer education." (Watson & Watson 2000, p101) (Tas DoH&HS, SA DoH, WA DoH).

ASMI considered that the key components of an education strategy for nutrition and health claims include:

- The place of claims in context of total diet;
- The importance of warnings tied to substance and conditions (they added that this has not been adequately addressed in the present consultation);
- The importance of health professional advice; and
- The role labelling and advertising has in conveying this information.

CML suggested that there is an information session for manufacturers and consumers about the new claims and the framework system, complaints process etc, as well as communication of advice of new claims that are approved. They also suggested linking the claims issue to broader national public health strategies (i.e. SIGNAL).

It was felt that special attention should be given to an education strategy for industry, as well as to other measures that could help with the transition, as there will be significant implications for existing claims. In line with this it was recommended that an industry implementation/advisory group be set up to act as a resource to assist industry make the transition. This group could report to the ISC and have a 1800 call line and workshops to help (Sanitarium Health Food Comp.).

Support for the five suggestions for promotion of health claims, as recorded on page 72 of the Initial Assessment Report, was expressed by NHF Aust., NHF NZ and DAFF.

Canterbury DHB considered it important that the emphasis is on packaged, fresh and non-manufactured food so as not to present an unbalanced view, i.e. what does it mean if a product does not have a claim?

Hort. & Food Research Instit. of NZ supported this and recommended that sources of information are particularly important for fruit and vegetable products often unlabelled. They suggested the use of sources of information such as that provided by manufacturers and producers about nutrition, composition and research, popular press, NGOs and education programmes, e.g. '5+ a Day'. They also recommended that the standards take care to ensure the flow of information from these sources is factual while being uninhibited.

Fonterra suggested communication of the framework would be an essential component of an education strategy (this was supported by Mainland Products).

Unilever Australasia suggested that the essential components of an education strategy would depend on who the target audience will be, whereas NZ MoH said it would depend on the regulatory approach taken in the Food Standards Code, and NZFGC said it would be dependent on the type of claim being made. NZ MoH added that education is likely to have many components. NZFGC also noted that the type of messages, promotional material, advertisements etc. would be dependent on the recipients of the claim.

NZFGC further explained that the components for a folate claim to reduce neural tube defects would be different from a calcium claim linked to osteoporosis. They added that it might also be dependent on whether or not it is a high or general level claim.

Tas DoH&HS noted that there should be an evaluation of messages and the impact on consumer behaviour and food choices.

Consumer education

A recommendation was made that consumer education needs to focus on providing information regarding making informed choices for healthy living based on the food pyramid. It needs to clearly define that foods cannot replace controlled therapeutic supplementation and therefore consumers should not be misled into believing that health requirements are being provided by certain foods (CHC).

It was felt that it is essential that both industry and consumers are educated about claims and the framework, and that there is consistency between what both industry and consumers understand about the standards/guidelines and their wording (Aussie Bodies).

NSW DoH – N&PA Branch suggested a consumer multi-media campaign that is aimed to communicate the basic facts about the claims system and how they can be used to enhance a healthy eating pattern.

Concern was expressed that a large proportion of the community have little knowledge or understanding of the current NIPs and a program focusing on this area is a necessary first step. It was stated that the research quoted in the IAR (Levy, Derby and Roe 1997) suggesting that consumers were less likely to read NIPs in the presence of a health claim on the front of a food package highlights the need for a meaningful and broad education program. Therefore it was proposed that there is a well-funded, high quality education campaign for both the public and health professionals on nutritional information, health claims and healthy eating. A single one-off education program – even a high impact program – would be of very limited benefit outside the context of such a broad and ongoing program. Currently nutrition education programs are limited in scope and reach – with some fruit and vegetable promotion programs operating in some states to varying levels (TCCA).

Nutrition Aust. agreed that the campaign should be ongoing to be effective.

NCWA suggested that an essential component of an education strategy should provide increased knowledge to consumers about recommended dietary intakes and when supplements may be appropriate.

Similarly a suggestion was made for consumers, that the national dietary guidelines and food selection guide should form the basis of education activity. Clear explanations of nutrition health and related claims that are permitted and simple interpretations are needed, within the context of understanding food labels (Horticulture Aust., SA DoH, WA DoH).

An education campaign that would support consumer understanding of the different types of claims and encourage overall food choice which is in keeping with the dietary guidelines established by the NHMRC is needed (NSW Food Authority).

Wyeth Aust. recommended education strategies should include targeted messages to the wider community and to particular at-risk populations.

Sanitarium Health Food Comp believed the strategy needs to include an explanation of what health claims are and what they mean, as well as guidance on how to use the health claim in the context of a healthy and balanced diet. They cited the example that Sanitarium worked alongside FSANZ to update consumers about the new labelling requirements of the 2002 FSC.

Nutrition Aust. noted the need to address those issues that cause the most confusion to consumers and have the most potential for misinterpretation of claims. They added that consumer research conducted by FSANZ would be helpful in constructing an effective program.

ANIC considered it would be essential for the ability for industry to refer to diseases and biomarkers in educational material for consumers that discusses food and products that are eligible to carry the health claim.

Education for different sectors

Some submitters suggested the specific topics that they thought should be directed towards each type of sector.

It was considered that an education campaign should target all stakeholders/sectors of the food industry, health professionals, consumers (Tas DoH&HS, Dairy Aust.) and enforcement agencies (Horticulture Aust., SA DoH, NCEFF) so that all of these stakeholders are fully informed as to the requirements of the system and the interpretation of the messages (PHAA (supported by ACA), Monash Uni – N&D Unit). NSW DoH – N&PA Branch also considered it very important that the education strategy is well thought out and adequately resourced to effectively target consumers, food industry and health professionals.

Nutrition Aust. also recommend the campaign involve stakeholders, these being public health groups, health professionals, educational institutions, industry, media and retailers).

For the food industry (primary producers, food manufacturers, brokers, wholesalers and retailers) - education for all sectors is needed to ensure they fully understand what is required if they wish to make nutrition health or related claims (Horticulture Aust., SA DoH, WA DoH).

For health professionals - education on claims is needed in the context of providing dietary advice, and assessing risk factors and biomarkers. This is to provide adequate information to assist health professionals dealing with consumer concerns. This is particularly relevant for nutritionists, dietitians and GPs (Horticulture Aust., SA DoH, WA DoH).

For enforcement agencies - education is needed on the safety issues of the nutrition health and related claims standard. It is possible that the agencies won't regard the claims as a priority area unless the public health nutrition implications of vague, false or misleading claims are fully communicated (Horticulture Aust., SA DoH, WA DoH).

National Foods suggested messages are directed to the food industry (including the awareness & utilisation of regulatory system, substantiation processes, complaint resolution procedures), health professionals (including awareness and boundaries of regulatory system) and consumers (including awareness & confidence in government food regulation).

It was recommended that the food industry must find the education campaign user friendly; consumers need to understand the meanings behind the claims and the purposes of the standard, and health practitioners need to be conscious of their role in this context (NCEFF).

CHC thought that education should focus on consumers, marketers and manufacturers. They added that the food industry has a very poor understanding of the difference between a health claim and a therapeutic claim that may lead to compliance problems.

FSANZ was encouraged to ensure that the strategies that are developed are appropriate for nutritionally vulnerable groups such as Maori, Pacific Islanders and those in lower socioeconomic groups. The strategies should be integrated into any broader social marketing approach to nutrition that may be developed in either country (NHF Aust., NHF NZ).

Methods of delivery

A number of submitters made recommendations regarding the way the education campaign should be delivered, such that the essential components of an education strategy should:

- Contain messages that are appropriate and targeted, with regular evaluation to ensure that the messages are being received (Griffins Foods).;
- Be based on simplicity, awareness etc (Bakewell Foods);
- Be that it is kept simple and consistent in terms of the message (NZ Dairy Foods);
- Deliver consistent messages (Nutrition Aust.);
- Have wording should is simple, concise and specific (Dairy Aust.); and
- Consist of clear and concise messages for a targeted audience (Goodman Fielder).

Means of communication

The use of an independent web site resource on which this information is kept and readily accessible to the general public, similar to the web based access for medicine data sheets, was recommended. This would be useful for industry, advertisers and ad agencies and people who may approve advertisements. In addition it was recommended that FSANZ undertake television advertising and produce and disseminate educative material for the public on a broad front. Consultation with industry would ensure complementary advertising and promotion (ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, NZTBC, NZ Magazines, Naturo Pharm).

NZFGC submitted that using companies, FSANZ and other government agencies websites would be an effective way of disseminating education material to some sectors of the community. They added that the media should be engaged. They also suggested that once a standard is enacted it should be included in courses for food technologists, nutritionists, dieticians and doctors.

The CMA recommended that the education strategy should use established marketing communication techniques to identify the target audience, messages and cost-effective mechanisms for information delivery (this was supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA).

It was suggested that the Nutrition Labelling Toolkit, developed by Health Canada after extensive consultation with consumers, is a useful model that FSANZ should consider. The toolkit was distributed free to educators across Canada, with production costs of $15-20 each, not including staff time to develop materials. The Toolkit contained: a booklet, a CD PowerPoint presentation, tear out fact sheets, and Pamphlets; and had a website with an interactive quiz. The Canadian Dietetic Association and Diabetes Association were also funded to develop more targeted education material for people with low literacy and people with diabetes (approx $200,000) (NCEFF).

NZ Dairy Foods said that the communication must flow through popular media (magazines, newspapers, radio, television etc.) and it must include a whole diet approach to health.

Financial resources

It was stated that adequate financial resources must come from the federal government to conduct a comprehensive campaign via GPs, schools, community health centres, individual doctors and others. This submitter also suggested that a tax on foods bearing health claims could be made to raise money if there is an inadequate budget for education (Dr R Stanton).

A number of other submitters also noted that the campaign should be adequately funded or resourced (NSW Food Authority, Nutrition Aust., Tas DoH&HS, Monash Uni – N&D Unit, PHAA (supported by ACA), SA DoH, WA DoH).

Some submitters noted experience from the Folate-Neural Tube Defect Health Claims Pilot, which indicated that education can account for over half the total costs ($550,000 in this case) of the whole system (Monash Uni – N&D Unit). The report of the process evaluation of the Folate-Neural Tube Defect Health Claims Pilot noted, "if health claims are perceived as a public health intervention, then it is logical to expect a well-resourced public education campaign." (ARTD, 1999) (PHAA (supported by ACA), SA DoH, WA DoH).

Large education campaign not necessary

It was submitted by CSIRO – HS&N that there doesn't need to be anything other than having a web link to a site, which explains the process in simple terms. This is because the whole point of health claims is that they are simple and easy to interpret and an education campaign defeats this purpose. However they suggested that education might be needed for industry but not for consumers.

It was also suggested that if appropriate consumer research is conducted around the wording of the claims, then these should be stand-alone and not require accompanying explanation. Therefore, funds should not be diverted for a specific education campaign (Auckland Reg. PHS).

Responsibility for undertaking this education

Some submitters included who they thought should be responsible for the education strategy, in answer to this question. Their comments were as follows:

Five submitters recommended that FSANZ consider NCEFF take on a coordinating role in developing an education strategy for nutrition and health claims (GW Foods, AFGC supported by MasterFoods Aust. NZ, Parmalat Aust., Nestle). Goodman Fielder also supported this recommendation and suggested NCEFF as a group that could be considered to assist with an education program.

Sanitarium Health Food Comp felt that the role of education should be the responsibility of industry, FSANZ and the Implementation Sub-Committee of the Food Regulation Standing Committee. Cadbury Schweppes recommended the education campaign have a consistent source of information.

It was noted that under the *Food Standards Australia New Zealand Act*, FSANZ has a role, in co-operation with States and Territories, to develop food education initiatives including the publication of information to increase public awareness of food standards and labels, therefore FSANZ have a role to inform target audiences of such future changes to regulations of food labels (Dairy Aust.).

Wyeth Aust. considered that independent groups such as FSANZ, NHMRC, Nutrition Australia, and AFGC should lead education strategies. They suggested that these groups should provide broad, objective information. In addition, product-by-product information should be the responsibility of individual companies and industry associations.

It was suggested by Canterbury DHB that education should have a strong public health impact and not be left to the food industry. They recommended that an inter-sectoral group with clear objectives and framework be established to oversee this e.g. framework for Foodsafe Partnership. They noted that this should not be at the expense of a comprehensive nutrition social marketing strategy, and health claims should be one strand of a bigger consumer education programme, as in isolation this will have a limited (or even a potentially negative) impact.

Nutra-Life H&F believed that specialist groups (e.g. NHF, Diabetic Society, Allergy Awareness, Plunket, schools) should educate their members, and manufacturers could educate their consumers through publications, product labelling etc.

NCWA said that the campaign should be co-ordinated with Public Health Associations (Nutrition Aust, DAA), Health Departments (Dietary Guidelines, Recommended Dietary Intakes, Eat Well Australia) and include broader information of Public Health Nutrition strategies.

PB Foods suggested communication of the new framework to all stakeholders with briefing sessions in each state, with assistance from the Health Department and involvement of medical profession and academia.

Reasons for an education strategy

Some submitters pointed out the reasons that they considered that an education strategy is important. These were as follows:

- An education is essential for nutrition, health and related claims to fulfil the policy principle of "protecting and improving the health of the population", stated in the Policy Guideline (Horticulture Aust., SA DoH, WA DoH);

- An education strategy is essential in order to put Nutrition, Health and Related Claims in context (PHAA, supported by ACA) and prevent problems with consumers interpreting claims inappropriately (SA DoH); and

- A comprehensive education strategy for manufacturers and the public is needed for health claims to have any benefits for consumers, and therefore improve public health (Canterbury DHB).

General comments

Having both general level and high level claims captured in the Standard is an essential first step in any education process. Manufactures may not adhere to guidelines because they're not legally bound and therefore consumers may not be provided accurate and consistent information (Cadbury Schweppes).

If a list of pre-approved general level claims were to be included in the standard it would simplify the education process and increase consumer confidence in the validity of claims (NSW DoH – N&PA Branch).

Naturo Pharm recommended that there is harmonisation of all Australian and NZ RDI values so that manufacturers may include percentages of RDI amounts per portion of the food in NIPs. They suggested that RDI Information is provided for all key ingredients such as sodium, fats and vitamins.

Other comments provided but not in direct response to the question

The ACA noted that as there are many factors that influence health, they considered it irresponsible to imply that individual food products can bring about significant health benefits. They considered that education campaigns must be in place to ensure that consumers are not misled by health claims, to assist consumers to use these claims in the context of a healthy lifestyle and to provide general nutrition and healthy eating messages. In addition they noted that FSANZ should not overestimate the role of consumer education in preventing consumers from being misled by persuasive claims about the potential health benefit of individual food products.

They added that education campaigns should also target the food industry - providing advice on the responsible use of health claims and enforcement agencies – re the provision of consistent interpretation and enforcement of the standard.

A number of Australian consumer submitters recommended that consumers should be educated about how to check whether claims are truthful and also possibly how to read the NIP and what is/is not an acceptable claim (Lisa Russell, Annemarie Neville, Fiona Wright, Kathy McConnell, Glenn Austin, Amanda Barnett & Family, Julie Gelman, Sarah Ritson, Mrs Adriane Swinburn, Anna Karolyi, David Dwyer).

WA DoH commented that effective consumer education about nutrition health and related claims is essential, however, claims should be seen as only one of the elements of nutrition education, within the larger perspective of multifaceted public health nutrition strategy. They noted that the need to inform and educate consumers about claims was identified in qualitative studies of consumers' use of claims on foods, commissioned by FSANZ. Additionally, consumers want standardisation of claims, with common meaning for the various words and terms. They also stated that nutrition health and related claims would not solve nutrition related problems in Australia and New Zealand, in isolation.

The SA DoH noted that in relation to education specific to claims, the Folate Health Claim Pilot indicated the essential role of education in informing all stakeholders, in particular consumers (ANZFA, "Evaluating the folate-neural tube defect health claim pilot. Sept 2000), which requires sufficient funding to be effective.

In relation to nutrition education in general, they believed that health claims will not solve nutrition-related problems in Australia and New Zealand, and they recommended that they should be viewed as one element of nutrition policy. They added that health claims are not a substitute for a comprehensive, multifaceted public health nutrition strategy. They noted that the Acting Commissioner of the US Food and Drug Administration, Dr Lester Crawford stated that the obesity crisis will need measures in addition to food labelling and claims about foods to be effective (Crawford L. Speech before Harvard Medical School. March 10 2004. (www.fda.gov/oc/speeches/harv0310.html. Accessed 14/09/2004).

Campbell Arnott's Asia Pacific supported the need for an overall communication programme to inform stakeholders about the new health claims regulatory system. They suggested that FSANZ adopt a supportive role by conducting a 'communication programme' which is supported by a 'nutrition education programme', to provide information on:

- General 'system' information;
- The substantiation process for general level claims and high level claims;
- Enforcement; and
- Health claims on product packaging/advertising material.

Four submitters recommended that the introduction of health claims is supported by well-funded education campaigns for both the public and health professionals on nutritional information and health claims and healthy eating, to improve the consumer's ability to interpret nutrition, health and related claims on food labels and their knowledge of compliance and enforcement issues (ACDPA, NSF, Kidney Health Aust, TCCA). It was stated that this is necessary to maintain and/or improve the dietary intake of the population (ACDPA, NSF, Kidney Health Aust, TCCA). NSF added that consumer education around any changes to health claims is essential to ensure that consumers are not misinformed.

Kidney Health Aust. added that it is essential that education campaigns should also include marketing campaigns around food related health products, in addition to food labelling, as these have an important impact on consumers.

The Consumers' Instit. of NZ noted that they consider education to be essential to a robust claims regime and that consumer need to fully understand the status of claims. They added that education is also important to put the claims made on individual foods in to the context of a balanced diet and lifestyle. They are concerned that adequate resource, including funding, will not be available to achieve this.

Beef & Lamb Marketing Bureau commented that an education strategy is essential. They recommended that it should involve education of health professionals and industry, as well as a comprehensive programme for consumers explaining how to use the claims.

In a boarder context, ANA supported the need for a comprehensive national nutrition social marketing strategy as identified in the New Zealand Ministry of Health "Healthy Eating Healthy Action Strategy", to improve the nutrition of the population. However they argued that a comprehensive integrated national nutrition social marketing strategy would be a more effective way of changing consumer behaviour and improving population health. They noted that consumer education around changes to health claims is essential to ensure consumers are well informed and to improve their ability to interpret claims and their knowledge of compliance and enforcement issues.

Some submitters commented that education campaigns should be part of a wider social marketing strategy that conveys information about healthy eating to consumers. They added that as a minimum, there should be a comprehensive, clear and well-funded social marketing campaign to support healthy eating, within which

information about new health claims can be conveyed. Presenting health claims information to consumers with no context and no overarching healthy eating campaign is likely to confuse the public (Cancer Society NZ, Auckland Cancer Society; Cancer Society NZ -Waikato/Bay of Plenty Div, Cancer Society NZ - Rotorua Branch).

The OAC NZ noted that consumer education regarding health claims is essential. They gave a reason that it is known that claims presently made on food labels are confusing for many consumers – a new lot of claims is likely to add to this confusion. They recommended that the education programme be planned, independent, not run by, or left to, industry and should emphasize the total diet intake rather than focusing on claims for single nutrients.

Question 62

Who should be responsible for undertaking such education activities?

Out of 147 submitters, 48% (70 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	26	14	4	2	46
Government	6	2	-	-	8
Public health	8	4	-	-	12
Consumers	2	-	-	-	2
Other	3	-	-	-	3
Total	**45**	**20**	**4**	**2**	**71**

Overview

It was recommended that education should be undertaken by various combinations of sectors which included the following organisations: FSANZ, New Zealand Food Safety Authority, governments (federal, New Zealand, states and territories), non-government organisations, state and territory health departments, public health associations, National Centre of Excellence in Functional Foods, health professionals, the food industry, industry associations, universities, schools, consumer organisations and Health Sciences and Nutrition unit of the Commonwealth Scientific Industrial Research Organisation. Some submitters clarified that the education process was a joint responsibility by all parties. Others stated that each sector should be responsible for specific tasks. However, some submitters recommended that FSANZ be responsible for undertaking education activities in consultation with other sectors.

