Additional Comments made by submitters in response to the Initial Assessment Report for P293 – Nutrition, Health and Related Claims

National Nutrition Survey

ACA considered that there must be a Commonwealth commitment to update the National Nutrition Survey and an undertaking to collect this information on a regular basis to ensure that food policy and regulation is based on relevant, up-to-date consumption data.

Queensland PHS supported the maintenance and continuation of the National Nutrition Survey. They noted the last survey conducted in 1995 and further information is required to appropriately evaluate the introduction of the health claims framework due to vast changes to food standards that have occurred since that time. Survey should provide sufficient information to evaluate changes in food purchasing patterns, changes in food supply and food composition.

Kidney Health Aust and NSF sought commitment for the conduct of the National Nutrition and Physical Activity Survey, as this P293 has the potential to influence dietary intakes, so it is essential to get an accurate picture of nutrition consumption as a base line so as to allow measurement of this and other influences.

An effective monitoring and evaluation program is required to ensure protection from public health and safety and prevention of misleading and deceptive practice. It is critical that a National Nutrition Survey is completed as a matter of urgency prior to the implementation of the system to regulate nutrition, health and related claims. This will provide essential baseline information. Ongoing surveys will be required to evaluate the impact of changes in the food supply and the effects on dietary behaviour and intake (Nutrition Aust.).

PHAA (supported by ACA) believed it is premature to be developing a health claims standard in the absence of up to date national nutrition survey data (and a commitment to ongoing surveys), as information gained from these surveys will be able to indicate trends in dietary intake over time and will be invaluable in determining benefit or harm as a result of health claims. In addition, there is a concomitant need to update the tables of food composition so that accurate assessments of intake can be made.

J Seal – PH Nut. was concerned that the Initial Assessment Report makes no reference to monitoring and surveillance of the impact of health claims on human nutrition. While aware that monitoring of human health/nutritional status is not the responsibility of FSANZ, an evaluation of the effect of health claims on food composition, food consumption and nutritional status requires appropriate monitoring systems. Believe it would be negligent if these systems were not in place. She was also concerned that the Australian Government is considering a system of health claims without any recent baseline data, or process to collect future data, on the nutritional health of Australians.

Registered trademarks

Registered trademarks have the capacity to undermine the health claims standard as manufacturers make the name of the product a registered trademark in order to avoid health claims regulation (ACA).

Funding

The estimated cost of the Folate-Neural Tube Defect Health Claim Pilot was $1.1 million for one claim. There are significant costs associated with substantiation, enforcement and education for nutrition, health and related claims. Adequate funding is required to ensure that the introduction of health claims does not confuse consumers or diverts resources from other public health nutrition strategies (Tas DoH&HS, PHAA, ACA).

Funding in addition to the current limited amount provided for public health nutrition in Australia will need to be found to ensure that all aspects of the system operate as effectively as possible. Health claims promote commercial interests at the expense of public health interests; consequently it will be incumbent upon these commercial interests to fund the system adequately. This could be on a user pays basis (with manufacturers paying a fee – based on their annual turnover to use any of the pre-approved claims) or a levy applied to sales/advertising of foods with a high energy, low nutrient density (PHAA, ACA).

Potential funding sources for nutrition health and related claims need to be considered. There are substantial costs associated with all aspects of the system to regulate nutrition health and related claims, which include substantiation, enforcement and education. There is a risk that equally important public health nutrition work will suffer if funds are diverted to support nutrition health and related claims. Suggests that funding options include a fee system for use of the claims, and/or a levy on sales of foods making claims on labels or in promotion (WA DoH).

Consideration of other policies and standards

Amendments to Fortification Policy and the Review of Novel Foods Standard should be considered at the same time as Nutrition Health and Related Claims (WA DoH). SA DoH also has concern for policy development in relation to associated issues in isolation. For example, policy regarding the following issues has been/will be set in isolation to policy regarding nutrition, health and related claims:

- Fortification of food with vitamins and minerals;
- Fortification of food with substances other than vitamins and minerals; and
- Novel foods and non-culinary herbs.