Combination of sectors

A number of submitters recommended that the education should be carried out by a combination of different sectors including:

- FSANZ, universities, industry bodies, schools and health professional organisations (NCEFF);
- FSANZ, NZFSA, NGOs and the food industry (NHF Aust., NHF NZ);
- FSANZ together with State Government (PB Foods);
- A coordinated approach by Public Health Associations (Nutrition Aust, DAA); Health Departments (Dietary Guidelines, Recommended Dietary Intakes, Eat Well Australia) (NCWA);
- Non-government organisations, the Federal Government, New Zealand, States and Territories (ABC, National Foods, AFGC supported by MasterFoods Aust. NZ);
- The education process is a joint responsibility by all parties, FSANZ, manufacturers, consumer groups, enforcement agencies and industry associations (Cadbury Schweppes);
- Non-government organisations, FSANZ, State and territory health departments, NCEFF & health professionals (GW Foods);
- Government and non-government organisations (Goodman Fielder);
- Industry to share the responsibility for education with Government (Horticulture Aust.);
- A joint approach by regulators, public health and industry (NZFSA);
- Stakeholders in the nutrition and health fields including government agencies (Griffins Foods);
- Government and local bodies with industry involved, possibly to help distribute information (NZ Dairy Foods);
- Industry/regulators in partnership (CHC);
- Government health, non-government health and food industry should all be responsible, though on different levels (Diabetes Aust., GI Ltd); and
- Industry, health professionals, consumer organisations, CSIRO, academia and government regulators (if education is required), with FSANZ responsible for the web link and developing a user guide for industry (CSIRO – HS&N).

Further to their recommendation above, Diabetes Aust. and GI Ltd agreed with FSANZ's proposal to be responsible for the claims on food as a result of the new legislation and the system operation/substantiation/complaint processes. In addition they recommended Commonwealth and State/Territory Health Departments, non-government organisations and food industry should be responsible for approved claims; linking individual claims into public health nutrition strategies; and individual claims in relation to specific foods with input from FSANZ where appropriate.

ANIC recommended that industry should be responsible for education regarding the importance of the food or nutrient referred to in the health claim, whereas government should be responsible in relation to explaining the new system to health professionals and consumers.

It was recommended that in addition to FSANZ, public health and not-for-profit organisations being involved in consumer education; manufacturers should be encouraged to educate consumers about health claims generally, as well as the meaning and appropriate use of health claims on their products (Sanitarium Health Food Comp.).

NSW Food Authority suggested that the education activities should be under the overall guidance by the Department of Health and Ageing, with funding from the Department of Health and Ageing, DAFF, health professionals and possibly industry.

Another suggestion was that the framework should be developed by an inter-sectoral group but with resourcing from government and the food industry (Canterbury DHB).

A number of submitters recommended that the regulator should be primarily responsible, with assistance from industry groups. They added that the advertising industry would willingly give assistance (ASA supported by NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, NZ Magazines, NZTBC, and Cadbury Confectionery).

It was considered by NZFGC that the responsibility for undertaking education activities about claims rests with Government (Ministry of Health & FSANZ), and non-Governmental organisations that work in the health and nutrition fields may share such activities. This was because information is rated more credible if it comes from Government Authorities.

NZFGC noted that they would be willing to assist in disseminating information about the use of claims to individual member companies. They added that the course of promotional and advertising activities could play an educative role (NZFGC).

The relevant government departments and non-government organisations that are involved in providing health education need to undertake the education strategy for consumers (Nestle).

Some submitters listed what they considered each sector should be responsible for as follows:

- The Federal Department of Health could be responsible for providing an overview of the new regulations;

- FSANZ has a statutory obligation to provide information to industry, health professionals and consumers on the practical implications of the Standard;

- State Departments of Health and Ageing (enforcement agencies) could be responsible for providing an overview of the enforcement mechanisms; and

- Communication experts could provide advice and guidance in relation to effectiveness of communication and comprehension (Tas DoH&HS, DAA, NZDA).

Five submitters made comments regarding the lack of suitability of industry to undertake this education:

- It is important to avoid potential industry bias (NCWA);

- Industry is not likely to be seen as a credible source of information, but a number of non-government organisations have a history of working with industry to provide credible information to the consumer, which needs to be done carefully to avoid being perceived as an endorsement (Nutrition Aust.); and

- Industry may not be a trusted source of education because consumers can view claims as forms of advertising (FSANZ, 2003) (PHAA (supported by ACA), Monash Uni – N&D Unit).

CHC recommended that manufacturers must seek pre-approval for any educational material.

NZ MoH thought there would be likely to be a variety of organisations involved, and there may be different approaches in Australia and New Zealand.

Nutrition organisation

It was suggested that an authoritative nutrition organisation would need to be established to fulfil this role. This might be linked to FSANZ or might be an independent not for profit entity with nutritional expertise (TCCA).

Another suggestion was that the Nutrition Foundation could provide the technical expertise for education (Nutra-Life H&F).

The CMA noted that the NCEFF has already played a facilitation role in the development of health claims and may have an important part to play in the delivery of any future strategy together with identified key stakeholders (this was supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, and CM of SA).

Food Standards Australia New Zealand

A number of submitters indicated that FSANZ should primarily be responsible for undertaking such education activities (Aussie Bodies, Bakewell Foods, CML, Parmalat Aust.), with many mentioning this should be in support from or in consultation with:

- Federal and state Departments of Health and with communication experts from public health and industry should be responsible for undertaking such education activities (with roles as outlined below) (Tas DoH&HS, DAA, NZDA, National Starch, Solae Comp.);

- State governments, Nutrition Australia, the NHF and other groups (Dr R Stanton);

- Industry, health professionals, and government and non-government organisations, as deemed appropriate (Dairy Aust.);

- Industry (Parmalat Aust.);

- Relevant health and nutrition organisations and industry (Wyeth Aust.);

- The food industry, state and local government, professional bodies (EHO's, Nutritionists), consumer organisations and the education department (i.e. schools), who also have roles to play in terms of education (CML); and

- The overall guidance of the Department of Health and Ageing (NSW DoH – N&PA Branch).

In relation to this, Parmalat Aust. noted that industry bodies such as Dairy Australia are expected to provide more industry-based support rather than individual companies. They suggested that companies would continue to educate consumers on the benefits of their own products.

DAFF recommended that industry should recognise that they also stand to benefit and be prepared to contribute.

Some submitters mentioned that FSANZ has a statutory obligation to provide information to consumers (PHAA (supported by ACA), NSW DoH – N&PA Branch, Monash Uni – N&D Unit, SA DoH) and that FSANZ should be responsible for ensuring implementation of the education strategy (WA DoH). It was added that the results from the Folate-Neural Tube Defect Health Claims Pilot indicate that FSANZ would prefer to limit this information giving function to general aspects of labelling rather than specific information on each specific health claim (ARTD 1999), therefore it was considered that Commonwealth, State and Territory and local government health departments, dietitians, nutritionists and health promotion workers should be responsible for such education activities. In addition, non-government organisations and other related groups established could either support and/or educate members (e.g. in the case of professional associations) or educate the public about a particular health issue (SA DoH, PHAA (supported by ACA), Monash Uni – N&D Unit, Tas DoH&HS, Nutrition Aust.). Care would need to be taken in relation to endorsements

and cause related marketing if these groups are involved in education regarding claims (PHAA (supported by ACA), Monash Uni – N&D Unit, Tas DoH&HS, Nutrition Aust.).

WA DoH agreed that government health departments, health charities and professional associations should be responsible for providing public health nutrition input. They suggested that this group could work with food industry to develop a Guideline or Code of Practice that sets out preferred consumer education messages, for nutrition health and related claims e.g. it could recommend referencing the Australian Guide to Healthy Eating (WA DoH).

Tas DoH&HS highlighted that health claims are not the only source of nutrition information and not all public health nutrition resources should be directed in this area.

Reasons provided by some submitters for considering FSANZ to be the best organisation to provide this education were:

- So that there will be consistency across industry and consumers and the authoritative profile of FSANZ will be enhanced in the eyes of industry and consumers, as 'educators' often carry greater authority than regulators (Aussie Bodies);

- That FSANZ already has an established communication network and is best placed to be the main provider of information (CML);

- FSANZ is also viewed by the public as being independent, and are more believable (CML); and

- FSANZ has the credibility (Fonterra supported by Mainland Products).

Fonterra added that companies will still do their own campaigns and many would support FSANZ where appropriate (supported by Mainland Products).

DAFF submitted that the groups raised in the IAR (pg 72) are suitable. They noted that the legislative restraints on FSANZ must be acknowledged and that perhaps it is an issue of communication rather than education.

Manufacturer

ASMI considered that quality use information of the product to ensure best health outcomes is the responsibility of the manufacturer to be responsibly conveyed through labelling and advertising.

SA DoH believed that industry might not be a trusted source of education because consumers can view claims as forms of advertising (FSANZ, 2003).

SA DoH added that use of claims, in terms of accuracy, is covered by the proposed Standard. They provided an example of consumer education on the role of fibre in the

diet offered by food industry (www.kelloggs.com.au/DisplayPage.asp?PageID=631&brandid=16).

It was considered by SA DoH that it is highly likely that health claims will be used in advertising and promotions encouraging purchasing decisions, given that nutrition content claims are currently used as a marketing tool (refers to a Kellogg's information box, pictured). They suggested a Guideline or Code of Practice that sets out preferred consumer education messages may be a useful tool for the food industry, in which the Australian Guide to Healthy Eating is referenced.

A voluntary system was outlined by SA DoH, which is used by reputable companies in the U.K. food industry is the British Nutrition Foundation's Nutrition Service, which offers services such as providing informed comment on a variety of diet, health and nutrition topics, news stories, interviews, writing articles and checking text (www.nutrition.org.uk). They suggested that food companies may engage third parties, such as health charities to communicate or endorse their education messages, regardless of whether the endorsement is used on the label. Provides a partnership example:

- Marks and Spencer, in conjunction with the charity 'Weight Concern', provided an education tool for customers that addressed weight issues. The Weight Concern logo has never been used on product labels (www.marksandspencer.com/eatwellfeelgreat) (SA DoH).

Funding

Three submitters suggested that the food industry could fund the education, either via:

- Fees for making claims (Canterbury DHB);

- Imposing a funding levy on food industry (Nutra-Life H&F) or food advertising (TCCA); or

- Arrangement through industry trade associations (Nutra-Life H&F).

It was added that this is because claims are a marketing tool for the food industry and so it should not be the taxpayers' role to promote them (Canterbury DHB).

It was submitted that the ability of the various jurisdictions to commit resources to education on health claims will be very limited, as resources are likely to be prioritised towards implementation of other public health nutrition initiatives (NSW DoH – N&PA Branch).

General comments

Other recommendations made regarding the education campaign were that:

- The messages should be simple, the more extravagant (albeit truthful) the claims the less consumers will understand it (Cadbury Schweppes);

- It should include broader information of Public Health Nutrition strategies (NCWA);

- The activities have credibility and that there is openness and transparency (CSIRO – HS&N); and

- It must target all relevant audiences through mediums most acceptable to each – presumably a combination of electronic and print media – be ongoing, and regularly monitored and evaluated for its effectiveness (Dairy Aust.).

It was noted that nutrition content claims are currently used by the food industry as a marketing tool and the food industry is also most likely to gain from introducing nutrition health and related claims. A Guideline or Code of Practice that sets out preferred consumer education messages may also be useful for the food industry and could, as an example, reference the Australian Guide to Healthy Eating (Horticulture Aust.).

AFGC noted that they are willing to assist in providing education for manufacturers in appropriate use of nutrition, health and related claims. National Foods, as a member of AFGC, supported this offer.

Unilever Australasia supported the AFGC suggestion (made in response to question 61) that FSANZ consider the NCEFF to take a role in developing an education strategy for nutrition and health claims.

The Auckland Reg. PHS stated that claims should not require explanation so funds should not be diverted to a specific education campaign.

Other comments provided but not in direct response to the question

The ACA considered that consumer education campaigns should be the responsibility of government agencies (e.g. FSANZ, the Commonwealth Department of Health, NHMRC and State and Territory Government agencies).

Campbell Arnott's Asia Pacific believed that the current Policy Guideline does not imply that it is FSANZ s role to undertake education programs to promote healthy food choices. They added that although education initiatives should be supported by the health claims regulatory system, initiatives should be developed and/or extended by nutrition educators (from government, non-government organisations, community, and food industry organisations). They recommended that the health claims regulatory system supports community initiatives such as high quality endorsement programmes.

Campbell Arnott's Asia Pacific noted that opportunities for food manufacturers to work with government and non-government organisations, to promote healthy lifestyles, would increase under the health claims regulatory system. They considered that the new regulatory system would provide a collaborative action among those enforcement agencies, industry and consumers with similar messages to optimise educational resources, and will act as a catalyst for the development of new resources by others.

Four submitters suggested that an independent organisation should be established to fulfil the role of providing education campaigns (ADCPA, TCCA, NSF and Kidney Health Aust). Three of these submitters also suggested options for funding this campaign may include imposing a funding levy on the food industry or food advertising, or could be funded through application fees by manufacturers seeking to make health claims (ADCPA, Kidney Health Aust., NSF). In addition they recommended that health claims are pre-tested with consumers representative of the intended target audience, independently of food industry (supported by TCCA).

A number of New Zealand submitters commented that education campaigns should not be left to industry. They gave the reasoning that Australian evidence indicates that the communication goals of industry do not always match well with those who seek to protect and promote public health (Smith, A.M., Kellet, E., Schmerlaib, Y., & Sindall, C. (1999)) (Cancer Society NZ, Auckland Cancer Society, Cancer society NZ - Waikato/Bay of Plenty Div, Cancer Society NZ - Rotorua Branch).

The OAC NZ recommended the education programme be run by an organisation/s with recognized, respected and credible nutrition expertise. They added that an industry run programme may leave consumers wondering how to differentiate between advertising material and genuine nutrition information.

J Seal – PH Nut recommended that organisations with no conflict of interest undertake education activities and she suggested that this be FSANZ, working in conjunction with state and territory governments. She noted that additional funding is necessary for consumer education to prevent redirection of existing resources from other high priority public health nutrition initiatives.

The Consumers' Instit. of NZ considered that education activities could be delivered by a combination of industry, government and public health and consumer organisations.

ANA commented that experts independent of the food industry should carry out consumer education. They added that it would be unreasonable for the consumer to fund the education campaign as the potential for population health gains has not been proven and would appear to be quite low. Additionally, higher mark up on foods with a perceived increase in values with health claims affects lower socio-economic groups more heavily and would have a negative effect on health disparities. They suggested funding could come from a funding levy on the food industry of food advertising and/or funded through application fees by manufacturers seeking to make health claims as the food industry is likely to increase market share of their products and gain financially with introduction of health claims. Health claims are voluntary for the food industry and costs for these claims should not be imposed on the consumer.

Question 63

How can stakeholders work together to develop and implement an education strategy for industry, health professionals and consumers in relation to the proposed regulatory framework for nutrition health and related claims?

Out of 147 submitters, 43.5% (64 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	21	13	4	2	40
Government	6	2	-	-	8
Public health	7	4	-	-	11
Consumers	1	-	-	-	1
Other	4	-	-	-	4
Total	**39**	**19**	**4**	**2**	**64**

Overview

Almost half the submitters recommended the establishment of a working group with aims that included reviewing proposed claims, developing and implementing an education strategy and orchestrating an appropriate communication strategy. Some submitters suggested that the working group should represent various stakeholder groups (e.g. industry, health professionals, consumers, government, non-government organisations, and consumer communication experts). It was also recommended that FSANZ, supported by specific combinations of other groups, coordinate the educational process to target groups such as manufacturers, health professionals, consumers and enforcement agencies.

Working group

Thirty submitters recommended that a (small) working group be established to:

- Develop and implement an education strategy (Griffins Foods, Goodman Fielder, National Starch, Solae Comp., DAFF, Mainland Products, NZFSA, NZFGC, DAA, NZDA, CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA);

- Examine proposed claims in order to establish an appropriate education strategy (CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA);

- Formulate the basis of an education strategy (Diabetes Aust., GI Ltd);

- Road test proposed claims in order to establish an appropriate education strategy (ABC, AFGC supported by MasterFoods Aust. NZ, Parmalat Aust., Unilever Australasia and Nestle, National Foods, GW Foods); and

- Orchestrate an appropriate communication strategy (Dairy Aust. supported by Parmalat Aust.).

Some of these submitters suggested that the working group should represent:

- Each key stakeholder group (Diabetes Aust., GI Ltd, National Starch, Solae Comp., NZFSA, NZFGC, CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, and CM of SA);

- Industry, health professionals, consumers and government (ABC, AFGC supported by MasterFoods Aust. NZ, Parmalat Aust., Unilever Australasia and Nestle, National Foods, GW Foods);

- Health professionals, consumer communication experts and industry (DAA, NZDA);

- Government and non-government organisations, industry, health professionals (Dairy Aust. supported by Parmalat Aust.);

- All the different interested sectors like industry (small and large companies), consumer organisations, FSANZ and health professionals (Goodman Fielder);

- Stakeholders from nutrition and health fields (Griffins Foods); and

- Both countries with representatives from industry, health professionals and consumers (Mainland Products).

Likewise, CML suggested that an independent group be established to oversee this project (like the allergen group that has been formed to address allergen related issues), with input from all stakeholders – possibly FSANZ could facilitate or provide administrative support.

In addition to the representatives recommended above, National Foods also suggested that there be input from communication specialists.

DAA said that they could provide a representative for the working group to provide guidance.

It was suggested by two submitters that a report from this working group could then be released for public comment and the outcomes would determine how the strategy would be implemented (Diabetes Aust., GI Ltd).

As an alternative to the working group mentioned above, a written form of consultation was suggested as another consultation mechanism that could be used (National Starch, Solae Comp, DAA, NZDA).

It was added by two submitters that FSANZ should have the responsibility for coordinating the implementation of all communication strategies. This was because

they are seen as objective and credible amongst the various target audiences. In addition, peak service organisations, like Dairy Australia, the AFGC, Meat and Livestock Australia, and professional bodies such as the Dietitians Association of Australia and the Australian Medical Association, could play a role in disseminating information under the guidance of FSANZ (Dairy Aust. supported by Parmalat Aust.).

DAFF suggested that the working group be facilitated by FSANZ.

NZFGC noted that such a working group would need to determine the most effective way of disseminating information. They added that it will be important for Government Agencies and health professionals to advise that health and nutrition claims are based on a robust regulatory system, where health and safety is of prime importance. In addition, they stated that many consumers are unaware of the high onus placed on manufacturers to produce safe food.

Other groups

For producers and manufacturers, seven submitters suggested that FSANZ, enforcement agencies (including AQIS) and industry bodies could work together to develop an education campaign and industry could (partially) fund the education process (PHAA (supported by ACA), Tas DoH&HS, NSW DoH – N&PA Branch, SA DoH, WA DoH, Monash Uni – N&D Unit). FSANZ roles would include ensuring that industry education efforts cover all industry stakeholders (SA DoH). However, given that industry bodies do not capture all producers/manufacturers/importers it will be essential for FSANZ to ensure that industry education efforts are broad enough to cover all industry stakeholders (PHAA (supported by ACA), WA DoH, Monash Uni – N&D Unit).

For health professionals, these seven submitters considered that FSANZ, Commonwealth, State and Territory health departments and professional bodies such as PHAA (supported by ACA), DAA, Nutrition Aust, AMA could work together to develop and disseminate an education campaign (PHAA (supported by ACA), Tas DoH&HS, NSW DoH – N&PA Branch, SA DoH, WA DoH, Monash Uni – N&D Unit). They noted that the education messages would need to be widely disseminated. Professional associations could provide access to members by allowing inclusion of education, materials/notices etc in newsletters/electronic mailing alerts etc. It was recommended that the food industry should not be involved in educating health professionals as messages may be seen as implicit health claims (PHAA (supported by ACA), Tas DoH&HS, WA DoH, Monash Uni – N&D Unit, SA DoH). NSW DoH – N&PA Branch noted that it would need to be very well managed and resourced and undertaken in a timely fashion.

For consumers, they recommended that FSANZ and consumer bodies such as ACA and appropriate non-government organisations (health charities) can work together to develop an education program (Tas DoH&HS, PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit). This would need to link in with health professional education as it is important for health professionals to be aware of what is targeted at consumers and be able to reinforce the pertinent messages (Tas DoH&HS, PHAA (supported by ACA), SA DoH, Monash Uni – N&D Unit). Once again, the food industry should not be involved with developing consumer education

(Monash Uni – N&D Unit). The food industry may have a (real and/or perceived) conflict of interest, and to promote credibility the information on health claims would be better from an 'authoritative' source (Tas DoH&HS, SA DoH, WA DoH). However, there is certainly a role for the food industry in disseminating approved educational materials to consumers, e.g. at point of sale (PHAA (supported by ACA), Tas DoH&HS, SA DoH).

For enforcement agencies WA DoH considered that FSANZ and public health nutrition professionals should deliver education material on population health and safety implications of vague, false or misleading claims.