PHAA (supported by ACA) noted that as FSANZ is also considering the revision of the novel foods standard and the application of the policy guidelines on the addition of vitamins and minerals to foods, it would be important to assess likely impacts (health and cost) with all of these changes in mind. They added that that vitamin and

mineral content claims are not included in the Initial Assessment Report at present. It will be essential in developing the draft assessment report to include the likely effects of the application of the guidelines.

ASMI considered the high level health claims system needs to take into consideration the Novel Foods evaluation procedure. They noted that it is also not clear whether a Novel Food will need to undergo a separate evaluation from the Novel Food process for claim under the high level claim system.

P260 - Use of Non Culinary Herb in Foods and P235 Review of Food Type Dietary Substances are both directly related to the outcomes of P293 and should not be reviewed in isolation. Outcomes of these proposals may allow food manufacturers and marketers to expand the range of health claims further into area of medicines (Campbell Arnott's Asia Pacific).

Bioavailability

The Initial Assessment Report does not address how the issue of bioavailability is going to be addressed for different food matrices. Believes bioavailability needs to be demonstrated in the food matrix about which claim is being made or otherwise a claim should not be permitted (SA DoH).

ASMI considered qualifying claims need to take into account not only the presence of a nutritive substance but whether the vehicle allows the substance to be present at the end of the shelf life as well as being bioavailable in that form. The test methods utilised by companies in order to verify this also need to be relevant to the food tested as scientifically validated. This is especially true of biologically active substances not already encompassed in general standards for nutrition labelling. This information needs to be made available to the regulator or State jurisdiction authorities on request.

CHC commented that the P293 Initial Assessment Report makes no reference to manufacturing controls and CHC suggested this is a critical issue especially for foods making high level claim. There needs to be controls to assure that the ingredient or property is in the food, that the ingredient or property is consistently mixed, that the ingredient or property is in the food for shelf life and that it is bioavailable. CHC proposed that each and every food with a high level claim that has been evaluated be issues with a number, not unlike the AUST L number so consumers and industry can have a level of comfort that the food and claim have been evaluated.

Beef and Lamb Marketing Bureau recommended any criteria for claims needs to recognise the bioavailability of nutrients. They noted foods with inhibitors to absorption of certain nutrients.

Aust. Assoc. of National Advertisers comments

Aust. Assoc. of National Advertisers stated that they are not making a detailed submission at this time. They formally expressed their interest in participation in any proposals impacting the area of enforcement and compliance of advertising for food products making health, nutrition and related claims and registered their willingness

to provide the assistance and support of their extensive knowledgebase to FSANZ in the matter of further consideration of P293. They noted that their knowledge and experience includes the successful establishment of the self-regulatory mechanism that currently includes coverage of food and beverage advertising. Their submission gives information regarding their roles and previous submissions made to government.

AFGC comments

AFGC considered the proposed system unworkable for the following key reasons:

- The complexity of the substantiation process, together with the lack of protection for company intellectual property in high level claim makes it likely that the process will not be used by industry;

- The substantiation process for general level claims is overly complex for claims that are, in general, simple in nature. The priority of enforcement agencies, which must focus on public safety, means it is unlikely action will be taken with any speed on technical breaches of general level claims; and

- May reduce the commitment of industry to comply with general level claims when they see their competitors making unsubstantiated claims. The presence of unsubstantiated claims in the market may reduce consumer confidence in the system to the detriment of all concerned.

They proposed that the regulatory framework should:

- Simplify industry requirements for substantiating high level claim;

- Reduces time to market for high level claim;

- Ensure timely review of new high level claim approved by other authorities; and

- Ensure consumer confidence in general level claims through a pre market advisory service, a post market complaints handling service, ongoing and timely review of the guidelines.

Dot point 3 on page 19 of the Proposal P293 Initial Assessment Report asserts that foods carrying health claims may lead the consumer to believe that these foods are a better choice than foods not carrying claims. The example given is 'fruits and vegetables not carrying a claim could be replaced by processed foods claims a small amount of fruits and/or vegetables'. AFGC is not aware of any evidence of this occurring in countries where health claims are permitted.

Dot point 4 suggests that an adverse outcome for consumers might be 'exclusively following the advice of a claim on food and failing to seek or follow advice from a health professional'. The AFGC draws attention to the Ministerial guideline – under claim prerequisites Item 7, 'Claims that refer to the dietary management of a biomarker condition or disease that may require the supervision of an appropriate

health care practitioner must have an advisory statement to the effect that a health care practitioner's advice is required'. AFGC considers this is adequate risk management for consumers tempted to exclusively follow the advice of a claim on food.

AFGC considers certain statements contained in Section 5.0 to be without merit but intended to increase the perception that extra regulatory zeal will be required. Specifically, FSANZ (page 22) discusses adverse outcomes for consumers that might occur where reference is made to a health claims reducing the risk of disease. Dot point 1 suggests that over consumption of a food may occur because it carries a claim. The NHF 'Tick' Program experience has demonstrated that consumers do not do this, and in fact recognise that food with the 'tick' represents a choice beneficial to heart health rather than a choice to be over consumed. Dot point 2 assert that a food claiming 'may reduce the risk of developing heart disease' may not be a suitable choice should it be 'high in sugar content and low in fibre'. AFGC considers this to be a spurious example as health claims mentioning serious disease are to be fully evaluated by FSANZ before approval.

AFGC and National Foods considered that where the proposed definitions deviate from those contained in Codex, FSANZ should provide justification.

AFGC considers that such a wide definition of advertising in the Model Food Act could include academic writing or bona fide news items relating to food and recommends that FSANZ clarify the definition to exclude these items.

AGIS – discussion about negative claims

Negative claims about monosodium glutamate (MSG) and their potential to be misleading has not been mentioned in P293. Negative claims about MSG are common, even in food containing high levels of glutamate (glutamate can be naturally occurring or alternative ingredients rich in glutamate and/or sodium added). Consumers are not made aware that glutamate is naturally occurring when these claims are made, not enough information is provided to allow consumers to make an informed choice. Their submission quotes FSANZ User Guide on Representations About Food, regarding negative claims about naturally occurring additives, e.g. MSG (section of Guide attached). They recommended that the FSANZ User Guide on Representations about Food is implemented so that a negative claim on MSG is always accompanied with a statement that it is naturally occurring, and that the US FDA position re MSG is adopted (FDA Backgrounder on MSG attached to submission).

AGIS quoted the Food Industry Code of Conduct for the Provision of Information on Food Products re negative claims (attached to submission). Their submission details a survey carried out by AGIS on foods claiming "no added MSG" and test results for glutamate in these foods (results included in submission). They summarised that most, if not all products making such claims will contain some glutamate, and some will contain significant amounts. They also noted a study published by independent group that found that "39% of the foods for which it was claimed that no MSG was added were actually found to contain added MSG" (article attached to submission). Report - Survey of MSG in Processed, Restaurant and Unprocessed Food, also attached to submission. Submission details a survey carried out by AGIS on restaurants using 'no

added MSG" claims. They recommended that as measures already taken by FSANZ have failed to stop misleading claims about MSG, the next logical step would be to include rules about claims about MSG in the Food Standards Code. The Standard for Nutrition, Health and Related Claims is probably the best location for such provisions.

Therapeutic Goods and advertising

The existing arrangements of the Therapeutic Goods Advertising Code (TGAC), where capacity exists for the Complaints Resolution Panel to consider the advertising of products claiming to be foods but making representations that could be judged as presenting the good as a therapeutic (i.e. based on 'dosing' advice, presentation, claims), was noted by AMSI. If such a complaint was upheld by the Complaints Resolution Panel a recommendation could be made to either a State health authority or would be made to the TGA so that the good is declared an unregistered/unlisted Therapeutic Good under Section 7 of the Therapeutic Goods Act 1989 and compliance action enacted on a federal level. ASMI considered that as the implementation of health claims in food is likely to increase the number of products that may be referred to the Complaints Resolution Panel, it would be desirable for a regime of advertising control and complaints resolution to be implemented for the food industry.