It was recommended by TCCA that an advisory body overseeing the work of an appropriately resourced entity could provide technical and scientific input to ensure high quality scientifically validated nutritional information could be established with key stakeholders represented. Groups such as the Australian Chronic Disease Prevention Alliance (made up of non-government organisations such as they, Heart Foundation etc), the Australian Consumers Association, the Dietitians Association of Australia and similar groups would retain high levels of public confidence sufficient to conduct such a program. They added that this should not be commenced however in the absence of meaningful resources for such an endeavour.

NCEFF noted that they are well placed to facilitate this process by bringing together capabilities in Australia and New Zealand for its delivery.

Nutrition Aust. suggested that stakeholders can work together to develop and implement an education strategy but they acknowledged that different groups have different agendas, which can be barriers to effective partnerships. They added that this raises the issue of adequately resourcing such strategies (see Funding section below). It was recommended that FSANZ should coordinate the educational process especially in setting priorities and engage the various stakeholders in this process (Nutrition Aust.).

CHC considered that the regulators, in the interest of public safety, must drive education. They suggested that all stakeholders must be involved in the development of such programs.

Canterbury DHB stated that stakeholders could work together via a FSANZ led inter-sectoral framework group with responsible manufacturers.

Other approaches

It was considered that meetings should be held in neutral surroundings under the leadership of FSANZ or another independent person/group (Dr R Stanton).

ASA suggested that FASNZ should co-ordinate the approach by forming an education forum group to undertake specific tasks. They envisaged the advertising industry play a role (this was supported by Cadbury Confectionery, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, NZ Magazines, NZTBC).

Fonterra indicated that FSANZ and industry associations are likely leaders. Activities such as distribution of pamphlets, information provision to health professionals and publicity in mainstream media should be undertaken by FSANZ.

The NHF Aust. encouraged facilitation and investment by FSANZ into a robust implementation strategy that is inclusive of all relevant stakeholders and grounded in appropriate educational and learning theory (supported by NHF NZ).

It was suggested that an industry Guideline or Code of Practice that sets out preferred consumer education messages for nutrition health and related claims is essential (WA DoH). It was also suggested that NCEFF draw together stakeholders to develop a user guide (CSIRO – HS&N).

The need for the use of consultation was emphasised by Aussie Bodies. They indicated that web-based consultative forums could be effective.

It was considered that an education strategy could best be implemented with the establishment of a formal system of advertising control and adopting a co-regulatory approach where both industry and government are equal partners in the system. This enables consumers to understand the system and understand how to report complaints against manufacturers that contravene the policy on health claims (ASMI).

Cadbury Schweppes suggested that stakeholders would have to work via workshops such as those that were organised by FSANZ.

NSW Food Authority suggested that an education strategy be developed and implemented through policy to be developed by a Department of Health and Ageing process that involves all the stakeholders.

NZ Dairy Foods agreed with the approach as proposed under Section 7.7. They added that the lead would need to be taken in the information process or at least set industry guideline as to how to educate consumers.

NZ MoH noted it is likely to be a multi-institutional approach.

Funding

It was noted that funding should be provided for education purposes (Mainland Products) and this is required on a long-term basis (Sanitarium Health Food Co.).

CSIRO – HS&N believed that collaborative grants be made available and that they should not be excluded from applying for funding given their expertise.

Nutrition Aust. suggested that some funding should come from those that benefit commercially but they were mindful that not all funding should come from this source, as manufacturers/retailers etc. would drive the agenda.

Auckland Reg. PHS reiterated their comments from previous questions, that there are more important public health issues requiring education – if appropriate consumer research is conducted around the wording of the claims, these claims should be stand-

alone and not require accompanying explanation. Therefore funds should not be diverted for a specific education campaign.

Other comments provided but not in direct response to the question

Tas DoH&HS noted that education is essential to inform stakeholders of changes to the food standard. In addition they stated that nutrition, health and related claims may have a role in educating consumers about nutrition and health but are not the solution to all nutrition related problems in Australia and New Zealand. Claims can be considered as one element of nutrition education, however education alone is not an effective health promotion strategy. This is not a substitute for a comprehensive, multifaceted public health nutrition strategy outlined in Eat Well Australia 200-2010 and the (Draft) Tasmanian Food and Nutrition Policy 2004 (Tas DoH&HS).

Queensland Health – PHS recommended that the education should target manufacturers, health professionals, and consumers so that all these stakeholders are fully informed of the requirements and interpretation of messages. They also noted the importance of targeted education initiatives for groups on lower incomes that bear the greatest burden of diet related disease and the need for adequate consideration for the resourcing of such conditions. They suggested that FSANZ develop a series of key messages that are used as a basis by all other agencies for promotion of the system. They believed an advisory panel for the introduction of the Standard and interpretive guides will be beneficial to consistent implementation. The advisory panel should be chaired by FSANZ with regulators, industry and consumers, to facilitate consistent implementation of the substantiation framework.

CHAPTER 7: COMPLIANCE AND ENFORCEMENT

7.1 COMPLIANCE ACROSS THE CLAIMS CONTINUUM

Question 64

Would it be more appropriate for the 'manufacturer' or the 'supplier' to hold and produce evidence in relation to a general level claim?

Out of 147 submitters, 52.4% (77 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	28	17	5	2	52
Government	6	2	-	-	8
Public health	9	2	-	-	11
Consumers	2	-	-	-	2
Other	4	-	-	-	4
Total	**49**	**21**	**5**	**2**	**77**

Overview

Similar numbers of submitters responded as to whether it was appropriate for the manufacturer or the supplier to hold and produce evidence in relation to a general level claim. However, another 40 submitters stated that the entity making the claim (whether it be manufacturer, supplier, vendor or marketer) named on the product labels or packaging should hold the substantiating evidence. A few submitters believed that neither the supplier nor the manufacturer should hold and produce substantiating evidence, as they preferred that general level claims were pre-approved and listed in the Standard.

Discussion of submitter responses

Many submitters distinguished between food products produced within Australia or New Zealand and imported products. Seven submitters who responded in terms of Australian and New Zealand made products suggested that the manufacturer should be responsible for holding and producing substantiating evidence (NCWA, WA DoH, Cadbury Schweppes, Coles Myer, National Starch, Solae Comp, Tegel Foods) Foods). Six submitters believed that the onus was on the supplier (NZ Dairy Foods, GW Foods, Wyeth Aust., Diabetes Aust., GI Ltd). Griffin Foods believed that both the manufacturer and supplier should retain supporting evidence. The Tas DoH&HS suggested in their submission that the body responsible for marketing the products should be liable.

Of the 12 submitters that responded specifically with regard to importers, 7 indicated that the importer or distributor should hold substantiating evidence in relation to a general level claim (NCWA, Tegel Foods, Bakewell Foods, Cadbury Schweppes, National Starch, Solae Comp, National Foods). Other responses included the supplier

(Tas DoH&HS, Nutrition. Aust, DAFF), the primary marketer (Aussie Bodies), and the packer or vendor (National Starch, Solae Comp). The NZFSA suggested that a nominated 'responsible' party in the country of sale should be responsible for holding and producing evidence for imported products, and that imported food should be on a level playing field with locally produced product.

Three submitters believed that responsibility should rest with the entity that has legal responsibility for the product (ASMI, CHC, TGACC). The NZFSA recommended that the same person in the company who takes legal responsibility for ensuring compliance with the FSC should be responsible for holding evidence, and that delegation of these responsibilities should be clearly defined in written company policy.

Twelve submitters supported the view that the entity (manufacturer, supplier, vendor or marketer) named on product labels or packaging should hold substantiating evidence (Nestle, Unilever Australasia, ABC, AFGC, Masterfoods Aust. NZ, Dairy Aust, F & B Importers Assoc., National Foods, Parmalat Aust., NZFGC, NZJBA, Frucor). In addition, four submitters indicated that the brand owner (Aussie Bodies), or supermarket chain carrying home brand labels (AFGC, Masterfoods Aust. NZ, ABC) should hold and produce substantiating evidence. In their response, Nestle and Unilever Australasia suggested that if the product label specifies a third party manufacturer or supplier, then the third party would be responsible.

Three submitters supported the manufacturer making the claim as the holder of evidence, unless there are ingredient-specific claims in which case the manufacturers would need to source most of the research data from suppliers (PB Foods, Sanitarium Health Food Comp.), or the suppliers would themselves be responsible for holding evidence (CSIRO - HS&N). PB Foods noted the ingredients soya isolates and insulin as examples of where the manufacturer may defer to the supplier for ingredient specifications. Goodman Fielder recommended that manufacturers should be responsible, with the exception of home-branded products or licensed brands in which it should be the named company on the pack. The ACCC responded that the issue of supporting evidence would depend on the contractual supply arrangement between the manufacturer and the supplier. Nutra-Life H&F indicated that responsibility should be either the manufacturer or the supplier.

Seventeen submitters recommended that the onus for holding evidence should be on the entity making the claim, regardless of whether they manufacture or supply (NZ MoH, DAA, NZDA, NCEFF, Bakewell Foods, Cadbury Schweppes, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Heinz Aust./Heinz Watties NZ), and may extend to the agency responsible for home branded products and importers (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust, Palatinit GmbH, Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Heinz Aust./Heinz Watties NZ).

MLA indicated that their existing charter already requires them to be responsible or holding and producing evidence, given that they manage research, development, marketing and promotions for the red meat industry.

The WA DoH considered that the onus for pre-approval of general level claims should sit with FSANZ or an Expert Committee, similar to the framework used by the Joint Health Claims Initiative in the United Kingdom. They considered that the manufacturer should hold documentation necessary for verification that the claim meets the criteria specified for use. However, given that many stakeholders are responsible for a product (for example: farmers, growers, wholesalers, packers, manufacturers, retailers), requesting that food industry substantiate general level claims individually was thought to create an unnecessary burden on all stakeholders to repeat the work.

Nine submitters expressed the view that neither the supplier nor the manufacturer should hold and produce substantiating evidence, as they preferred that general level claims were pre-approved and listed in the Standard (NHF Aust., NHF NZ, TCCA, Tas DoH&HS, Dr R. Stanton, PHAA (supported by ACA), NSW DoH – N&PA Branch and NSW Food Authority). Three submitters provided alternative suggestions if their preferred Option 3 was not adopted. Dr R. Stanton suggested that substantiating evidence should be lodged a central place to allow easy access for all parties. The WA DoH, with the exception that evidence would only be available to all parties providing they meet specified criteria, expressed a similar view. The PHAA (supported by ACA) recommended that the manufacturer or whoever has the responsibility of ensuring the food meets all the requirements of the Food Standard Code should hold supporting evidence. This view was supported in a submission from the Monash Uni – N & D Unit. The NSW DoH – N&PA Branch responded that the entity responsible for the sale of the product under the Food Act should hold evidence. The NSW Food Authority supported this view.

TCCA recommended that substantiating evidence for those seeking to make a general level claim should be lodged and held by FSANZ, as this process would ensure greater rigour in substantiation, and ultimately reduce the likelihood of false or misleading claims. Mainland Products suggested that as long as the manufacturer has access to the information, it would not matter where it was held, or by whom.

The ASA suggested that evidence should be held by either the manufacturer or principal sponsor for Australian or New Zealand-made goods, or the distributor of foods manufactured outside these areas, and that this would need to be defined in the legislation. However, the ASA have also indicated that an entity based in the regulatory catchment area should be nominated to hold the responsibility. Cadbury Confectionery, Naturo Pharm, NZ Magazines, NPANZ, Assoc. of NZ Advertisers and the NZTBC have supported this view in their submissions.

Although Fonterra has suggested that the entity responsible for designing the label or making the claim should hold evidence, they have also stated that no specific entity should be required to actually hold the evidence; it should be held elsewhere and the body making the claim should ensure that the regulatory body has adequate access to it.

Since Dr C. Halais has opposed the use of health, nutrition and related claims, her view was that this question was not applicable.

Despite having provided a positive response ('yes') to this question, DSM Nut. Prod. did not state whether manufacturers or suppliers should hold and produce evidence.

The ASMI noted that if evidence was commercially sensitive, a process to provide the evidence to FSANZ directly for evaluation should be in place, bypassing the sponsor. In addition, the sponsor would be responsible for ensuring products are appropriately labelled if the evidence for claims cannot be substantiated.

Cadbury Schweppes recommended that only one dossier of evidence should be held by the primary source, to which enforcement officials be directed. They believed that multiple copies might lead to there being incorrect information, especially where the dossier has been updated to include new scientific evidence.

CML suggested that evidence should be readily available within seven days upon request from suppliers, retailer, consumers or regulators. The Tas DoH&HS also noted the importance of having supporting evidence readily available.

TCCA recommended that substantiating information should be publicly accessible, for example via the Internet.

Wyeth Aust. believed that the process for challenges to claims should be transparent.

The WA DoH recommended that clarification of claims might be addressed through two channels:

- The jurisdiction in which the non-conformance is identified. In this case the information could be sourced through the respective State or Territory to effect enforcement action; and
- The home authority principal where the matter is referred back to State or Territory for consideration. In this case the manufacturer should retain substantiation evidence. Home authority principals may need strengthening to enable the transfer of information from one jurisdiction to another.

Other comments provided but not in direct response to the question

Campbell Arnott's Asia Pacific believed that the marketer should hold substantiation evidence.

Queensland Health – PHS noted that the Standard must be clear that dossiers must be provided to enforcement officers upon request. They recommended that the following issues should be considered when determining which entity is to hold the evidence in relation to a claim:

- Manufacturers that produce food under licence for another entity that is making the claim and not necessarily involved with marketing the product they produce;

- May not be feasible for each retailer to hold evidence; and

- Consideration for the level of information that satisfies due diligence on behalf of manufacturers and retailers.

Question 65

What are the legal and/or practical difficulties for an enforcement agency when requesting and assessing evidence in relation to general level claims?

Out of 147 submitters, 42% (61 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	22	14	4	2	42
Government	5	2	-	-	7
Public health	5	3	-	-	8
Consumers	-	-	-	-	-
Other	4	-	-	-	4
Total	**36**	**19**	**4**	**2**	**61**

Overview

Submitters stated that the legal and/or practical difficulties for an enforcement agency when requesting and assessing evidence in relation to general level claims involved issues relating to insufficient resources (21), the requirement for a high level of technical expertise (19), timeliness of provision and evaluation of evidence (14) and handling confidential information (9). Two Australian government submitters noted that the Food Act does not currently provide enforcement agencies with the power to request substantiating evidence. A few others believed that enforcement would only be possible with a standard.

Discussion of submitter responses

Twenty-one submitters considered that having insufficient resources would create practical or legal difficulties for an enforcement agency (Canterbury DHB, NHF Aust., NHF NZ, DAA, NZDA, Unilever Australasia, ACCC, NSW DoH – N&PA Branch, Parmalat Aust., PB Foods, ABC, AFGC, Masterfoods Aust. NZ, Dairy Aust., GW Foods, Goodman Fielder, National Foods, CHC, NZFSA, Griffins Foods, NZFGC).

Eighteen submitters indicated that enforcers would require a high level of technical expertise to assess the complexity of substantiating evidence (NHF Aust., NHF NZ, Unilever Australasia, AFGC, Masterfoods Aust. NZ, Parmalat Aust., PB Foods, ABC, Dairy Aust., GW Foods, Goodman Fielder, Fonterra, Mainland Products, NZFGC, National Foods, CHC, NSW Food Authority, NCEFF). NHF Aust. considered that this requirement would effectively replicate the industry process for assessing quality, strength, totality and bias of evidence, without actually collecting it. This view was also supported in the submission from the NHF NZ. The ACCC suggested that since the Trade Practices Act had no provision for enforcement agencies to hold 'call in' or 'substantiation' powers, then the expertise in analysing supporting documentation would need to be sourced elsewhere, which would pose problems for injunctive relief or declarations. CHC recommended that meaningful enforcement strategies are

actively pursued and greater levels of funding for individual jurisdictions are provided.

Thirteen submitters mentioned that timeliness of provision and evaluation of evidence would potentially create difficulties for enforcement agencies (Unilever Australasia, Cadbury Schweppes, NZFGC, ABC, AFGC, Masterfoods Aust. NZ, GW Foods, Goodman Fielder, National Foods, CHC, Tas DoH&HS, Griffins Foods, Solae Comp.). The Tas DoH&HS believed those entities making a claim should not be allowed to stall until problems in the marketplace disappear. NZ Dairy Foods recommended that a suitable time for food industry to compile and send the information should be determined. The Solae Comp. suggested that time delays might occur if the supplier needs to source evidence from an overseas manufacturer.

Nine submitters indicated that enforcement agencies might encounter difficulties from handling confidential information (Unilever Australasia, AFGC, Masterfoods Aust. NZ), confidentiality around product formulation (NZ Dairy Foods, NZFGC), and whether sensitive information could be taken away (Parmalat Aust., PB Foods). The Tas DoH&HS noted that legal difficulties might include reluctance by manufacturers and suppliers to release commercially sensitive information, and that any enforcement activity will result in research and technical information being open to legal scrutiny. This notion was supported in the submission from WA DoH. CML considered that there might be difficulty in establishing whom the manufacturer is.

Other responses related to the evidence provided to substantiate general level claims. The TGACC noted that enforcement agencies may have difficulty obtaining suitable information from suppliers, and that leaving evidence only in the hands of industry would result in a lack of sufficient scientific rigour (TCCA). PB Foods indicated that appropriate assessment would depend on the scientific depths of the claim and evidence. Cadbury Schweppes highlighted difficulties that may arise from verifying substantiating evidence that is not from a recognised authority. The inaccessibility of the evidence dossier was also considered to be an obstacle (Cadbury Schweppes, TCCA). The CSIRO - HS&N considered the lack of reliable evidence for general level claims (with the exception of content and function claims) to be potentially difficult for enforcement agencies. Nestle suggested that enforcement agencies might lack understanding of the scientific evidence for general level claims that reference a non-serious disease. The NCEFF considered that the potentially high volume of general level claims, as evidenced by the U.S. experience where general level claims are more prevalent than high-level claims, could affect the capacity of enforcement agencies.

Two submitters noted that the Food Act does not currently provide enforcement agencies with the power to request substantiating evidence, rather only documents relating to the 'handling of the food for sale' (NSW DoH – N&PA Branch, NSW Food Authority). If the Guideline in Option 2 was adopted, three submitters noted that enforcement agencies would be unable to legally request information from suppliers (Diabetes Australia, GI Ltd, Nestle). Three submitters believed that enforcement would only be possible with a Standard (NZ MoH, NZFSA, NHF Aust.) and thus enforcement agencies would only need to ensure claims reflect the requirements of the Standard (NHF Aust.). In contrast, the CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA NZ

Branch, CMA - NSW Branch, CMA - QLD Branch, ICA) believed that compared to voluntary compliance with CoPoNC, the effectiveness of enforcement agencies ought to be improved given that the Guideline supporting the Standard would be viewed as being government endorsed.

Canterbury DHB believed that the responsibility for monitoring and enforcement should lie with public health units, with clear resources allocated to ensure topical issues are addressed adequately.

WA DoH stated that in Western Australia, the first step would be negotiation with manufacturers to comply with industry guidelines, with enforcement action being the last resort. WA DoH were concerned that the information compiled by industry and provided on request may be biased towards supporting the claim, although they considered that the proposed P293 framework might balance this issue out in the future.

NCEFF suggested adopting a model similar to the Swedish Nutrition Foundation model, in which a panel of 3 independent scientific experts are appointed to review the evidence. Although guidance documents would recommend a third party review, this would be voluntary as some companies may believe they have sufficient levels of scientific capacity within their own staff resources.

Mainland Products noted that the enforcement agency can make it as simple or as difficult as they choose.

Nutra NZ suggested that FSANZ develops a code of mandatory conditions to approve claims before use, to avoid any legal or practical issues e.g. The TGA has a 'conditions of listing' for complementary medicines which includes the requirement that the manufacturer holds 'satisfactory levels of evidence' to support the claim, which are available to the TGA on request.

CHC recommended that effort be made to ensure that enforcement agencies act efficiently, uniformly, consistently and timely with regard to breaches of the new Standard. They noted that more funding and education for jurisdictions would be required to achieve this. Dairy Aust supported this view in their submission and added that consistent interpretation of the Standard was important.

CHC also noted that each state has its own policies for dealing with breaches of the Food Standards Code, and that there appears to be an inconsistency in the application of penalties between each State Department. In addition, they noted that there is a reluctance to resolve non-compliance issues within the Courts due to high costs, resources and risks involved.

CHC recommended that enforcement officers be trained to assess substantiation documentation for validity, relevance and quality.

NZTBC considered that the proposed enforcement provisions are unwieldy and unnecessarily restrictive.

Bakewell Foods recommended following the same enforcement process as for other food regulation (for example NIPs), as long as the process is clearly defined.