Function claims, enhanced function claims and risk reduction claims (and higher claims) need to be subject to a suitable system of advertising control, as most enhanced function claims are comparable to many low to medium level claims on complementary medicines. State their position that legally enforceable advertising principles such as those encompassed in the Therapeutic Goods Advertising Code need to be embraced as a regulatory mechanism by the food industry and regulators. In the Complementary and over-the-counter (OTC) medicines industry it is not unusual for medicines to be "indicated" for a particular use, with associated claims being permitted for use in marketing activities provided that they are consistent with the approved indication, and subject to advertising pre-clearance under an industry-government co-regulatory model.

The market promotion and advertising of general and high level claims will result in the use of extended marketing claims which will be worded differently to any claims specified in a Standard. This is acceptable provided a suitable mechanism of national advertising control, preferably a co-regulatory like for the Complementary and OTC medicines industry, is implemented in the food industry for health claim related advertising above nutrition content claims. This works in the consumers best interest in ensuring truthful advertising and offering a transparent complaints resolution procedure that does not burden the compliance capacity of the State jurisdictions (AMSI).

There is currently an absence of any proposal for effective advertising control under this food standard, which is a concern when the communication of the health messages that would be permitted on labels will extend past this medium. If there are required contextual information and additional warnings or health advice required on labels, there is no indication that there would be any requirements for this information to form part of advertising. Arguably any loss of perspective on the use of a particular food in context to total diet may occur via advertising (ASMI).

ASMI considered the need to be couching health claims in terms of "high level health claims" and "biomarker claims" appears to serve little purpose other than to prevent the impression that foods are moving into territories currently fulfilled by Complementary and OTC medicines and minimise objections from these respective industries. Such an approach is unnecessary and only sets up additional interface areas that require to be monitored for compliance. Members expressed a concern that certain high level claims might be "generalised" in order to escape pre-market evaluation – i.e. research on food shows reduction in elevated cholesterol but food is marketed for the purposes of "maintaining normal cholesterol". This raises a question on how a consumer can easy differentiate between a high level claim and a general claim.

High level claim on foods must require an advertising pre-clearance number similar to the requirements for therapeutics' to be displayed on the advertising and labelling of the food. All advertising and labelling should require assessment and approval prior to market release. This would protect consumers from implied claims, inappropriate consumption claims, unduly glamorising, using testimonials and endorsement by health care professional. This system would allow quick identification of approved high level claim by regulators, industry and consumers (CHC).

Definition of 'claim' and 'advertising

Sanitarium Health Food Comp considered the definition of 'claim' and 'advertising' in the proposed standard to be ambiguous. They believed the standard should cover food labels and advertisements for branded products only. They believed the current definition could cover statements about food in academic writing or newspaper articles on food topics and could extend to verbal statements about food made in the privacy of their own homes.

They added that a nutrition and health claim standard should not cover publications such as Sanitarium's nutrition related publications targeting consumers e.g. Good Food news (refer to appendix provided with submission), in which company nutritionists discuss the pros and cons of various foods, based on reputable research. Consider the negative effects, which could arise from such publications i.e. as specified on pg.22 of P293, are more associated with statements on food labels and ads for branded products than general information about food. They believe anyone should be free to write/talk about the pros and cons of food without restriction (subject only to trade practices law) except in a situation where a supplier refers to that supplier's branded products. In addition there should be no restriction on discussing or writing about categories of food, as opposed to food brands (see examples to understand point, pg.8 of submission).

MLA expressed concern that the definition for a "claim" is too broad, in particular that the definition involves communications of an educational nature relating to food consumption, e.g. resources produced and distributed free of charge for patient education material used by health professionals, demand for which is high, >1 million on iron deficiency, healthy eating and weight management ahs been distributed nationally over the last five years.

NZ MoH strongly encourages FSANZ to consider and provide clarity on the definition of advertising in the Standard or Guideline.

Confidentiality of data

CRC for Innovative Dairy Products considers the UK Joint Health Claims Initiative to be an extremely helpful and a user-friendly system. It appears to have an attitude and outlook to facilitate companies with their goals. The Joint Health Claims Initiative offers technical advice on gathering and presenting data. Although the Joint Health Claims Initiative keeps the submitters data confidential, this is not the case in the US. CRC for Innovative Dairy Products considers exclusivity of the data and rights is an important issue and should be considered in depth. They believed there should be rewards for venture/risk and associated costs, which should provide for a period of exclusivity. CRC considers that this does not need to be as long as the patent system. They believed that having such a period of exclusivity would be an important factor in determining whether the system will encourage investment in innovation and growth in the food industry.

Further comments made by Langdon Ingredients

Stated their view that P293 does not have regard for the promotion of consistency between domestic and international food standards, does not promote an efficient and internationally competitive food industry, nor does it promote fair-trading in food. FSANZ must have regard for these regulatory measures in addition to its statutory objectives. Noted the complexity of the system and finds it quite confusing both in terms of the discussion paper and desired outcome. They support the development of the nutrition, health and related claims system but note it needs to be easy to use, easy to understand and interpret, and not prohibit product innovation, by way of cost, substantiation and time to market.

Prescribed wording of claims

It is vital that the wording of all general and high-level claims conveys the correct meaning to consumers and is not misleading. ACDPA recommended that FSANZ prescribe the exact wording of claims based on agreement amongst health professionals and the testing of claim interpretation with consumers. NSF supported this recommendation.

ANA stated it is important that the wording of general level and high level claims conveys the right message (message content and execution), and recommended FSANZ prescribe exact wording based on agreement with health professionals and testing of claim interpretation with consumers.

Kidney Health Aust. considered it is vital that the wording of all general and high-level claims conveys the correct meaning to consumers and is not misleading. They suggested that FSANZ prescribe the exact wording of claims based on agreement amongst health professionals and the testing of claim interpretation with consumers. They also suggested consideration is also given to the regulation of the size and location of the claim on the label, as is the case in the agro-chemical industry.

Consumer's Institute NZ considered the proposal to approve generic claims and then allowing manufacturers to make their own interpretation of the claims may be confusing. Messages may lose clarity as manufacturers try to make their products more attractive. They would prefer the wording of claims to be standardised or approved on a case-by-case basis by an independent expert panel. They recommended that FSANZ prescribe the exact wording of claims based on agreement amongst health professionals and the testing of the interpretation of claims by consumers.

OAC NZ preferred FSANZ to prescribe the exact wording of ALL claims, including general level claims. The use of pre-worded, standardised statements would likely reduce confusion and would mean that only claims which have been pre-tested with consumers and known to be least likely to cause confusion should be used. Standard wording of claims would prevent manufacturers trying to outdo each other and give consumers consistent message which would assist consumer understanding of the claims and would make education easier too.

OAC NZ felt that the use of standard, pre-worded claims would likely make enforcement easier. They commented that P293 does not give much detail regarding the enforcement processes. It is imperative that there be active enforcement of health claims. Health claims provide a very potent advertising opportunity for manufacturers that penalties should reflect the advantage manufacturers could gain from misleading, exaggerated or incorrect claims.

Opposition to health claims

PHAA remain opposed to health claims, as there is no evidence to indicate that they have any beneficial impact on public health and there is potential for harm from consumers choosing a diet less consistent with the dietary guidelines. They would prefer 'health claims' remain prohibited and that only nutrient content and function claims, with criteria and conditions in a standard, be permitted.