Nutrition Aust. noted in their response that they were unsure of the legal or practical difficulties for an enforcement agency when requesting and assessing evidence in relation to general level claims.

The ASA recommended a clearly established location for holding records within the regulatory catchment area, to ensure that this information is readily accessible and that the regulator is notified of the specific location. Cadbury Confectionery, Naturo Pharm, NZ Magazines, NPANZ, Assoc. of NZ Advertisers and the NZTBC supported this recommendation.

TCCA considered that consumer confidence in the substantiating evidence for health claims would drop if there were no requirement for industry to prepare and submit evidence.

Nestle suggested that these enforcement issues should be raised through the watchdog body that is proposed to assist with enforcement. Dairy Aust. supported this suggestion and recommended that a federal 'watchdog' type of agency (such as the ACCC, or the newly developed expert group proposed by FSANZ) be established. Members would have the relevant expertise to advise and evaluate the level of compliance to the Standard.

The TGACC considered that the majority of compliance activities for health claims would relate to advertising. Consequently, food industry regulators should consider a model similar to that being implemented by the Australian and New Zealand medicines industry, which is a self-funding co-regulatory model. Not all advertising would require "pre-approval", but could be notified to a central office under a delegated authority given to companies who have legally signed off as to the accuracy of representations made. Such a model, underpinned by a complaints mechanism, would have the power to enable advertising sanctions against non-compliant companies on a national level and would not take away resource from the State jurisdictions. This view was also supported in a submission from the ASMI, which has also recommended that the legislative underpinning of industry codes of practice within legislation is worthy of further examination; such as compliance to the Medicines Australia Code of Practice being a condition of market entry for all new prescription medicines.

Question 66

Under existing food legislation, are the current powers of enforcement agencies to 'call on' evidence in support of general level claims, adequate?

Out of 147 submitters, 32% (47 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	20	8	4	2	34
Government	5	1	-	-	6
Public health	4	1	-	-	5
Consumers	1	-	-	-	1
Other	1	-	-	-	1
Total	**31**	**10**	**4**	**2**	**47**

Overview

Twenty submitters (none from actual enforcement agencies) stated that under existing food legislation the current powers of enforcement agencies, to 'call on' evidence in support of general level claims, were adequate. Another 19 submitters (including some enforcement agencies) disagreed with this statement (further responses related to enforcement powers under the proposed Guideline or Standard). One submitter noted that adequacy of powers would depend on whether general level claim criteria and conditions are in a guideline or a standard.

Discussion of submitter responses

Fifteen submitters believed that the existing legislation provides adequate powers to enforcement agencies (Bakewell Foods, CML, Dairy Aust., DSM Nut. Prod., Goodman Fielder, National Foods, Parmalat Aust., Solae Comp., CSIRO - HS&N, Fonterra, Griffins Foods, Mainland Products, NZFGC, NZJBA, Frucor). Parmalat Aust. specified that enforcement powers be covered under the Food Act 2003. The Tas DoH&HS concurred and stated that the power to 'gather evidence' could extend to requesting, demanding or seizing documents relating to health claims. They noted, however, that it would be unlikely that such action would be used for general level claims, and recommended less confrontational mechanisms.

Although the AFGC (supported by Masterfoods Aust. NZ) indicated that adequate powers were conferred by existing legislation, they suggested that jurisdiction Food Acts could have minor amendments to allow for requests of information beyond the handling of food. ABC and Nestle supported this view in their submissions. The DAA believed that the scope is available within existing legislation, but has noted that resourcing may be an issue.

Nineteen submitters indicated that current powers of enforcement agencies are inadequate (NZDA, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, WA DoH, CHC, Wyeth Aust., Unilever Australasia, NSW DoH – N&PA

Branch, NSW Food Authority, DAFF, ASMI). The NZDA noted that resources are also inadequate with regard to 'policing' staff and legal expertise in public health units. The CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA) noted that this opinion was backed by a current non-compliance with the voluntary CoPoNC of 14.8% that was reported by FSANZ. Powers under Food Act are limited to requesting documents relating to the 'handling of food for sale' (WA DoH, NSW DoH – N&PA Branch, NSW Food Authority, DAFF).

The ASMI considered that State Health authorities are under-resourced, do not to have adequate regulatory powers, and are a costly method of enforcement. They also noted that State Health authorities failed to uniformly apply existing prohibitions, and considered that this failure might be partially due to having poor interpretive skills for the validity of health claims. The WA DoH noted that the Food Act failed to address issues of advertisement and promotional material, which are potential sources of nutrition and health claims. DAFF suggested that enforcement powers should be inserted in the proposed Standard, to simplify and avoid confusion.

The NCWA suggested that given some of the claims in the media, consumers might not perceive current powers to be adequate.

Fourteen responses related to enforcement powers under the proposed P293 Guideline or Standard (NZFSA, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, TCCA, Consumers' Instit. of NZ, WA DoH). The NZFSA believed that adequacy of powers would depend on whether general level claim criteria and conditions are in a Guideline or a Standard. The CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA) noted that their support for Option 2 is conditional on its successful implementation and enforcement. They recommended that if compliance under Option 2 does not improve, then the opportunity to adopt Option 3 should be considered at the 2-year review. TCCA noted that enforcement agencies will need to be proactive in enforcing the new Standard, and resourced sufficiently to carry out this work effectively. They recommended severe penalties for filing false substantiation information with FSANZ. The WA DoH recommended that the Standard includes two clauses: a requirement for documentation of the substantiation process, including references and documentation used in the decision making process; and a requirement for provision of this information on request by an authorised person.

The ASMI considered that food standard enforcement was more difficult than the therapeutic goods regime, which incorporates a register of products and enables marketing authorisations to be withdrawn using a much simpler enforcement process. They suggested that the establishment of a health claim enforcement mechanism for State Regulators, which made non-court based appeal provisions available to companies, would offer a more equitable solution.

The NZFGC noted that food legislation has not been a high priority in NZ, while the NZDA noted that food safety has been a higher priority for public health units, and is unlikely to change.

Three submitters believed that there was little evidence of an active enforcement program (TCCA, GI Ltd, Nutrition Aust.), and as a result, two submitters were unable to comment about the adequacy of current powers of enforcement agencies (GI Ltd, Nutrition Aust.).

Wyeth Aust. recommended that industry should have internal systems in place in order to provide an evidence trail should claims be challenged.

Nutra-Life H&F believed that if the overarching principle is 'consumer health and safety', then requests for supporting evidence should not be a contentious issue.

Other comments provided but not in direct response to the question

Two submitters expressed concern that the enforcement of all labelling requirements in New Zealand has not been given priority (NZFGC, F&B Importers Assoc.). The NZFGC noted that despite the domestic food industry having expended huge resource in ensuring compliance with the Food Standards Code, a high level of imported product has non-compliant labels. F & B Importers Assoc. questioned how quickly action would be taken on technical breaches of a Standard, and what the requirements would be for general level claims. They noted that imported products are inspected at the border by AQIS, which does not enforce labelling requirements, and believes that this system would be inequitable, confusing for consumers and contrary to Australia's WTO obligations.

Four submitters noted that the proposed system would require dedicated resources in general (ANA), and in the States and Territories (Kidney Health Aust., NSF, TCCA). Kidney Health Aust. believed that it is important to consider sustainability from a resourcing perspective in terms of FSANZ having responsibility for regulation and watchdog roles for both general and high level claims. They believed that if this was an unrealistic expectation, it would be better to put resources into regulation of the higher level claims.

Compliance monitoring and enforcement should be proactive and not just reactive to complaints (ACDPA, Kidney Health Aust., NSF, TCCA, Consumers Instit. of NZ, ANA, ACA). The OAC NZ stated that it is imperative that there be active enforcement of health claims, given that health claims provide a potent advertising opportunity for manufacturers.

The ACA indicated that penalties be put in place to discourage non-compliance. Other submitters recommended that penalties for manufacturers who breach the Standard must be of significant deterrent level (ACDPA, Kidney Health Aust., NSF, TCCA, Consumers Instit. of NZ, ANA). The OAC NZ believed that penalties should reflect the advantage manufacturers could gain from misleading, exaggerated or incorrect claims.

Before any health claims are approved, there is a need to resolve the role of industry in ensuring compliance. In this regard, it is recommended that serious consideration be given to establishing a Health Claims Ombudsman fully funded by industry and able to investigate and address consumer complaints. Under this model, reference to

jurisdictions for enforcement would only be made as a last resort. In addition, a national compliance assistance unit should be established, either as part of the Ombudsman's Office, or within Department of Health and Ageing/FSANZ, preferably funded by industry (Tas DoH&HS).

The ISC 'watchdog' will provide a focus for any complaints. An active enforcement and surveillance system is favoured over a predominantly passive complain based system (Tas DoH&HS).

7.2 ENFORCEMENT OF A STANDARD VERSUS A GUIDELINE

Question 67

From the point of view of industry, consumers, public health professionals and enforcement agencies, what are the benefits of including certain criteria and conditions relating to general level claims in a Guideline instead of a Standard?

Out of 147 submitters, 48.3% (71 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	28	14	5	3	50
Government	5	2	-	-	7
Public health	7	2	-	-	9
Consumers	2	-	-	-	2
Other	3	-	-	-	3
Total	**45**	**18**	**5**	**3**	**71**

Overview

Almost 80 per cent of submitters (56), from industry, consumers, public health professionals and enforcement agencies, identified the benefits of including certain criteria and conditions relating to general level claims in a guideline instead of a standard. These benefits primarily related to greater flexibility concerning the amendment of criteria. Guidelines also provided more flexibility to: incorporate new claims more quickly, explore product innovation and advances in nutrition research, and offer consumers more choice. Other benefits of guidelines included ultimate cost savings and that it was an easier option for industry and enforcers. The remaining 20 per cent of submitters supported the introduction of a standard so that general level claims could be legally enforced.

Discussion of submitter responses

Many submitters suggested that a Guideline would permit greater flexibility:

- To amend existing claims as new scientific evidence emerges (Heinz Aust/Heinz Watties NZ, Mainland Products, NZFGC, NZJBA, Frucor, Aussie Bodies, ABC,

AFGC, Masterfoods Aust. NZ, Bakewell Foods, Dairy Aust., F & B Importers Assoc., GW Foods, Goodman Fielder, MLA, National Foods, National Starch, Parmalat Aust., Sanitarium Health Food Comp., Solae Comp., Wyeth Aust., Diabetes Aust. GI Ltd, PHAA (supported by ACA), Tas DoH&HS, WA DoH, NSW DoH - N&PA Branch, NSW Food Authority, Monash Uni – N&D Unit);

- To incorporate new claims more quickly, in comparison with the slower process required for Standards (ABC, AFGC, Masterfoods Aust. NZ, Dairy Aust., GW Foods, Goodman Fielder, Nestle);

- To explore product innovation and advances in nutrition research (WA DoH, Aussie Bodies, DSM Nut. Prod, GW Foods, National Foods, Diabetes Aust., GI Ltd, PB Foods);

- By offering consumers more choices as more claims are developed (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, ABC, AFGC, Masterfoods Aust. NZ, Dairy Aust., GW Foods, Goodman Fielder);

- In responding to consumer needs (William Wrigley Junior); and

- In the wording of a general level claim (Heinz Aust/Heinz Watties NZ).

GW Foods suggested that a Guideline approach would mean that enforcement agencies would not have to enforce, and therefore would be able to focus on other issues.

PB Foods believed that as a consequence of adopting a Guideline, fewer amendments to the FSC would translate into reduced costs, which in turn might lead to reduced costs for consumers (Diabetes Aust., GI Ltd). PB Foods noted that during the folate approval process there were a number of amendments caused by updating the list of approved products carrying the folate claim.

Six submitters indicated that amendments would occur in a timelier manner if Guidelines were adopted (Goodman Fielder, Monash Uni – N&D Unit, PHAA (supported by ACA), NSW DoH - N&PA Branch, SA DoH).

Nestle suggested that a Guideline would be more enforceable from a trade practices perspective, as the ACCC, NZ Commerce Commission and the State and Territory Consumer Affairs departments would be more likely to become involved in breaches relating to false, misleading and deceptive practices.

The ASA (supported by Cadbury Confectionery, NZ Magazines, NZTBC, Naturo Pharm Ltd, NPANZ, Assoc. of NZ Advertisers) suggested that Guidelines would be easier for industry and enforcers (Sanitarium Health Food Comp.) to follow. In addition, the ACCC considered that any guidance and/or clarification would serve to better inform the market. Consequently, the have recommended that certain general level claim criteria and conditions are placed within a Guideline or in a supporting user guide.

Naturo Pharm added that Guidelines are more flexible and along with industry self-regulation, backed up by recourse to the regulator to deal with persistent offenders, are the best option.

Mainland Products suggested that voluntary compliance with a Guideline is viewed as agreed good practice in which industry can take responsibility and pride themselves for choosing to comply. A Guideline was considered more desirable given the litigious consequences of non-compliance with a Standard.

Thirteen submitters indicated that there would be no benefits of including general level claim criteria and conditions in a Guideline (Canterbury DHB, CHC, Tas DoH&HS, ASMI, TGACC, CSIRO-HS&N, Nutrition Aust., CML, NZDA, DAA, TCCA, NCWA, NZ MoH, Griffins Foods). The Tas DoH&HS believed that a Guideline would be insufficient because general level claims have many 'grey' areas. All 13 submitters supported the introduction of a Standard, which would enable general level claims to be legally enforceable (Canterbury DHB, NZDA, DAA, TCCA, Griffins Foods), which in turn would ensure greater compliance (Nutrition Aust.), and would provide the best protection for consumers (NCWA). CML noted that a Standard would have legislative backing and less scope for interpretation if criteria and conditions were clearly written. The ASMI believed that Guidelines are undesirable given that the current system is largely complaints driven and adherence to CoPoNC is voluntary. They considered that Guidelines would only be effective if all health claims were subject to a pre-approval based system. This system was thought to allow interpretive flexibility to be negotiated with the evaluator prior to market entry. These views were supported in a submission from the TGACC.

Although Guidelines might be more quickly and easily changed, Cadbury Schweppes believed that legislating claims in a Standard would result in greater acceptance by ACCC and easier enforcement by the regulatory authorities. They suggested that non-compliance to a Guideline might result in a lack of confidence and trust in the process, especially if there is no enforcement mechanism. Consequently, they have recommended the establishment of a Standard if there is no reduction in non-compliance by the two-year review.

The NZFSA recommended that essential criteria and conditions for general level claims be placed in a Standard. However, they have noted that Guidelines would assist industry with interpretation and implementation of the Standard by providing plain English explanations, worked examples, check lists, and other advice and supporting material.

The DAA suggested that if Option 2 was adopted, a Standard that states that manufacturers must comply with the Guidelines for general level claims should be developed. This would provide flexibility to change but also address compliance and enforcement. However, they have also noted that while Guidelines have more flexibility, general level claims are least likely to change given that they will only refer to well established and accepted knowledge, thus flexibility is unnecessary. The NZDA has supported the submission made by the DAA.
The DAFF response stated that the benefits of a Guideline would include flexibility, while still being enforceable, as the pre-requisites are in the standard, including the

pre-requisite that conditions and criteria for making claims must be met. Their view was that CoPoNC and the new general level claims would differ in this regard.

Although in support of a Guideline, Cadbury Schweppes have suggested that non-compliance may result in a lack of confidence and trust in the process, especially if there is no enforcement mechanism. They have recommended the establishment of a Standard if there is no reduction in non-compliance by the two-year review.

Heinz Aust./Heinz Watties NZ noted that all manufacturers should adhere to the same criteria and conditions, as there is significant risk that these will be ignored (Heinz Australia/Heinz Watties NZ).

Although the CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA) recognised potential misgivings of a Guideline, they have acknowledged that a government endorsed Guideline should hold more status in the regulatory environment. They also noted that certainty is required to achieve a consistent approach, which preferably is one that is internationally aligned.

Unilever Australasia indicated that the benefit of greater flexibility would depend on the framework and would rely on it being subject to regular review to maintain relevance.

Five submitters recommended the development of a more transparent and consultative process for making changes, to ensure confidence in the system. This process could be more responsive than the current standard setting and amendment process (SA DoH, WA DoH, PHAA (supported by ACA), Monash Uni – N & D Unit).

TCCA saw the establishment of criteria and conditions within a Standard as a means to minimising spurious claims. They recommended a wide range of inclusion and exclusion criteria excluding foods and food categories, which contain a high level of nutrients, which might contribute to ill health.

Wyeth Aust. stated that use of Guidelines reflects general regulatory principles of the benefit: risk ratio, whereby a greater risk of an adverse outcome requires greater control. They believed that general level claims represent low risk claims. The DAFF believed that the inclusion of details on low risk claims in a Standard would represent over-regulation.

The Tas DoH&HS suggested linking the Guideline to a more rigorous compliance mechanism, such as an Ombudsman.

The WA DoH noted that a framework for administering the Guidelines has yet to be fully considered and developed.

The PHAA (supported by the NSW DoH - N&PA Branch, SA DoH, Tas DoH&HS, and Monash Uni – N&D Unit, Dr R. Stanton, ACA) noted whilst Guidelines would enable greater flexibility to respond to changing circumstances, Guidelines are not changed often (Dr R Stanton) and there have been no changes to CoPoNC since its inception and so the requirement for rapid changes has not been demonstrated.

Nutrition Aust. noted that the consequence of not updating CoPoNC is that it has become less useful.

Nutra-Life H&F noted that Guidelines could be enshrined in an industry's Code of Practice, which may be a condition of membership, and would be enforceable within the by-laws of the association. They considered that self-regulation and/or co-regulation would be most appropriate for industries where public health and safety is concerned. In addition, they have suggested that consumer protection legislation in New Zealand and Australia could also be invoked.

Question 68

From the point of view of industry, consumers, public health professionals and enforcement agencies, what are the costs of including certain criteria and conditions relating to general level claims in a Guideline instead of a Standard?

Out of 147 submitters, 43.5% (64 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	24	12	4	2	42
Government	6	-	-	2	8
Public health	8	3	-	-	11
Consumers	2	-	-	-	2
Other	1	-	-	-	1
Total	**41**	**15**	**4**	**4**	**64**

Overview

The majority of submitters, from industry, consumers, public health professionals and enforcement agencies, identified the costs of including certain criteria and conditions relating to general level claims in a guideline instead of a standard. These costs primarily related to fair trading issues within industry that would arise from non-compliance with a guideline. Costs also related to criteria being open to interpretation and inconsistent application made to claims so that the consumer would ultimately lose confidence in health claims, food manufacturers and the food industry. Some submitters stated that there would be a greater likelihood of a guideline being breached because it was not legally enforceable. Eight submitters believed there would be no significant difference in costs between a guideline and a standard.

Discussion of submitter responses

Twenty-five submitters indicated that fair trading issues within industry would arise from non-compliance with a Guideline, in that manufacturers who abide the criteria and conditions would be disadvantaged (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Nestle, Tas DoH&HS, SA DoH, WA DoH, NSW

DoH - N&PA Branch, Cadbury Schweppes, GW Foods, Sanitarium Health Food Comp, Monash Uni – N&D Unit, TCCA, Diabetes Aust., Nutrition Aust., PHAA (supported by ACA), NZFSA). Costs would be greater for companies that are compliant with a Guideline (NZ MoH, Tas DoH&HS), whilst an unfair market advantage is gained by less reputable companies which do not adhere to Guidelines. Several submitters believed that this would reflect badly on the food industry (TCCA, Diabetes Aust., Nutrition Aust., PHAA (supported by ACA)). Three submitters believed that imported goods might avoid regulation thus creating an unfair advantage over local industry (DAA, NZDA, GI Ltd). The NZFGC noted that regardless of whether claims fall under Guidelines or Standards, there must still be compliance with Fair Trading legislation.

The Tas DoH&HS believed that a Guideline would not provide a sufficient legal deterrent for manufacturers and suppliers.

Under a Guideline, criteria may be open to interpretation and inconsistently applied to claims. Suggested possible outcomes for consumers include:

- A loss of confidence in health claims (Sanitarium Health Food Comp, CHC, ABC, NSW DoH - N&PA Branch), and confusion arising from misleading claims (NZFSA, CML, NHF Aust., NHF NZ). The AFGC (supported by Masterfoods Aust. NZ) and Goodman Fielder noted that while false claims could reduce the credibility of truthful claims, some costs of this nature are inevitable in any system;

- A loss of confidence in food manufacturers and food industry (TCCA);

- Diminished confidence or loss of faith in a system that is not readily enforceable and potentially has breaches occurring with no redress (Tas DoH&HS, SA DoH, WA DoH, Monash Uni – N&D Unit, Nutrition Aust., PHAA (supported by ACA), TCCA);

- Greater difficulty to make complaints and have any enforcement action taken (Dr R. Stanton);

- Less protection (NCWA);

- Paying more for products with no significant benefit (GW Foods, Diabetes Aust., GI Ltd, DAA, NZDA);

- A greater potential for choosing less nutritious products based on misleading food labels. Over-consumption of such products (which carry claims and may also have a high fat, sugar, energy and sodium content) might result in nutritional deficiency and/or excess. This may lead to poorer short and long-term health outcomes that may negatively impact on the health care system (Diabetes Aust., GI Ltd); and

- A potential worsening of the market for health information (ABC).

Other submitters proposed that the costs of including criteria and conditions relating to general level claims in a Guideline for public health professionals included: consumers being inadvertently misled and incorrect advice provided (GW Foods); a diminished confidence in a system that is not readily enforceable and potentially has breaches occurring with no redress (Tas DoH&HS, SA DoH, WA DoH, Monash Uni – N&D Unit, Nutrition Aust., PHAA (supported by ACA); and greater difficulty in making complaints and ensuring that any enforcement action is taken (Dr R. Stanton).

The CHC viewed potential misleading and inconsistent claims from a Guideline as a significant public health issue. This view was reflected in a submission from the Sanitarium Health Food Comp. The NCWA believed that the costs must be judged against ultimate health benefits.

Ten submitters believed that a Guideline is not legally enforceable and that lack of enforcement would increase the likelihood of the Guideline being breached (National Starch, Solae Comp, NSW DoH - N&PA Branch, SA DoH, WA DoH, NZFSA, Nutrition Aust., PHAA (supported by ACA), Monash Uni – N&D Unit). Two submitters referenced Williams et al., 2003 in support of this belief (WA DoH, SA DoH). Enforcers would either be unable to enforce recommended criteria (Tas DoH&HS, NSW Food Authority), or would find enforcement more difficult (CML, Tas DoH&HS, NSW DoH - N&PA Branch, SA DoH, WA DoH, PHAA (supported by ACA)). Six submitters warned that enforcement agencies would face greater workloads when addressing complaints and removing offending claims (Tas DoH&HS, NSW DoH - N&PA Branch, SA DoH, WA DoH, PHAA, (supported by ACA)). As a result of increased workloads, some submitters indicated that associated costs relating to staff, time and court action would also increase (TCCA, Nutrition Aust., ASMI, National Starch, Dairy Aust., Tas DoH&HS, NCWA) although other submitters noted that these occur now and are a resourcing matter for the agencies concerned (ABC, AFGC, Masterfoods Aust. NZ, F & B Importers Assoc., Goodman Fielder, National Foods). Although NZ Dairy Foods stated that costs are unknown, they considered that a guideline is open to more abuse, which could mean more money is spent on enforcement. In contrast, GW Foods suggested that enforcement agencies would incur no cost, as guidelines would not be enforced.

The DAA (supported by the NZDA) noted that costs would include the difficulty in prosecuting non-compliant manufacturers, and suggested that these costs would be ultimately borne by the tax-paying consumer. The CHC believed that legal challenges, especially from multinational companies, would cause unnecessary pressure on individual jurisdictions.

Eight submitters believed there would be no significant difference in costs between a Guideline and a Standard (ASA, Cadbury Confectionery, Naturo Pharm, NZ Magazines, NZTBC, Parmalat Aust., NPANZ, Assoc. of NZ Advertisers). The NZFGC did not expect compliance costs to be greater in a Guideline, while the NZJBA (supported by Frucor) believed that costs would be minimal. Eight submitters suggested that a Guideline would incur minimal costs compared to a Standard, in that changes would not require application to FSANZ or a proposal from FSANZ to modify such Guidelines (ABC, AFGC, Masterfoods Aust. NZ, Dairy Aust., F & B Importers Assoc., Goodman Fielder, National Foods, PB Foods).

Unilever Australasia noted that while it was difficult to determine at this stage, costs of a Guideline should be less than that of a Standard, but a Guideline should confer the same additional benefits. In all cases, none of the submitters had identified the costs for each sector.

The WA DoH noted that the legal system currently is reluctant to support the enforcement of industry guidelines and as a consequence, enforcement agencies are acutely aware of this legal position and in some cases have deferred enforcement activity.

The CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA) believed that costs would relate to non-compliance that is not rectified and noted that companies could achieve market advantage through non-enforcement of non-compliant product; for example, a niche market of low carbohydrate products which commercially penalises law abiding companies. However, they believed that these costs would be the same if either a Guideline or a Standard were adopted. In addition, they noted that costs would be 'difficult to measure from circumstance to circumstance'.

Nestle believed that regardless whether general level claims are in a Guideline or a Standard, public health professionals should be able to advise their clients or consumers about appropriate products, industry compliance is needed to ensure consumer confidence and provide credibility, and enforcement is required and the costs associated with enforcement would be the same.

The ICA believed that neither a Guideline nor a Standard in P293 would have regard for promotion of consistency between international food standards, promote an efficient and internationally competitive food industry and promote fair-trading in food.

A number of submitters recommended that enforcement agencies should make health claims a priority (AFGC, Masterfoods Aust. NZ, National Foods), and FSANZ should make consumer education (AFGC, Masterfoods Aust. NZ, National Foods, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA) and enforcement a priority (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA) to ensure credibility and promote compliance in the first two years.

National Starch suggested that a Standard is developed, which states that manufacturers must comply with the Guideline, and noted that the tax office uses this system to cover new regulations. This suggestion was supported in the submission from the Solae Comp.

The DAFF considered a 12-18 month process for any amendment to conditions and criteria for low-risk general level claims general level claims to be unnecessary and wasteful of resources for FSANZ, other government departments involved in the approval process through Ministers, and for industry. Diabetes Aust. (supported by

GI Ltd) believed that resources would be wasted educating consumers about rule exceptions created by foods not complying with the Guideline.

The WA DoH noted that experience from an enforcement perspective suggests that as competition enters the market place, guidelines are quickly challenged by industry and are sometimes overlooked. They quoted recent reports from Western Australia, which suggested that nutrition claims (such as 'low fat') are being made even though manufacturers are aware that their average nutritional analysis cannot support the claim.

The AFGC (supported by Masterfoods Aust. NZ) believed that innate consumer scepticism is likely to constrain any short run effects of advice disseminated without a credible basis. This belief was reflected in the submission from the ABC.

Other comments provided but not in direct response to the question

In their response to the previous question (Q67), Canterbury DHB stated that there would be no benefits of a Guideline and they preferred the adoption of a Standard. In response to the current question (Q68), which referred to the costs of a Guideline in comparison to a Standard, their answer was "Clearer interpretation and more ability to enforce- very important for a new concept". FSANZ notes that their answer implies the benefits of a Standard, rather than a Guideline.

7.3 MEASURES TO PROMOTE COMPLIANCE

Question 69

From the point of view of industry, consumers, public health professionals and enforcement agencies, which interpretive guides should be given priority during the Standard development process?

Out of 147 submitters, 46.3% (68 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	23	16	4	2	45
Government	7	2	-	-	9
Public health	8	1	-	-	9
Consumers	2	-	-	-	2
Other	3	-	-	-	3
Total	**43**	**19**	**4**	**2**	**68**

Overview

The majority of submitters, from industry, consumers, public health professionals and enforcement agencies, considered interpretive guides to be a priority during the standard development process, given that they involve substantiation, pre-approval of

high level claims, general level claims, model claims, interpretive advice, compliance with the Standard, education and communication strategies. It was suggested by 28 submitters that user guides for general level claims should take precedence over other user guides. Five of these submitters clarified that user guides for substantiation requirements of high level claims were also important. However, 10 submitters recommended that a full suite of user guides be developed prior to the implementation of the Standard.

Discussion of submitter responses

The priority list according to stakeholders is shown below:

1. The principles of substantiation as they apply across the claims continuum including how to compile and assess evidence.

   (NZDA, Nestle, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Tas DoH&HS, ACCC, NSW Food Authority, NCWA, Aussie Bodies, Cadbury Schweppes, CML, National Starch, Solae Comp. Parmalat Aust., Campbell Arnott's Asia Pacific, TCCA, Diabetes Aust., DAA, GI Ltd, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm Ltd, NZ Magazines, NZTBC, NZ MoH, Dairy Aust., Nutrition Aust.)

   - NZDA referred to this issue as a support for enforcement agencies;
   - The CMA (supported by CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA) noted that guidance on substantiation is critical in order to avoid stakeholder confusion and possibly misinterpretation; and

   - Campbell Arnott's Asia Pacific supported FSANZ's recommendation for user guides to clarify the levels of scientific evidence.

2. Instructions for applicants about the procedure for seeking pre-approval of high level claims including review mechanisms as new scientific evidence becomes available.

   (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Tas DoH&HS, ACCC, Cadbury Schweppes, CML, National Starch, Solae Comp. TCCA, DAA, NZ MoH, PB Foods, Nutrition Aust.)

3. The process by which manufacturers should collect, assess and hold evidence in support of general level claims.

   (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Tas DoH&HS, ACCC, Cadbury Schweppes, CML, National Starch, Solae Comp. Diabetes Aust., DAA, NZFSA, NZ MoH, Nutrition Aust.)

4. Model claims and interpretive advice regarding the wording and representation of claims, particularly general level claims.

   (NZDA, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Tas DoH&HS, ACCC, Cadbury Schweppes, CML, National Starch, Solae Comp. Diabetes Aust., DAA, NZFSA, NZ MoH, Nutrition Aust.)

   - National Starch and the Solae Comp suggested that this user guide should be illustrative.

5. The process for assessing compliance with the Standard and the likely steps to be undertaken by the jurisdictions where the evidence held by manufacturers in support of general level claims might be considered inadequate.

   (Nestle, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Tas DoH&HS, ACCC, Aussie Bodies, Cadbury Schweppes, CML, National Starch, Solae Comp. Diabetes Aust., DAA, NZFSA, NZ MoH)

6. Education and communication strategies to support consumers' use of claims.

   (NZDA, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Tas DoH&HS, ACCC, Aussie Bodies, Dairy Aust., Cadbury Schweppes, CML, TCCA, DAA, GI Ltd, NZ MoH)

   - TCCA noted that this user guide would be closest to the aims and objectives of FSANZ. Nutrition Aust. recommended it should be made available when claims first appear to inform consumers of the new Standards, and to ensure consistent messages are received.

Several submitters had ranked the list of issues in order of perceived importance (Dairy Aust., Cadbury Schweppes, CML, TCCA, Diabetes Aust.).
Nutrition Aust. recommended that points 1,2,3 and 4 are the most important for ensuring that the Standard is implemented smoothly (accounted for above points 1 – 4). The guideline for assessing compliance (Point 5) would not be needed until the Standard has been implemented. A user guide for consumer education and communication strategies (point 6) would be needed by the time claims first appear to ensure consumers are informed and are receiving uniform and consistent messages.
NZ Dairy Foods considered that while all issues listed were important, guides for industry should take precedence over guides for consumer, given that there is a 'need to start at the beginning of the process'.

The DAA considered that priorities from the perspective of the enforcement agency (points 1, 2), industry (points 3, 4, 5) and public health professionals (point 6). In contrast, the NZFSA viewed points 3, 4, and 5 as priorities from an enforcement perspective.

Despite not specifying particular user guides, 28 submitters recommended that user guides for general level claims should take precedence over other user guides (Nestlé, Unilever Australasia, CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Goodman Fielder, National Foods, ABC, AFGC, Masterfoods Aust. NZ, F & B Importers Assoc., GW Foods, Campbell Arnott's Asia Pacific, Parmalat Aust., CSIRO-HS & N, GI Ltd., NCWA, Griffins Foods, NZFGC, NZJBA, Frucor). Reasons given in support of developing user guides for general level claims first: they would be adopted ahead of high level claims (NZFGC); they would provide confidence in the system for consumers, industry and government (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, ABC, AFGC, Masterfoods Aust. NZ, GW Foods, Campbell Arnott's Asia Pacific, NZJBA, Frucor); they would provide clear guidance for compliance and substantiation requirements (ABC, AFGC, Masterfoods Aust. NZ, F & B Importers Assoc., GW Foods, Campbell Arnott's Asia Pacific); and they would enable enforcement agencies to take action against non-compliance (Nestle, ABC, AFGC, Masterfoods Aust. NZ, GW Foods, Campbell Arnott's Asia Pacific, NZJBA, Frucor). The DAFF acknowledged that general level claims would gather considerable interest from industry, hence the need for interpretive user guides.

Five of the submitters, who recommended that the development of interpretive user guides for general level claims should be top priority, indicated that user guides for substantiation requirements of high level claims are also important (Nestlé) and that guidance for high level claims substantiation should take second priority to general level claims (AFGC, Masterfoods Aust. NZ, Goodman Fielder, National Foods). Dairy Aust. suggested that priority guidance documents should include general level claims including substantiation, and substantiation documents for high level claims.

Three submitters believed that interpretive user guides on criteria for general level and high level claims were equally important (ASMI, CHC, TGACC). Dairy Aust. suggested that priority guidance documents should include general level claims including substantiation, and substantiation documents for high level claims.

Fourteen submitters recommended that the full suite of user guides be developed (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA, Tas DoH&HS, ACCC, Monash Uni – N&D Unit, NZ Dairy Foods) prior to the implementation of Standard 1.2.7 (CMA, CMA-Vic Branch, CM of SA, Mandurah Aust., Palatinit Aust., Kingfood Aust., CMA NZ Branch, CMA - NSW Branch, CMA - QLD Branch, ICA.), and before allowing health claims (Tas DoH & HS). The ACCC noted that the full list of guides is equally important in preventing market failure.

The NZDA noted that criteria for prioritising development of interpretive user guides must be based on the ability to meet the first stated principle in the Policy Guideline "Give priority to protecting and improving the health of the population".

Goodman Fielder noted that manufacturers, particularly those of small or medium size, would be apprehensive and concerned about the new system for general level claims and the level of evidence required. Consequently, they believed that any guidance would be beneficial.

Other submitters suggested that industry should be involved in the development of interpretive guides to ensure appropriate workability in the use and assessment of suitability of claims and substantiation (Nestlé, AFGC, Masterfoods Aust. NZ, National Foods, Campbell Arnott's Asia Pacific). National Foods strongly supported active food industry participation to trial the interpretive guides for general and high level claims to ensure a robust regulatory system for nutrition, health and related claims.

Five submitters noted the need for food industry and enforcement agencies to be fully aware of the requirements to ensure protection of public health and safety (SA DoH, WA DoH, Monash Uni – N&D Unit, PHAA (supported by ACA)), and that guidance for these sectors should be a priority (WA DoH). Three submitters believed that a comprehensive consumer education programme would negate the need for interpretive guides for consumers (SA DoH, WA DoH, Monash Uni – N&D Unit). Nutrition Aust. believed that consumer research will be important in establishing education and communication strategies and would like to see this guideline set the framework for a national education campaign involving industry, health professionals and consumers.

National Foods recommended that all guideline documents should be made available upon gazettal of the Standard. This recommendation was supported in a submission from Mainland Products, who have noted that it is frustrating and costly for industry to obtain this information after a Standard is in place.

TCCA suggested that a longer time frame might be required to implement changes to ensure a Standard is developed to the required high quality.

Although Dr R Stanton considered that interpretive guides for industry are important, none of the issues listed in 7.8.3 of the IAR were specified.

Since Dr C. Halais has opposed the use of health, nutrition and related claims, her view was that this question was not applicable.

The Tas DoH&HS suggested that in addition to the list of issues in 7.8.3, there are three other user guides, which might be helpful. The first would be a user guide for education and communication strategies for enforcement agencies, particularly for local government. The 'FLIP' model was given as an example. A second user guide would encompass recommendations and industry requirements for removing existing illegal health claims. A third user guide would cover exclusion criteria.

The NZFGC believed that guidelines that assist with definitions should be a priority. Fonterra (supported by Mainland Products) recommended that the definition of a 'biomarker' and the seriousness of diseases and conditions should also be addressed in guidance documents. The WA DoH recommended that guides should contain a specified section to clearly distinguish between 'function' claims and 'enhanced

function' claims. Differentiation of general level, high level and therapeutic claims should be specified (Fonterra, Mainland Products, PB Foods), along with the definition of 'serious disease', high level claims and therapeutic claims (PB Foods).

Nutra-Life H&F considered that Guidelines for expression of content (what can and cannot be added to specific foods) are priority, with regard to defining the level of ingredients against the Recommended Dietary Intake. The example given was the restoration of nutrients lost in processing and proven nutrient deficiencies in the population, such as iodine.

Other comments provided but not in direct response to the question

Four submitters did not believe the development of interpretive user guides would be sufficient to ensure compliance with any new Guideline or Standard (ACDPA, Kidney Health Aust., NSF, TCCA).

Comments in relation to compliance and enforcement that were not in direct response to questions 64 – 69

The NZ MoH noted that the role of the whole environment in which people make choices about food is highlighted in the NZ MoH's 'Healthy Eating-Health Action (HEHA) Strategy, which is their basis for promoting healthy nutrition to improve nutrition, increase physical activity and reduce obesity. HEHA recognises that legislation has a role in positively influencing the NZ food environment. In the HEHA Implementation plan, outcomes around legislation are identified.

One submitter commented that P293 does not give much detail regarding enforcement processes (OAC NZ), and five submitters stated that they would like to see more detail about how the new Standard will be monitored and enforced (ACDPA, Kidney Health Aust., NSF, TCCA, ANA).

In a campaign letter, 11 Australian consumers requested that FSANZ develop procedures so health claims are monitored and when an untrue claim is made food manufacturers can be prosecuted (L Russell, A Neville, F Wright, K McConnell, G Austin, A Barnett & Family, J Gelman, S Ritson, A Swinburn, A Karolyi, D Dwyer).

ICA held the view that P293 does not:

- Have regard for promotion of consistency between domestic and international food standards;
- Promote an efficient and internationally competitive food industry; or
- Promote fair-trading in food.

They recommended that the proposed system should be easy to use, understand and interpret, and should not prohibit successful product innovation by way of cost, substantiation and time to market. They also supported development of provisions that will permit truthful, scientifically substantiated information about foods that help consumers make informed choices, leading to improved consumer nutrition and

health outcomes. The system needs to protect public health and safety and consumers must have confidence in it.

CM of SA believed that the Guideline should have traction through effective and consistent enforcement and communication. ICA shared this belief in their submission. The OAC NZ suggested that the use of standard, pre-worded claims would make enforcement easier.

Four submitters recommended that the minimum requirements of a compliance and enforcement system should be that it is independent of the food industry and accessible to the public (ACDPA, Kidney Health Aust., NSF, TCCA). The NSF noted that if a health claims system is introduced, strong safeguards such as compliance and enforcement powers, and a publicly accessible complaints process should accompany it.

The ACA proposed a complaints mechanism that would include the following elements:

- Should not place undue burden on the complainant as this will discourage complaints;
- Should not require the complainant to have a detailed understanding of the nutrient and health claims Standard;
- Be simple and accessible, and consumers need to be aware that the mechanism exists and how they can access it; and
- Provide feedback to the complainant about the progress and outcome of their complaint.

The ACA believed that considerable investment is required in the establishment of a pro-active watchdog; however, they believed that this is necessary if the Standard is going to be effective. A commitment from State and Territory enforcement agencies to monitor and enforce the Standard is also required.

The AFGC (supported by National Foods and Masterfoods Aust. NZ) recommended that the processes of the 'watchdog' for monitoring and acting on complaints be public and convincing in their action in order to enhance consumer confidence in the system. They supported the reporting line of the proposed Implementation Sub-Committee (ISC) 'Watchdog' as it provides a direct conduit to the policy making body.

The AFGC (supported by National Foods, Masterfoods Aust. NZ and Campbell Arnott's Asia Pacific) also recommended that a Technical Complaints Panel (TCP) reporting to ISC, be established. The terms of reference for TCP would be:

- To assess the nature of the complaint;
- To recommend action on the complaint; and

- To receive outcome of action on complaint; and report to ISC annually.

The AFGC suggested that the composition of the TCP should include an ISC member (Chair), FSANZ, industry associations, consumer associations and professional associations representing food scientists and social scientists.

To retain confidence in the system and to ensure transparency and accountability, the AFGC (supported by Masterfoods Aust. NZ) suggests that a website is established to list complaints, actions taken and final determination, taken from the annual report to ISC. The website should also facilitate the complaints process for all stakeholders wishing to register a complaint. They believed that the costs of such a system should be shared between all stakeholders with an interest in maintaining a credible system.

CHC have also suggested that a co-regulatory complaints committee is established to consider breaches of the Standard, similar to the CHC Compliant Resolution Committee. Membership of the committee would comprise of all regulatory, consumer and industry stakeholders, including food regulators. They noted that for this type of complaints committee to be effective it would require regulatory underpinning, timely and effective enforcement and meaningful solutions.