'Toothfriendly' logo

Toothfriendly Sweets Int. (TSI) stated that during review of Proposal P153 they made a submission concerning the use of the TSI logo and the associated term "Toothfriendly" (refer correspondence dated 4 Dec 1997). In this submission they presented the case that the TSI logo "Toothfriendly" and statements such as "does not promote tooth decay" should not be considered as health claims. They stated in their submission to P293 Initial Assessment Report that FSANZ (then ANZFA) had agreed with this opinion and included confirmation of this in the Final Assessment Report for P153 (pg88). They noted that they have not identified any further reference to this matter and therefore presume that the decision reported in P153 Final Assessment Report is still valid, however they would appreciate confirmation of this.

'May' statements

Consumer's Institute NZ considered "may" statements to be particularly unhelpful. Given the uncertainty of the relationship between food and disease, in many areas it is likely that claims will contain "may" statements.

Consumer understanding

Naturo Pharm believed that regulators overestimate the level of consumer understanding, and marketers take advantage by using simple benefit messages that only offer 'part of the story'. They noted that food technology enables manufacturers to radically alter food composition. They are concerned that fortification will become a marketing tool, causing further public confusion. Clear identification of food ingredients would allow consumers to make an informed choice. Clearer labelling should include:

- Added minerals/vitamins should be clearly identified in the Nutrition Information Panel, with words like "added...X" and amount/source clearly specified;

- Foods that have undergone a manufacturing process, which by itself increases the amount of vitamin/mineral beyond the level normally expected, then this should be clearly identified in the Nutrition Information Panel; and

- If the food has undergone modified restoration (restoration of up to 25% RDI when naturally occurring vitamin/mineral levels would contribute at least 5% of the RDI in a reference quantity of food) then the process/amount exceeding natural levels/nutrient source should be made clear. Consumers expect processed foods to contain less vitamins/minerals than fresh foods.

Exclusivity of claims

NZ Dairy Foods suggested further clarification is required regarding exclusivity when an organisation makes a submission on a high level claim to allow recovery of costs that are associated.

Biomarkers

NZ Dairy Foods stated that biomarker claims are claims that the industry wishes to make. They considered that biomarkers should not fall within the definition of a high-level claim; they should be included in the definition of general level claim.

Evidence in support of health claims

The Cancer Society NZ (supported by Auckland Cancer Society; Cancer Society NZ - Waikato/Bay of Plenty Div, Cancer Society NZ - Rotorua Branch) noted their concern about the complete lack of evidence to support health claims as an effective tool to increase consumer understanding, change behaviour or improve health. Evidence shows that New Zealand consumers are confused and misled by health claims on labels (Scott, V., & Worsely, A.F. (1994)). There is a significant amount of international literature display the wide variation in consumer responses to simple claims and this is summarised within the P293 Initial Assessment Report.

Tas DoH&HS considered that the proliferation of new products developed over the past 15 years, while health claims have been prohibited, indicates that innovation has not been stifled by the current system.

They noted that the Ministerial Council has endorsed the policy guidelines for nutrition and health related claims, effectively sanctioning the introduction of health claims. No evidence has been presented that health claims provide any public health benefit. There are concerns about whether the process is an effective use of scarce public health and FSANZ resources. It appears, however, that the prohibition on health claims will be lifted shortly.

Health Impact assessment

A number of submitters recommended that a health impact assessment should be undertaken on Proposal P293, which would place health at the centre of decision-making process. They suggested this be carried out instead of an economic cost benefit analysis.

Submissions to the Proposal P293 Initial Assessment Report

NZDA found the length of the Initial Assessment Report, the number of attachments and the number of questions asked a considerable barrier for members in providing feedback. They suggested dividing the submissions into several sections and staging the submission process over a number of months would have meant more effective consultation and therefore more representative feedback and they recommend considering this for the Draft Assessment Report.

Other comments

The Ministerial Council Policy Guideline (Policy Principle 7, p.3) requires that claims referring to a disease, condition, ailment, defect or injury should include a statement explaining how the claimed benefit is achieved (SA DoH).

A "socially responsible" claim needs more detailed definition, as does "irresponsible food consumption patterns". For example, it is not socially responsible to market general health 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 (SA DoH).