Kellogg's Aust. supported the need for a regulatory process that provides a transparent, strong and rigorous process to allow effective enforcement. They agreed that the enforcement process should include a monitoring system and recommended that a complaints resolution panel be established. In addition, Kellogg's Aust. has recommended food industry involvement in the development of this enforcement and monitoring system.

The ASA (supported by CAANZ, NZTBC, NPANZ, Assoc. of NZ Advertisers) believed that the weakest part of P293 is enforcement. The proposal for the "watchdog" to receive and forward complaints to various national and state regulators was considered unwieldy and too slow for advertising (ASA, CAANZ, NZTBC, NPANZ, Assoc. of NZ Advertisers), and unnecessarily restrictive (NZTBC).

NZTBC believed that the ASA/ASCB self-regulatory system of handling advertising complaints is effective and respected by industry and consumers alike. A similar body in Australia would be available to handle Australian complaints.

NZFGC expressed concern with the lack of enforcement of food legislation generally, which they noted is frustrating for companies that expend considerable resources ensuring compliance while other companies breach the regulations and go undetected. They considered that as a result of this discrepancy, the integrity of the industry is undermined and it is not helpful to consumers. In addition, the NZFGC have stated that P293 refers to the fact that some manufacturers and importers may choose not to comply with the provisions in the Guideline. They noted, however, that Guidelines and Standards command similar levels of compliance and manufacturers must first comply with the Food Act and Fair Trading Act.

NZFGC recommended adequate monitoring and enforcement of health and nutrition claims through the establishment of a complaints handling agency. They suggested that this agency could be managed in the way the ASA deals with complaints about

advertising, which the NZFGC noted has proved to be highly effective in New Zealand.

AFGC (supported by National Foods, Masterfoods Aust. NZ and Campbell Arnott's Asia Pacific) recommended that the Food Regulation Secretariat establish a small pre-market advisory service working group consisting of Food Regulation Secretariat (Chair), FSANZ, an enforcement agency, industry associations, consumer associations and professional associations representing food scientists, nutritionists and dietitians. The purpose of the working group would be to receive, in confidence, proposed claims food businesses may which to make and the type of evidence held by the food business to substantiate such a claim. The terms of reference for the working group would be to:

- Classify, according to the final claims framework, claims proposed by industry;
- Recommend if the type of evidence (but not to evaluate that evidence) proposed could support the claim;
- Develop over time a set of principles, drawn from real examples, for classifying claims and the evidence that supports such claims; and
- Report every six months to the Food Regulation Standing Committee (FRSC) on the nature and type of claims considered.

The AFGC noted that the determination of this working group would be non-binding and would offer an 'advice only' service to the businesses. Stakeholder groups would use the process to promote confidence in the system. The AFGC noted that in order for the advisory service to be effective and useful, the process duration would need to be rapid, providing advice in less than 20 days from receipt of the information. They proposed that the cost of this process should be borne by government as part of their commitment to educate stakeholders on the use of the system.

CHC believed that careful consideration should be given to managing enforcement of the new Standard, monitoring of manufacturer and marketer compliance and control of consumer advertising and marketing. They recommended that the enforcement process should include an on-going post-market assessment of manufacturers and marketers with respect to manufacturing standards and evaluation of claim substantiation, especially for general level claims.

ASA (supported by Assoc. of NZ Advertisers and CAANZ) proposed a new system that requires advertisements about high level claims to be pre-vetted, on a user pays basis. Consideration would be given to pre-vetting general level claims at a later date. Advertisements pre-vetted in either country would be valid for both countries. The ASA noted that both Australia and New Zealand run pre-vetting systems for therapeutic and liquor advertising so are familiar with the concept. The entire cost would be the responsibility of the advertising industry. FSANZ could have an auditing role. ASA have spoken to their Australian colleagues about this proposal, who are giving it consideration but are unable to give their unqualified support at this stage. Once ASA have approval for their proposals they will negotiate the detail with the Australian advertising industry. The NZFGC supported the establishment of a pre-

market vetting and advisory agency, and suggested that this could be modelled on the way advertising is managed in New Zealand.

NPANZ supported current specialised pre-vetting system by a Therapeutic Advertising Pre-vetting System (TAPS) adjudicator that is in place for therapeutic advertising, which approves advertisements for publication. NPANZ is therefore supportive of a similar regime to scrutinise high level claims about the health benefits of certain foods, and supportive of a system that would provide more consumer information from product advertising.

ASA have noted that advertising is a creative activity and is more flamboyant than labels, and another feature is its speed; therefore need to have the ability to react speedily to any complaint (supported by CAANZ and Assoc. of NZ Advertisers). However, they also noted that a consistent standard for advertising in Australia and New Zealand is warranted.

ASA suggested that under the proposed "watchdog" system each State, Territory and Government could take different action by way of prosecution, for the same new product/advertising. There could be several different outcomes, which would be chaotic for advertisers and disadvantage consumers. Instead, the ASA (supported by CAANZ, NZTBC, and Assoc. of NZ Advertisers) proposed a self-regulatory solution, where there would be a Trans-Tasman Food Advertising Code, which would be owned and operated by advertisers, agencies and media on both sides of the Tasman. The Code would be developed in consultation with FSANZ, industry and consumer groups. Consumer complaints would be heard by the ASB in Australia and the ASCB in New Zealand. Given that both are currently operating complaints systems, the ASA considers that the additional costs would be marginal. A Trans-Tasman Appeal Board would be established to resolve any varying standards. Decisions made by the ASB or ASCB would be binding in both countries. Advertisements in breach of the advertising code would be withdrawn and 100% compliance would be expected.

NPANZ have acknowledged their involvement in the development of the Trans-Tasman harmonisation of therapeutic advertising and would support a Trans-Tasman code for food advertising. They believed that the self-regulatory model has been extremely successful in New Zealand and it ensures quick compliance with advertising codes. Given that the self-regulatory model provides a faster complaint resolution process than a govt body could be expected to do, NPANZ have advocated this model.

NPANZ have noted the significant amount of compliance work undertaken prior to publication of any advertising. They also noted that sales representatives receive training on the importance and application of the ASA Advertising Codes of Practice, which has ensured that complaints are usually a matter of interpretation rather than blatant breaches of the codes.

Naturo Pharm recommended that a combination of Guidelines, industry self-regulation, and available recourse through a regulator offered the best option.

CHAPTER 8: OTHER RELEVANT ISSUES

8.1 THERAPEUTIC GOODS AND FOODS

Question 70

From the point of view of food and medicine enforcement agencies and food and medicine manufacturers, can the proposed FSANZ Conceptual Framework for the Regulation of Nutrition, Health and Related Claims ensure a clear boundary at the food-medicine interface for foods carrying health related claims?

Out of 147 submitters, 47.0% (69 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	23	14	4	4	44
Government	6	2	-	-	8
Public health	9	1	-	-	10
Consumers	2	-	-	-	2
Other	4	1	-	-	5
Total	**44**	**17**	**4**	**4**	**69**

Overview

Almost thirty per cent of submitters (20) stated that the proposed FSANZ Conceptual Framework for the regulation of Nutrition, Health and Related Claims would ensure a clear boundary at the food-medicine interface for foods carrying health related claims. Another 12 implied agreement, some conditional on the development of certain definitions. Eighteen submitters stated or implied that the proposed framework would not ensure a clear boundary at the food-medicine interface for foods carrying health related claim. A number of submitters raised the issue of the differences in the definition of 'therapeutic claim' in the Food Standards Code when compared to the Therapeutic Goods Act.

Can ensure a clear boundary

There were 20 submitters that clearly said that the proposed FSANZ Conceptual Framework for the regulation of Nutrition, Health and Related Claims would ensure a clear boundary at the food-medicine interface for foods carrying health related claims (NCWA, ABC, AFGC, Dairy Aust., DSM Nut. Prod, F&B Importers Assoc., Goodman Fielder, National Foods, Parmalat Aust., ASA, Cadbury Confectionery, NZ Magazines, NPANZ, Assoc. of NZ Advertisers, NZTBC, Griffins Foods, NZJBA, Frucor, Nestle, Unilever Australasia).

DAA (supported by NZDA) added the proviso that it should be adequately resourced.

In order for a clear boundary to be achieved, the ASA commented that there has to be consistency (the same definition) with the definition of 'therapeutic purpose' and 'therapeutic claim' between the Joint Agency for therapeutic goods and FSANZ for

foods, so there is no regulatory gap. If this is adopted then there has to be clear guidance on the differences between a High Level Claim for a Food and a Therapeutic Claim (this view was supported by NPANZ, Assoc. of NZ Advertisers, NZTBC, Cadbury Confectionery, Naturo Pharm and NZ Magazines).

National Foods added that an open and transparent system for claims, as per the Conceptual Framework, ensures a clear boundary at the food-medicine interface. F&B Importers Assoc. noted that the document clearly shows the boundary.

A number of submitters recommended that due to issues where the boundary is challenged it might be necessary for the jurisdictions to establish an expert reference panel on interface matters to adjudicate boundary issues as they arise (ABC, Dairy Aust., National Foods, AFGC supported by Masterfoods Aust. NZ, Nestle and Parmalat Aust, NZJBA supported by Frucor). It was further recommended that such a panel should include FSANZ, TGA, Medicines Australia, the AFGC and representatives from enforcement agencies (AFGC supported by Masterfoods Aust. NZ, ABC, Nestle and Parmalat Aust., National Foods). This panel would closely monitor the whole issue of the food-drug interface and provide a bridge between FSANZ, the Therapeutic Goods Act and Medicines Australia (Dairy Aust.).

Twelve submitters implied that they agreed that the proposed FSANZ Conceptual Framework for the regulation of Nutrition, Health and Related Claims would ensure a clear boundary at the food-medicine interface for foods carrying health related claims but they, and made the following comments (Diabetes Aust., GI Ltd, Nutrition Aust., PHAA (supported by ACA), Tas DoH&HS, SA DoH, Monash Uni – N&D Unit, WA DoH, NSW DoH – N&PA Branch, DAFF, NZFGC).

Although therapeutic claims have always been prohibited under the Food Standards Code, the problem has been lack of enforcement and the ability of suppliers to walk the line between the food/therapeutic goods interface. The TGA's section 7 and the proposed Framework should improve the situation significantly if adequate resources are allocated to implement it effectively (Diabetes Aust., GI Ltd).

It was considered by some submitters that the Conceptual framework does as much as possible/attempts to ensure a clear boundary at the food-medicine interface (Nutrition Aust., PHAA (supported by ACA), Tas DoH&HS, SA DoH, Monash Uni – N&D Unit). Some difficult issues that still need to be clarified were highlighted, relating to definition, e.g. therapeutic claim, serious disease/condition and the prohibition of certain words like prevent, treat, cure etc, as well as prescribed wording of claims which could be ambiguous (PHAA (supported by ACA), WA DoH, Tas DoH&HS, SA DoH, Monash Uni – N&D Unit). WA DoH and NSW DoH – N&PA Branch believed that the FSANZ Conceptual Framework could ensure a clear boundary at the food-medicine interface for foods carrying health claims providing these definitions are clarified. It was added that it is important that cooperative action takes place between Food Enforcement agencies and TGA to quickly deal with any interface issues that arise.

It was noted that it is important to take into account consumer perception of claims. As noted in the UK study (FSA 2002), consumers do not have the same interpretation

as the regulatory system and hence may interpret high level claims as therapeutic claims (PHAA (supported by ACA), Monash Uni – N&D Unit).

DAFF considered that as long as the definitions are the same, this is as much as the nutrition, health and related claims framework can do for this issue. They added that the issue of new fortified products is/will be regulated elsewhere in the Code (DAFF).

NZFGC also considered that if the definition of 'therapeutic' and 'high-level claims' is clear and unambiguous the FSANZ Conceptual Framework for the regulation of claims should ensure a clear boundary at the food-medicine interface for foods carrying health related claims. They recommended that if the New Zealand Dietary Supplement Regulations were repealed, which is currently under consideration, it would be of utmost importance to ensure that the definition of dietary supplements that fall within the ambit of the Food Standards Code are defined clearly and unambiguously because of the implications this could have on regulatory regimes for claims.

Cannot ensure a clear boundary

There were 11 submitters that explicitly said that the proposed FSANZ Conceptual Framework for the regulation of Nutrition, Health and Related Claims did not ensure a clear boundary at the food-medicine interface for foods carrying health related claims (CSIRO – HS&N, Nutra-Life H&F, NZFSA, Hort & Food Research Instit. of NZ, Palatinit GmbH, CHC, Wyeth Aust., Cadbury Schweppes, CML, Nutra-Life H&F, TCCA).

Cadbury Schweppes and CML doubted that the framework adequately ensures that there is a clear boundary between foods and therapeutics, as issues will come in the wording of claims, in particular those in the high level claim and biomarker categories. Cadbury Schweppes recommended that if actual claims were to be approved by FSANZ as part of the approval process manufacturers would have some assurance that they had not crossed from a food to a therapeutic. An unknown factor is the impact on consumers and an education program will be important. They queried will consumers be able to clearly distinguish between some high level claims and therapeutic claims.

CML required more information about the TGA process. They also recommended definitions that clarify the difference between food and a therapeutic good, and a health claim and a therapeutic claim'.

CHC noted that a lack of understanding of the difference between health claims and therapeutic claims could lead to an escalation of illegal therapeutic claims on foods and could move beyond control of enforcement agencies. Manufacturers could also take advantage of the new provisions. They added that there are still unresolved issues over manufacturing quality issues and over equity in advertising standards of high level claims. They stated that the anomalies involving goods imported into Australia from or through NZ would continue.

It was believed that the proposed Framework would not ensure a clear boundary at the food-medicine interface because if the definitions and the standards of evidence or

regulatory processes remain the same, the issue of whether or not a therapeutic claim is being made will remain (Wyeth Aust.).

It was stated that the boundary would become increasingly blurred if health/disease claims were allowed on food. A recommendation was made that this overlap may be overcome if there was a special category created to allow for dosage etc (e.g. Therapeutic Type Dietary Supplements or Foods for Special Medical Purpose) (Nutra-Life H&F).

NZFSA commented that the interface boundary would be multi-faceted. The proposed framework should be able to be used but the distinction of what is a food and what is a therapeutic will be dependent on many other factors than claims.

Hort & Food Research Instit. of NZ also felt the boundary between foods, dietary supplements and therapeutics is increasingly blurred. They stated that FSANZ assumes that foods cannot be therapeutic, however there is evidence to indicate this is not the case and this will strengthen with continuing research. They recommended that FSANZ ensure that foods/supplements pairs are identified and given special treatment, e.g. Cranberry supplements and juice drinks are both active against urinary tract infections, so if a therapeutic claim is relevant for the supplement logically it should also apply to the food (with substantiation). This is also relevant to herbs and herb extracts, as it is sometimes possible to obtain greater amounts of biologically active components from food sources than the related supplement. They noted that there would be inherent contradictions between food and therapeutic regulations if this issue were not reconciled.

Concern was expressed that there is no clear consistent distinction between health claims as related to foods and regulated by FSANZ on one side, and therapeutic claims as referring to goods regulated by the Therapeutic Goods Administration on the other side (Palatinit GmbH).

The TCCA submitted that the boundaries remain unclear and it is anticipated they will be actively pushed and tested by those marketing a range of food products. Their reasoning for this opinion was that the definition of a Therapeutic Good in the *Therapeutic Goods Act* highlights the issues raised in the Health Claims discussion at hand. The first two points (ref p 80 of the IAR) "relating to preventing diagnosing or curing an ailment …etc" and "influencing inhibiting or modifying a physiological process…etc.." would seem to closely mimic some of the intention or implication if not the explicit claim linked to food related health claims. A legal test case in discriminating these definitions in some current product health claims would make for interesting reading!

There were another six submitters that implied that the boundary at the food-medicine interface will not be clear, with the following answers (Dr R Stanton, Coeliac Society of Aust., Tomox, NSW Food Authority, NZ Dairy Foods, Naturo Pharm):

- A totally clear-cut boundary is unlikely. Cooperative action between the Food Enforcement Agencies and the TGA to deal rapidly with interface issues is essential (NSW Food Authority);

- Dr R Stanton considered that many products that would be better as supplements where the dose can be controlled are likely to appear in foods where the dose is less controlled (especially if the component is present in more than one food);

- Concern was expressed that the well-proven link between gluten and coeliac disease may be interpreted as a therapeutic claim (Coeliac Society of Aust.);

- Tomox felt that confusion is likely with novel foods;

- NZ Dairy Foods noted it is always difficult to get a clear boundary at the food-medicine interface; and

- Naturo Pharm noted that presently in New Zealand all products except registered medicines are prohibited from making a therapeutic claim, and foods with a therapeutic use would be caught under the definition of 'related product' contained in Section 94 of the Medicines Act. They added that the Medicines Act will likely be replaced if Trans-Tasman harmonisation of therapeutic goods goes ahead, however it is important that the interface between TGA and FSANZ is clear and there is no gap. They noted that there is no reason that a food could elect to be a therapeutic product and given the changing nature of our foods (including the move towards fortified foods) that many foods have in reality already become therapeutic products and related products. They stated that it is just because the interface is so unclear at present that these products are not being consistently regulated and so the playing field is not level.

General comments

Aussie Bodies believed that for general level claims, it is unlikely that there would be any boundary issues. However with high level claims there is the potential for uncertainty about the boundary, especially given the current uncertainty about whether certain herbs are foods or medicines and likelihood of more foods that contain ingredients that by themselves are regarded as therapeutic agents, e.g. Stevia, the extract of which is a TGA listed substance but the whole herb is a food. It was suggested that the distinction might lie in dosage.

Two submitters considered this question to be difficult to answer in the absence of progress on the FSANZ consultations for Food Type Dietary Supplements, Formulated Beverages and Non-culinary Herbs in Food (ASMI), which could clarify the issue with regard to presentation, which serves as an important distinguishing feature between foods and medicines (TGACC). They noted one significant benefit of the FSANZ conceptual framework that will allow a suitable distinction between complementary medicines and foods is that 'traditional claims' that have not been scientifically validated are not included within the framework of allowable sources of substantiation. They also considered there to be issues over equity in manufacturing quality issues and issues over equity in advertising standards of similar claims.

NZ MoH recommended that wherever possible the Food Standards Code and Therapeutic Goods Act should be consistent. This issue was also raised by ASMI who said it is still a conceptual problem that the definition of 'therapeutic claim' under the proposed system will not accord with the definition under the Therapeutic Goods Act, thereby giving the false impression that the desired health outcomes between a medicine and a food will always be different. This view was also supported by TGACC who added that in reality, the only real difference might be one of dietary context.

With regards to this, it was believed that the FSANZ claim descriptor for therapeutic claims attempts to clarify which food claims may not be permitted. Given that compliance for high level claims submissions must be considered during the pre-market approval process, regulators will need to consider at this point if the benefit claim being sought is therapeutic in nature. It was suggested that consumer research might assist in this determination (National Starch, Solae Comp.).

CMA noted that they understood that FSANZ has every intention to delineate between the food/medicines interface, but foods carrying health claims will reduce the distinction that currently exists. They noted that it is important to ensure clear definitions between foods and therapeutic goods and delineation between the two to minimise the impact of confusion. Whether consumers are able to make the distinction is unknown, however the proposed education process will need to alleviate this (these views were supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, and CM of SA).

Horticulture Aust. recommended that functional foods should be considered in the context of the review of claims, particularly for unprocessed primary produce. This was because such foods which have higher levels of particular nutrients by virtue of their breeding, selection or consistency of availability of a particular nutrient (as compared, for example, to genetically modified products) will be and are currently available without labelling and licensing. For such products, the issue is with the claims that may be made rather than safety or environmental issues. Functional foods should be able to claim the increased quantum of the relevant ingredients as a matter of course and without further data requirements.

They went on to say that the only exception to this would be nutrients where there is a clear maximum daily intake either in total or for particular physiological states e.g. Vitamin A. They recommended that the way to deal with this could be to allow the above for all foods that are not more than 100% RDI and for which there is no physiological limit. In addition, genetically modified foods should be considered in a similar manner, noting that the Office of Gene Regulation addressed safety and environmental issues. Fortified foods would also potentially fall into this category, but would not be classified as unprocessed primary produce.

Uni. of Adel. & Uni. of SA. – Nutrition & Physiology Research Grp believed that such a boundary at the food-medicine interface would be arbitrary, undesirable and counterproductive.

William Wrigley Junior noted the need for a clear distinction between therapeutic goods and foods.

Other comments provided but not in direct response to the question

The DITR commented that they understood that the Australian medicine industry has raised concerns that regulation of nutrition, health and related claims for foods could place medicine manufacturers at a disadvantage relative to food manufacturers, where similar claims are permitted but substantiation requirements for claims on food are less onerous. They recommend that the regulation of food health claims should allow the food-medicine interface to be clearly identified, preserve its integrity and provide a level playing field for the regulation of claims on each side. They stated that the medicine industry supports a level playing field. DITR also highlighted the importance of FSANZ working closely with the pharmaceutical industry in progressing P293 to ensure the new food standard does not put the pharmaceutical industry at a disadvantage.

The ASMI noted that in the European Union Proposed Regulations on Nutrition and Health Claims in food, 'therapeutic claim' has not been separately defined to differentiate it from claims made in food. The acceptance of 'health' and 'therapeutic' claims as potentially being synonymous requires a significant change in current thinking and potential legislative amendment for both foods and medicines, but it would greatly assist in making the interface between foods and medicines more defined.

The ASMI added that a flow-on effect of this is to remove the contentious issues over whether certain foods deliver their therapeutic benefit through an appropriate 'serving' or an appropriate 'dose'. It is clear to the Complementary and OTC medicines industry that certain novel foods containing biologically active substances (i.e. phytosterols) function on a minimum daily intake, which can only be described as a dose. If it is acknowledged that foods do make therapeutic claims – in context to overall diet – the need to couch minimum dietary intake of these biologically active substances in language other than 'dose' becomes redundant and may reduce the potential for ineffective administration through ad lib consumption.

CHC stated that workshops conducted by FSANZ clearly demonstrated that food industry members do not have a clear understanding of the difference between a 'health claim' and a 'therapeutic claim' and this is of great concern to the complementary healthcare industry. They noted that numerous breaches have been brought to the attention of the complementary healthcare industry complaints bodies and that in the past it has been extremely difficult to resolve non-compliance issues within the food sector.

They added that if there are accepted public health/safety/welfare reasons to impose particular advertising or labelling requirements on therapeutic goods then these should also be applied to foods making claims for risk reduction of a serious disease. The CHC strongly recommended that the food industry adopt the principles of the Therapeutic Goods Advertising Code for both general and high level claims. They also recommended that manufacturers and marketers should sign a statutory declaration stating that their advertising, labels and substantiation complies with the

standard for health and nutrition claims. Statutory declarations would help deter breaches and allow for a more efficient enforcement system.

Mandurah Aust. also noted their concern that there is no clear consistent distinction between health claims as related to foods, and therapeutic claims as referring to goods regulated the TGA.

Question 71

From the view point of food and medicine enforcement agencies and food and medicine manufacturers, would the proposed FSANZ Conceptual Framework for the regulation of Nutrition, Health and Related Claims and proposed Substantiation Framework promote equality between the regulation of foods and medicines?

Out of 147 submitters, 35.4% (52 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	22	14	5	2	42
Government	2	1	-	-	3
Public health	2	-	-	-	2
Consumers	1	-	-	-	1
Other	3	1	-	-	4
Total	**30**	**15**	**5**	**2**	**52**

Overview

Forty-six per cent of submitters (24) agreed, or implied agreement, that the proposed FSANZ Conceptual Framework for the regulation of Nutrition, Health and Related Claims and proposed Substantiation Framework would promote equality between the regulation of foods and medicines. Seven submitters did not agree that these proposed frameworks would promote equality between the regulation of foods and medicines.

Would promote equality

There were 21 submitters that thought that the proposed FSANZ Conceptual Framework for the regulation of Nutrition, Health and Related Claims and proposed Substantiation Framework would promote equality between the regulation of foods and medicines (Diabetes Aust., GI Ltd, ABC, AFGC, Masterfoods Aust. NZ, Dairy Aust., DSM Nut. Prod., F&B Importers Assoc., Goodman Fielder, National Foods, Parmalat Aust., CSIRO – HS&N, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, NZ Magazines, NZTBC, NZJBA, Frucor, Nestle).

The main reason given by submitters for this opinion was that both the Frameworks for the development of claims and for the regulation of medicines are based on the principle of risk (AFGC, Masterfoods Aust. NZ, Parmalat Aust., ABC, Dairy Aust., Goodman Fielder, NZJBA, Frucor, Nestle).

In addition it was recommended that regulation should be commensurate with risk regardless of whether it is a food, complementary medicine or prescription medicine (AFGC, Masterfoods Aust. NZ, Parmalat Aust., ABC, National Foods, NZJBA, Frucor, Nestle, NZFGC). National Foods noted that they strongly supported the COAG principle for minimum necessary regulation.

Although they agreed that proposed framework would promote equality with medicines regulation, the ASA recommended that the definition of 'therapeutic claim' should to be consistent with the medicines version (this was supported by NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, NZ Magazines and NZTBC).

One potential inconsistency between the two systems was noted by two submitters – that of the management of biomarkers for non-serious diseases. Under the food regulation system this would require pre-approval by FSANZ. Under the therapeutic system, a biomarker may be classified as a complementary food requiring pre-approval by the TGA but not based on the substantiation of the evidence – the manufacturer would be required to hold the evidence (Dairy Aust., Parmalat Aust.).

Three submitters implied that the proposed framework would promote equality or thought that it might, with the following comments (NCWA, Cadbury Schweppes, TGACC):

NCWA also said that there is a high possibility it would promote equality.

Cadbury Schweppes said that the substantiation framework appears to mirror the procedures required by the TGA for therapeutic goods. They noted that reaching equality is an important step as the gap between high level claims and therapeutic claims is minimal so the substantiation process must also be seen as very similar if not identical. They raised concerns that consumers may not see a difference between "prevent" and "may reduce the risk of" and they recommended that definitions of serious and non-serious disease must be a joint agreement between FSANZ and TGA.

TGACC believed that the proposed framework may promote equality but only if equity is achieved on other important issues such as compliance monitoring and enforcement, and advertising control.

Would not promote equality

There were 8 submitters that did not agree that the proposed FSANZ Conceptual Framework for the regulation of Nutrition, Health and Related Claims and proposed Substantiation Framework would promote equality between the regulation of foods and medicines (ASMI, CHC, Wyeth Aust., NSW Food Authority, Uni. of Adel. & Uni. of SA – Nutrition & Physiology Research Grp NZ MoH, Hort. & Food Research Instit. of NZ, Naturo Pharm).

The reasons provided by some of these submitters for this view were that:

- Equality will only be achieved with common definitions, standards of evidence and regulatory control (Wyeth Aust.);

- This equality is unachievable and unnecessary. Foods and therapeutic goods are distinctly different products, governed by separate legislation, serving to protect the interests of consumers (NSW Food Authority);

- It sets up an artificial delineation on claims based on semantics rather than "health outcomes" (ASMI);

- There is a "pro-active" programme of post-market surveillance of health claims for therapeutic goods as opposed to a "reactive" environment (ASMI);

- Inequalities already exist because of a lack of understanding; and

- Communication across this interface, for example the pilot project on folate/neural tube defect health claims (Naturo Pharm).

NZ MoH thought that equality would not achieved at the moment because high level claims may have elements of a therapeutic nature.

In addition to their answer above, Wyeth Aust. added that equality is achievable as long as the health claim can be substantiated. For example, if a product claims to lower blood pressure, it should be irrelevant whether it is a food or medicine providing there is evidence to support the claim.

It was stated that FSANZ assumes that foods cannot be therapeutic; however there is evidence to indicate this is not the case and this will strengthen with continuing research. It was recommended that FSANZ ensure that foods/supplements pairs are identified and given special treatment, e.g. Cranberry supplements and juice drinks are both active against urinary tract infections, so if a therapeutic claim is relevant for the supplement logically it should also apply to the food (with substantiation). This is also relevant to herbs and herb extracts, as it is sometimes possible to obtain greater amounts of biologically active components from food sources rather than related supplements. There will be inherent contradictions between food and therapeutic regulations if this issue is not reconciled (Hort. & Food Research Instit. of NZ).

General comments

Aussie Bodies noted that they had no concerns with general level claims but with high level claims, dosage differences may solve the issue.

It was considered by two submitters that the proposed framework for health claims for foods is generally sound, however they were concerned that complementary products can cite "traditional evidence" and that there is no public comment on such claims, whereas foods can only cite scientific evidence and food claims attract public comment. It was therefore suggested that greater equality might be achieved if complementary products can only use scientific evidence and that such claims were open to public consultation (National Starch, Solae Comp.).

DAFF stated that the table in the IAR is quite misleading. They considered it inaccurate to call the TGA notification scheme "pre-approval". In addition, the

nutrition, health and related claims framework does not regulate food safety, or food premises. A complementary medicines business planning to by-pass the TGA regulations by producing food would still need to comply with these standards also. Therefore, you could not say that the regulation of food is softer than for complimentary medicines.

It was considered that the framework appears to require a proportionately higher level of substantiation for food than complementary medicine. This is contrary to the principle of a risk-weighted framework (Fonterra).

NZFGC submitted that if based on the risk principle then the proposed substantiation framework should ensure equality between the regulation of foods and medicines. However they noted that they are concerned that under the proposed framework, high-level claims for foods have the potential to be under a more onerous regulatory regime than some medicines.

A number of submitters noted that a clear distinction between therapeutic goods and foods is required. They recommended alignment between regulatory terms in food and therapeutic goods regulations is imperative to assist in this delineation as determined by risk assessment (CMA supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, and CM of SA).

Heinz Aust/Heinz Watties NZ believed that the wording of high level claims should not be more restrictive than claims made on medicines and dietary supplements. For example, a comparison should be made of the permitted folate statements in Standard 1.1A.2 against the statements made on the labels of folate tablets (particularly Blackmores).

Nutra-Life H&F believed the issues appear to revolve only around the matter of health claims for foods and without these there is clear separation between food and medicines with foods being unable to make therapeutic claims. They commented that medicines must be manufactured according to Pharmaceutical Good Manufacturing Practice, which involves extensive testing of all raw materials, finished product and tight controls on labelling, dosage, reporting of untoward effects etc, therefore it is unlikely that medicine regulators will concede that equality exists with foods.

Unilever Australasia proposed that the FSANZ Conceptual Framework should not promote equality between the regulation of foods and medicines. Any regulation in either of these areas should relate to the risk. Mainland Products also opposed the promotion of equality between the regulation of foods and medicines, given that medicine is for the sick and food is for everybody.

CML commented that they don't really understand the relevance of the question, but said that equality between medicine and food manufacturers will probably be achieved through the processes put in place for assessing high level claims but this is not necessary for general level claims.

Other comments provided but not in direct response to the question

The ASMI considered it is largely accepted that foods will be making therapeutic claims provided criteria are met:

- Equity with Complementary and OTC medicines in substantiation for claims;
- Equity on quality and manufacturing principles to ensure the product is capable of delivering the claim; and
- Equity with Complementary and OTC medicines on compliance measures for labelling and advertising.

They considered a health claim in a food (which may be regarded as potentially synonymous with a therapeutic claim in a medicine) is any claim above a nutritional context claim that is made in context to total diet. With this approach, the issue no longer becomes whether a food is masquerading as a therapeutic good or making a therapeutic claim, but instead whether the product is being clearly presented as a food, and whether the claim is suitably in context to dietary and nutritional intake. They suggested that FSANZ might wish to dictate areas in which no health claim can be made by specific prohibition.

NZ F&V Coalition requested that consideration be given to consistency in messages across foods dietary supplements (and therapeutics where appropriate). They added that the value of foods should not be presented as inferior to supplement-type products due to the nature of labelling statements.

Additional comments from TGACC

<u>TGACC roles</u>

The TGACC outlined their establishment in the Therapeutic Good Regulations 1990 to administer the co-regulatory controls on the advertising of therapeutic goods. Key responsibilities include:

- Ensure that the TGA Code is current, relevant and reflects community values/standards;
- Ensure uniformity in approval processes and standards across advertising in all media.

They also make recommendations to the Minister for Health and Ageing regarding amendments to the legislation and the Code. Accepted amendments are published in the Government Gazette and become the applicable standard.

<u>TGACC concerns regarding advertising of therapeutic claims</u>

TGACC members have become increasingly very concerned at the number advertisements for food products that breach current food standards for health claims, particularly with respect to the level of therapeutic claims made. They welcome the opportunity for discussion of: therapeutic, health and related claims in relation to food

advertising; the interface between food and therapeutic products; and how equity can be achieved.

Equity of regulation of claims for food and therapeutic products

TGACC noted the consultation undertaken as part of the Toogoolawa Report on a proposed trans-Tasman system of advertising regulatory controls for therapeutic products during 2002, for consistency and equity in the regulation and enforcement of therapeutic claims made for foods, cosmetics and therapeutic products.

This report concluded that equity/consistency of the regulation of claims for foods/therapeutic products would be ensured by removing the prohibition on the making of therapeutic claims on food products, while providing that any therapeutic claim made in respect of food product be governed by the Therapeutic Products Advertising Code and subject to the same pre-approval and complaints handling processes in the trans Tasman agency arrangements.

TGACC noted that while it is currently not lawful for therapeutic claims to be made in the advertising of foods in either country, some product advertisements include illegally made therapeutic claims and there is minimal, if any, enforcement action taken against them. They added that the Toogoolawa Report suggested that a consistent approach could be achieved if the food and cosmetic regulators were to adopt the Code, or at least the complaints resolution powers, into their legislation. The Interim Advertising Council (IAC), established to further the recommendations of the Toogoolawa Report, was particularly concerned about the joint Food Regulation Ministerial Council decision to allow nutrition and health related claims on food. They believed the Policy Guideline could have serious implications for a level playing field for complaints handling, enforcement and sanctions between products regulated as foods, and those regulated as medicines.

With regard to pre-approval of "serious" food health claims (including biomarker maintenance claims) they expressed their concern that unless these claims are permitted only in the context of a level playing field for complaints handling, enforcement and sanctions between products regulated as foods and those regulated as medicines; the medicines industry clearly will be put at a disadvantage when promoting certain medicinal products with similar therapeutic claims.

TGACC noted that the IAC has strongly advocated the need for the pre-approval for any food health claims, which could be considered to be therapeutic claims, and for appropriate processes to be set in place for monitoring and enforcement. They added that therapeutic claims in food advertisements always have been prohibited under the Food Standards Code.

TGACC concerns

At the TGACC meetings held in June and August 2004, the following concerns were expressed, as to:

- The necessity for consistency of definitions and nomenclature between therapeutic goods and foods arenas, for example 'serious disease', 'health claims', 'therapeutic claims';

- The suggestion that the regulatory distinction between therapeutic products and foods might need to be clarified;

- The omission of obesity from the priorities list;

- The fact that there is no international standard and, therefore, there must be compliance with Australian requirements;

- Level playing field issues between foods and therapeutic products, such as the standards of manufacture, licensing and annual costs, in the context of competing interests and similar claims; and

- The handling of advertisements for foods in which therapeutic claims are made.

Concern was also expressed as to the effectiveness of multiple jurisdictions dealing with day-to-day advertising breaches. A simple amendment to the Therapeutic Goods Act suggested the removal of the current exemption for food as the most effective approach to achieve an equitable situation. Ms Major considered it unlikely that this approach would be taken for the following reasons:

- To avoid the possibility of confusion, such as FSANZ approving the use of a high level claim and then the TGA declaring the product to be a therapeutic good, there would need to be a referral mechanism between the two agencies;

- The addition of complementary medicinal substances to food and the implied health claims that may be conveyed, regardless of label claim; and

- Equitable quality platforms, i.e. stability data.

The issue of effective enforcement was identified as a major concern, although this is outside the purview of FSANZ. TGACC members have noted that States and Territories and New Zealand will deal with complaints about advertisements, after a central logging process. Historically, dealing with problems in food advertising by States and Territories in Australia has been found difficult in terms of priority, resources, consistency and timeliness. As well, although it is possible to do so, reliance on declaring a product to be a therapeutic good under the Therapeutic Goods Act 1989 can be cumbersome and not always appropriate.

Additional comments from Naturo Pharm

Naturo Pharm stated that there is significant potential for increased confusion and inequity of treatment between foods and therapeutic products. They submitted that health, food and medicines existed on a continuum, which starts a primary foods and moves through processed foods to fortified foods/dietary supplements, then on to therapeutics (including medicines). They believed that some foods could reduce the risk of specific diseases and increase ability to prevent the onset of specific illness (noting the similarity with dietary supplements). Other foods can cause ill health. We can still suffer ill health and if so, turn to products to reduce, treat, relieve, cure and/or alleviate a disease or condition or symptoms of that disease or condition. They proposed that it is clear that some products, irrespective of whether a food, dietary supplement or therapeutic:

- Establish and maintain good health, reduce risk of disease and increase our body's ability to prevent the onset of ill health; and

- Reduce, treat, relieve, cure and/or alleviate a disease or conditions of ill health and/or symptoms of that disease or condition.

Naturo Pharm also stated that products claiming to do/doing a similar job should be treated alike, largely irrespective of the nature of the product. All products should be classified by claim and ingredient, not by whether they have been historically understood as food, dietary supplements or therapeutics.

Naturo Pharm noted that FSANZ, TGA and Medsafe have the same primary function (to protect public health and safety). Given this, the fortification of foods and that the boundaries between foods and therapeutics are blurring, they stated that it seems sensible to move towards similar standards.

They noted that there are current differences in standards and implementation of these standards between Medsafe and NZ Ministry of Heath. Manufacturers perceive additional benefits/incentives from classifying products as foods, and these differences in standards provide incentive for manufacturers to manipulate their products so as to ensure they fall within one jurisdiction or the other.
Naturo Pharm provided three examples of current inequities between the two jurisdictions:

- Good Manufacturing Practice (GMP) is followed by dietary supplements/CAMs manufacturers to produce consistent, safe products. If food manufacturers were held to a lesser standard, it would be inequitable and consumer safety may be at risk;

- Advertising, claims, labels (risks/contraindications) - refers to fortification issues; and

- Levels of evidence for products seeking to make claims - notes current discrepancies between New Zealand/Australia, and queried the logic of requiring different levels of evidence for a product if it is a food or a therapeutic if similar claims are sought in respect of that product.

Naturo Pharm recommended that all products that wish to market themselves as wellness products should be required to meet the same standards for similar levels of claims, considering P293 outlines pre-market approval for high level claims and post market surveillance for lower level claims, compared with the Australia New Zealand Therapeutic Product Advertising Code which sets out a system for pre-market approval.

Naturo Pharm noted various regulatory options currently under consideration, and other possible options for regulation (refer to submission for more detail). They stated that who regulates is less critical than the parity that should be achieved across the manufacturing process, claims and minimum information requirements in respect of products containing common ingredients and carrying similar types and levels of risk of claims.

8.2 Fair Trading legislation

Question 72

With the exception of unqualified 'free' claims, are there any areas where the regulation of nutrition, health and related claims and fair trading provisions might be inconsistent or in conflict?

Out of 147 submitters, 36.1% (53 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	21	13	5	3	42
Government	4	-	-	-	4
Public health	3	2	-	-	5
Consumers	-	-	-	-	-
Other	2	-	-	-	2
Total	**30**	**15**	**5**	**3**	**53**

Overview

More than half of the submitters that responded to the question agreed that it was unlikely that there were any areas (with the exception of unqualified 'free' claims), where the regulation of nutrition, health and related claims and fair trading provisions might be inconsistent or in conflict. However, several areas of inconsistencies were identified such as limits of detection versus absolute values (i.e. zero) and the use of the word 'health' and 'weight' in brands, logos and trademarks. It was noted that health claims, which imply that people 'need' a nutrient or certain food, contravene the Fair Trading Act where no 'need' has been established. It was also suggested that the Standard should recognise that Certified Trade Marks are assessed under fair trading legislation.

Discussion of submitter responses

Several submitters (CSIRO – HS&N, Dr C. Halais, Griffins Foods, Heinz Aust./Heinz Watties NZ, Nestle and Nutrition Aust.) were unable to identify or did not believe there were any areas of conflict or inconsistency. The NZFGC believes that apart from 'free' claims there are no other areas of inconsistencies or conflict.

Nine submitters (AFGC (supported by Masterfoods Aust. NZ), ABC, Dairy Aust., F & B Importers Assoc., Goodman Fielder, National Foods, Parmalat Aust. and Unilever Australasia) noted that conflicts or inconsistencies would be unlikely given the Memorandum of Understanding (MOU) between the ACCC and FSANZ. National Starch and Solae Comp. stated that the ACCC and NZ Commerce Commission are well placed to identify such issues should they appear in the market place. NZJBA (supported by Frucor) said there might be areas of conflict but that these should be dealt with as they arise.

Whilst some submitters (ASA, Cadbury Confectionery, Naturo Pharm, NZ Magazines, NZTBC, Assoc. of NZ Advertisers and PB Foods), generally accepted that so long as claims are truthful there doesn't appear to be inconsistencies or conflict, they did acknowledge that the regulation for nutrition, health and related claims may restrict truthful claims from being made and this may be considered as a conflict with the spirit of fair trading. Further to this, Mainland Products considered the addition of more words or definitions to the framework creates opportunity for conflict. However, Cadbury Schweppes recommended that the regulation for nutrition, health and related claims be encompassed in a Standard, as a guideline will continue to see inconsistencies between fair-trading and food standards.

Fonterra mentioned that the regulations may restrict claims which may not be misleading, specifically noting the requirement for claims that mention biomarkers to be pre-approved as potentially inconsistent with fair trading legislation. PB Foods also considered that biomarker claims are best categorised as general level claims as consumers are aware of biomarkers so they present a lower risk.

The NSW Food Authority, supported by NSW DoH – N&PA Branch indicated that there would be no inconsistencies provided any false and misleading claims could be effectively enforced by the jurisdictions and the ACCC. The ACCC indicated that they are unlikely to initiate enforcement action in the absence of:

- Consumer health risk or detriment;
- Consumer complaint; and
- Any apparent competitive detriment flowing from the claims.

Aussies Bodies, did not rule out the possibility of there being inconsistencies between regulation and suggested that FSANZ needed to supply ACCC and other government enforcers with clear guidelines, for example, on statements such as 'high' and 'low'. Further to this, the CHC in their submission raised the issue that inconsistencies arise because monitoring and enforcement of fair trading provisions by State Health Departments is managed according to different priorities and interpretations which

has lead to a lack of uniformity with respect to technical breaches, allowing food companies the opportunity to avoid penalties for breaches of the current standard.

The NSW Food Authority and NSW DoH – N&PA Branch considered that the pre-requisites for making claims should adequately protect the consumers from false and misleading claims. Cadbury Schweppes Pty Ltd also noted that there would be a greatly reduced risk of claims being false, misleading or deceptive because of the requirement for all claims to be scientifically substantiated.

DAFF were not aware of any other areas of conflict but noted it is important to consider this in the context of international markets not just fair trading legislation.

In the submission from the ACCC, it was clarified that according to Halsbury's Laws of Australia, which addresses the issues of inconsistencies between subordinate legislation and it's enabling statute, that the provisions of an Act will override provisions in regulations prescribed under that Act.

CML considered that there were several areas of inconsistencies such as limits of detection versus absolute values (i.e. zero) and the use of the word 'health' and 'weight' in brands, logos and trademarks (examples provided were Healthy Choice, Weight Watchers brands). They recommended that there need to be some guidance from either FSANZ or ACCC/NZ Commerce Commission over the use of words such as fresh, natural, traditional, nutritious, wholesome, goodness etc. CML also queried whether ACCC has information as to what constitutes 'substantiation' highlighting that this could be and area of conflict if it is different to what FSANZ is proposing.

NCEFF suggested that it would be too problematic for implied claims to be regulated under a Standard and that they may need to be addressed by the ACCC.

The NHF Aust. (supported by the NHF NZ) indicated that it was important to ensure that there is no duplication or inconsistency with the processes already undertaken for approval of Certified Trade Marks (e.g. the 'pick the tick' program). They suggested that the Standard should recognise that CTMs are assessed under fair trading legislation.

The NZDA outlines that the NZ Fair Trading Act Section 13 (h) states that 'no person shall, in trade…make a false or misleading representation concerning the **need** for any goods or services. They suggested that as health claims imply that people 'need' a nutrient or certain food this contravenes the Fair Trading Act where no 'need' has been established.

Free claims

Whilst question 72 of the IAR asked submitters to provide details of any potential inconsistencies or conflicts between the regulatory framework for nutrition, health and related claims and fair trading legislation, other than those relating to 'free' claims, a number of submitters still provided comments in relation to this issue.

The AFGC (supported by Parmalat Aust, Nestle and Masterfoods Aust. NZ), Dairy Aust., National Foods, William Wrigley Junior and CMA (supported by Mandurah

Aust., Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, ICA, CM of SA) did not support FSANZ's interpretation that there is an inconsistency between Codex Guidelines for Use of Nutrition Claims related to the use of the term 'free' and Codex General Guidelines on Claims. These submitters do not consider that permitting tolerance levels in the nature indicated by the Codex Guidelines for Use of Nutrition Claims, where a nutrient is present at physiologically insignificant levels, represents false, misleading or deceptive conduct.

CMA (supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, ICA, CM of SA) recommends that prescription of criteria for claims such as 'sugar free' is necessary for consumer understanding and to avoid any potential conflict or perceived inconsistency between food regulations and fair trading legislation. In their submission they explained that the processing of 'sugar free' products, which are made from polyols instead of sugar, produces trace quantities of sugar as a by product. They contest that this is unavoidable and nutritionally represents a physiologically insignificant quantity. Therefore they recommend that criteria for 'sugar free' claims be aligned with the criteria currently provided in CoPoNC that allows for a tolerance 0.2% sugars when making the claim, recognising that this would be more restrictive than Codex, which allows a 0.5% tolerance.

Cadbury Schweppes recommended that 'free' claims should be allowed but a standard must qualify them. To the contrary, Mainland Products believes that areas such as free claims that are clearly regulated by fair trading legislation should not be duplicated in the Food Standards Code.

8.3 Monitoring and Evaluation

Question 73

Can the jurisdictions provide enforcement data on food categories where the use of nutrition, health and related claims may be a problem?

Out of 147 submitters, 18% (26 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	5	9	1	1	16
Government	5	2	-	-	7
Public health	3	-	-	-	3
Consumers	-	-	-	-	-
Other	-	-	-	-	-
Total	**13**	**11**	**1**	**1**	**26**

Overview

More than one-third of submitters (9) stated that government might be unable to provide enforcement data in relation to advertising where the use of nutrition, health and related claims might be a problem. Four submitters agreed that jurisdictions could provide enforcement data on food categories (including long life soups and meat products). One submitter recommended the New Zealand Commerce Commission. Five stated that this question required a government response or were unable to answer the question.

Discussion of submitter responses

Nine submitters commented that there was a strong suggestion that government cannot provide enforcement data on advertising where the use of nutrition, health and related claims might be a problem (ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZTBC, NZ Magazines, CAANZ, NZFGC). They argued that the fast pace of advertising requires the fast response capabilities of self-regulation, and proposed that a Trans-Tasman Advertising Code be set up and operated by the Advertising Standards Board (ASB, Australia) and Advertising Standards Complaints Board (ASCB, NZ). In this context, pre-vetting (pre-approval) of high level claims and general level claims would be based on the system in place for therapeutic advertising, which these submitters noted works well.

New Zealand Magazines (supported by Assoc. of NZ Advertisers, CAANZ) made a number of detailed comments on the monitoring of advertised health claims. They stated that the 'watchdog' proposal is unwieldy and not suited for advertising.

The submission raised the following additional points:

- Advertising is creative and more flamboyant than labelling, and that speed is a feature that requires a quick reaction to any complaint;
- A possibility of inconsistency across jurisdictions;
- Self-regulation would be superior to legislation due to the ability of such an approach to respond rapidly to changes in advertising strategies;
- There should be a self-regulated, Trans-Tasman code operated by agencies, advertisers and media, and developed in consultation with FSANZ, industry and consumer groups;
- Costs, complaints and pre-vetting systems of a self-regulated code should be the responsibility of the advertising industry. FSANZ would have an auditing role;
- Complaints should come from consumers and be handled by the ASB and ASCB, where decisions of either board would be binding in both countries, and a Trans-Tasman appeals board set up to resolve differences in opinion;
- High level claims should be pre-vetted; a user-pays system should be initiated; applied in both countries;

- General level claim also pre-vetted at a later stage; applied in both countries; and

- It was noted that a similar system exists for therapeutic and liquor advertising.

Benefits from such as system would include consumer protection and empowerment, a speedy resolution following input from the ASB and ASCB (beneficial to FSANZ and industry), and clear guidance for advertisers, agencies and media regarding what is or is not acceptable.

Five submitters stated that this question required a government response, were unable to answer the question, or thought the question was not applicable to them (AFGC, Masterfoods Aust. NZ, Dr. C. Halais, GI Ltd, William Wrigley Junior).

General comments and recommendations

The CHC noted that the collection of data might be difficult given the lack of resources and funding.

National Starch and Solae Comp believed that the jurisdictions would be in a position to provide enforcement data on food categories as per the proposed on-going survey framework, in which compliance would be ensured through laboratory testing and review of labels and advertising. In addition, they considered the importance of monitoring unpackaged foods (e.g. fresh juices) to ensure equity with processed/packaged foods. Juice bars are well known for making inappropriate claims.

NZFGC considered that the Commerce Commission in New Zealand might be able to provide a response in respect of this issue. They expressed concern with the lack of enforcement of food legislation, noting that this generally frustrates companies that expend considerable resources to ensure compliance when other companies that breach the regulations are undetected. NZFGC recommended the following to ensure a health and nutrition claims framework is adequately monitored and enforced:

- Establishment of a pre-market vetting and advisory agency, possibly modelled on the way advertising is managed in New Zealand; and

- Establishment of a complaints handling agency, which could be managed as for the NZ Advertising Standards Authority complaints procedure.

WA DoH stated that the Department of Health could provide information regarding nutrition, health and related claims on long-life soups. They noted that the Department also has evidence of nutrition claims made on meat products, supported by NIPs, which are not being confirmed by product testing in the market place.

NSW Food Authority (supported by NSW DoH – N&PA Branch) highlighted New Zealand products that fall under the Dietary Supplements Regulations, which are admitted as a listed product in Australia by the TGA (e.g. therapeutic soft drinks).

Other comments provided but not in direct response to the question

Campbell Arnott's Asia Pacific supported recommendations made by AFGC to set up a pre-market advisory service and post-market advisory complaints handling service to ensure consumer confidence in general level claims.

Nutrition Aust. considered that an effective monitoring and evaluation program is required to ensure protection for public health and safety and prevention of misleading and deceptive practice. They believed that it is critical that a National Nutrition Survey is completed prior to the implementation of a regulatory system for regulate nutrition, health and related claims, as this would provide essential baseline information. Ongoing surveys would also be required to evaluate the impact of changes in the food supply and the effects on dietary behaviour and intake.

Three submitters believed that a national, systematic and co-ordinated food and nutrition monitoring and surveillance system is required, on which to base assessments of public health and safety and the impact of changes to the Food Standards Code, food choices, food availability and nutrient intake in response to nutrition, health and related claims (WA DoH, Tas DoH&HS, SA DoH). SA DoH believed that it would be difficult to see how the proposed Standard could function in the absence of such a system, which would enable ongoing public health risk assessment and management.

WA DoH considered that baseline population dietary intake information is urgently needed, before any claim system is established. They quoted Eat Well Australia (NPHP 2000) which recommended a "coordinated national food and nutrition monitoring system is needed to provide appropriate data for policy development; coordination and review; program planning and evaluation; reporting against national goals and targets; and reporting internationally". WA DoH stated that an active enforcement and surveillance system is preferable to relying purely on a passive complaint based system, to ensure population dietary intake is not adversely affected.

Question 74

Can the food industry provide data on the types of food categories currently carrying content or function claims, a folate/neural tube defect health claim or endorsements?

Out of 147 submitters, 26.5% (39 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	19	6	5	3	33
Government	2	2	-	-	4
Public health	2	-	-	-	2
Consumers	-	-	-	-	-
Other	-	-	-	-	-
Total	**23**	**8**	**5**	**3**	**39**

Overview

The majority (28) of the submitters provided general or specific data on claims carried by products.

Discussion of submitter responses

Twenty-four submitters from the food industry did indeed provide data on claims carried by their products (CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA, CML, Dairy Aust., Fonterra, Mainland Products, GW Foods, National Foods, Nestle, Parmalat Aust., PB Foods, Sanitarium Health Food Comp. Heinz Aust/Heinz Watties NZ, Tegel Foods, Unilever Australasia, William Wrigley Junior). Details on the types of claims and products have been summarised in Table 1, following the discussion.

National Foods stated that the majority of their milk, flavoured milk, dairy foods and soy foods currently include nutrition content and/or nutrient function claims. They have made a folate health claim on the brand Pura Edge (then regulated as a Supplementary Food) and currently make a folate content and nutrient function claim on Pura Boost (a Formulated Supplementary Food). National Foods intend to conduct a label audit and review of nutrition and related claims as part of the company initiatives to meet P293, which will produce information that could be provided on request.

CML listed the categories that currently contain content and function claims: canned fish (Omega 3), bread (fibre, calcium, iron, DHA, phytoestrogens, Omega 3), dairy (calcium, reduced fat, lactose free), sports drinks (essential vitamins and minerals, isotonic-electrolyte claims in relation to hydration), beverages (diet/low joule, sugar free), juices (vitamins), processed foods (reduced salt), jam (reduced sugar), prepared meals (low fat), snacks (reduced fat) and soy products (lactose/dairy free).
They also noted products containing folate claims, as per the FSANZ website.

The CMA (supported by Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA) provided an illustrative list of claims and endorsements for the confectionery industry, which included: sugar free, no added sugar(s), % fat free, the tooth friendly logo, does not promote tooth decay, World Dental Federation, low carbohydrate, cholesterol claims, diet, lite, comparative claims, specifically relating to fat quantity.

William Wrigley Junior also noted sugar free, the tooth friendly logo and the World Dental Federation.

Dairy Aust. noted that a range of food products currently carry permitted content, function and health claims (folate). They noted that this was true for dairy foods such as milk, cheeses and yoghurts.

Heinz Aust/Heinz Watties NZ stated that they will make nutrition content claims, as per CoPoNC, whenever possible. Currently they make general level claims on baked beans, tuna and tomato-based products.

Parmalat Aust. stated that they currently apply content/function claims and/or endorsements to functional milks, flavoured milks, yoghurts, dairy desserts, soymilks and soy yoghurts.

Tegel Foods noted that many products carry the National Heart Foundation 'Tick' symbol.

Nestle noted that there are numerous foods within different categories that are carrying content or function claims and endorsements. They noted that these are quite varied and their use would be dependent on market forces at the time. Some of these include dairy foods and meal-type products.

Unilever Australasia have many different types of products that carry nutrient content and function claims, including: spreads, beverages, recipe/pasta sauces and bases, instant soups, cereals, pasta and rice.

Other submitters that supported provision of data from food industry

Four submitters did not provide general or specific data on food categories currently carrying claims, although they suggested that the food industry should be able to provide such data (CHC, Goodman Fielder, Solae Comp, Dr. C. Halais). Goodman Fielder suggested that supermarkets or major retailers should be able to provide a concise list of product categories that use claims.

Six submitters did not have any data, or felt they were unable to comment (ABC, NZ Dairy Foods, Nutra-Life H&F), or thought the question was not applicable to them (GI Ltd, NZ MoH, NZFSA).

General comments and recommendations

Dr C Halais believed that industry might withhold conflicting or unequivocal data, and suggested that FSANZ should actively seek data from industry.

It was recommended that FSANZ continue to undertake periodic label monitoring, with its sampling strategies based on data obtained from major retailers and retaining the labels for future analysis (AFGC, Masterfoods Aust. NZ). In addition, FSANZ should work with market researchers (e.g. AC Nielsen) and large retailers to track claims (National Starch).

AFGC (supported by Masterfoods Aust. NZ) recommended that FSANZ utilise data available from major retailers to obtain volume data for sampling strategy.

National Foods noted that some product labels are too small to carry claims (e.g. dairy food, yoghurt, specialty cheeses).

Three submitters perceived the folate claim as too negative and therefore not an advantage for marketing (PB Foods, Fonterra, Mainland Products).

Other comments provided but not in direct response to the question

Nutra-Life H&F believed that food folate claims should match complementary medicine claims for folate. They suggested that folate claims are likely to be unsupportable given that only 45ug is commonly added to a serving, whereas 400ug per day is required by the TGA to support a neural tube defect claim on complementary medicine. In addition, they believed that food manufacturers should be subject to the same restrictions if they are to make similar claims.

WA DoH and SA DoH stated that updated Australian (and New Zealand) food composition data is urgently needed before any claim system is established, particularly as there has been a significant number of new products launched in Australia and New Zealand since 1994. SA DoH quoted research from Leatherhead Food International (2004) that indicated 5651 new products launched in Australia and 1796 in New Zealand since 1994. SA DoH considered that population dietary intakes might have changed since the most recent National Nutrition Survey (1995). These products equate to a significant proportion of the total food supply and highlighted the need to update the current database.

Table 1. Label claims and products submitted.

Label claim	Product and/or category	Submission
Calcium[1]	Creamed rice, dairy, breads	Heinz Aust/Heinz Watties NZ, PB Foods, CML, Fonterra, Mainland Products
Carbohydrate[2]	Confectionery	CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA
Cholesterol	Confectionery	CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA
Diet	Confectionery, beverages	CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA, CML
Dietary Fibre[3]	Baked beans, Prepared spaghetti, Frozen Veg., quick serve meals, soups, breads	Heinz Aust/Heinz Watties NZ, CML
Does not promote tooth decay	Confectionery	CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA
Endorsements	Confectionery, dairy, prepared meals, breads, cakes, muffins	CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA, Nestle, GW Foods, William Wrigley Junior
Essential vitamins and minerals	Sports drinks	CML
Fat[4]	Baked Beans, Spaghetti, Creamed Rice, Frozen Veg., Prepared Soups, Prepared Tuna, Prepared Meals, Quick Serve Meals, Confectionery, dairy, snacks, chicken	Heinz Aust/Heinz Watties NZ, CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA, PB Foods, CML, Tegel Foods, Fonterra, Mainland Products
Folate[5]	Frozen Veg, dairy, breads, various products[a]	Heinz Aust/Heinz Watties NZ, National Foods, GW Foods, CML

Table 1. (Continued)

Label claim	Product and/or category	Submission
Free, dairy	Soy products	CML
Free, Fat[6]	Dairy	Dairy Aust.
Free, lactose	Dairy, soy products	CML
Free, Salt	Frozen Veg	Heinz Aust/Heinz Watties NZ
Free, Sugar	Frozen Veg, Confectionery, beverages	Heinz Aust/Heinz Watties NZ, CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA, CML, William Wrigley Junior
Hydration	Sports drinks	CML
Iron[7]	Baked beans, frozen veg, quick serve meals, breads	Heinz Aust/Heinz Watties NZ, CML
Isotonic	Sports drinks	CML
Logos	Confectionery, chicken	CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA, Tegel Foods, William Wrigley Junior
Lycopene[8]	Sauces, prepared soups	Heinz Aust/Heinz Watties NZ
Omega 3, DHA[9]	Prepared tuna, prepared salmon, canned fish, bread	Heinz Aust/Heinz Watties NZ, CML
Phytoestrogens	Breads	CML
Protein[10]	Baked Beans, Frozen Veg, Quick serve meals, Prepared Soups, Prepared Tuna	Heinz Aust/Heinz Watties NZ
Reduced energy[11]	Confectionery, beverages	CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA, CML
Salt[12]	Baked Beans, prepared spaghetti, sauces, soups, processed foods	Heinz Aust/Heinz Watties NZ, CML
Serves of Vegetables	Soups	Heinz Aust/Heinz Watties NZ

Table 1. (Continued)

Label claim	Product and/or category	Submission
Sugar[13]	Sauces, Confectionery, jam, beverages	Heinz Aust/Heinz Watties NZ, CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA, CML
Sustained Energy	Prepared soups,	Heinz Aust/Heinz Watties NZ
Unspecified comparative claims	Confectionery	CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, CMA-Vic Branch, ICA, CM of SA
Unspecified content claims	Dairy, prepared meals, soy products, breads, crumpets, crisp breads, muffins, cakes, spreads, beverages, sauces, soups, cereals, pasta, rice	Nestle, National Foods, Parmalat Aust., Sanitarium Health Food Comp, GW Foods, Dairy Aust. Unilever Australasia
Unspecified function and health claims	Dairy, prepared meals, soy products, breads, muffins, dairy, spreads, beverages, sauces, soups, cereals, pasta, rice	Nestle, National Foods, Parmalat Aust., Sanitarium Health Food Comp, GW Foods, Dairy Aust., Unilever Australasia
Various vitamins[14]	Frozen Veg, juices	Heinz Aust/Heinz Watties NZ, CML

[1]Source, [2]Low, [3]Excellent source, Source, High in, [4]Low in, % Free, % fat, [5]Source, high in, rich in, [6]x% fat free, [7]Source, high in, rich in, [8]Rich in, [9]Rich in, [10]Good source, high in, rich in, [11]lite, low joule, [12]Low in, reduced, [13]Low in, no added, reduced, [14]Good source
[a] referenced to FSANZ web site