P293 – Nutrition, Health and Related Claims

Submitter responses to questions 1 – 26 of the Initial Assessment Report

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CHAPTER 1: REGULATORY PROBLEM

1.1 POTENTIAL RISKS TO PUBLIC HEALTH AND SAFETY

Question 1

To what extent does the level of compliance and non-compliance with the Code of Practice on Nutrient Claims in Food Labels and Advertising (CoPoNC) impose costs on industry and consumers? How significant are these costs?

Out of 147 submitters, 51.7% (76 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	18	4	3	50
Government	6	2	-	-	8
Public health	8	5	-	-	13
Consumers	2	-	-	-	2
Other	3	-	-	-	3
Total	**44**	**25**	**4**	**3**	**76**

Overview

Costs of non-compliance to consumers related to provision of misleading information, confusion and resulting loss of confidence, as well as paying higher costs for foods making non-compliant claims without recognised benefits. Other costs to consumers related to the cost of products with claims compared to those without claims, the perceived benefits of products with claims compared to products without claims and the subsequent equitable application of policy. The main cost of non-compliance to industry was an unfair marketing advantage for companies who choose not to comply. Costs of compliance were those of analysis ($1000 to $10,000 per product per annum) and of ensuring truthful and accurate labels.

Costs of non-compliance to consumers

Some submitters identified the following costs to consumers of non-compliance, as per the following comments.

The costs associated with misleading information and confusion from non-compliance were identified as:

- Provision of misinformation, which inhibits consumers' capacity to make informed food choices. This may contribute to over-nutrition and/or under-nutrition thereby increasing the risk of diet-related diseases/conditions occurring in the short term and long term. (TCCA);

- Misleading information, with the potential for consumers making poorer dietary choices (PHAA (supported by ACA), NHF Aust. supported by NHF NZ, Cadbury Schweppes, CML, NSW DoH – N&PA Branch, SA DoH, Dr R

Stanton, Northland Health Dietitians). This may adversely affect nutritional status/health (PHAA (supported by ACA), CML, NSW DoH – N&PA Branch, SA DoH, Northland Health Dietitians). There is therefore reduced potential for public health improvements (NHF Aust. supported by NHF NZ);

- Many consumers do not understand the meaning of claims such as fat reduced, x% fat free, high fibre etc. Consumers choosing foods on the basis of a health claim can increase kilojoule intake and neglect healthier choices (Dr R Stanton);

- Purchases made based on untruthful, misleading or deceiving claims are likely to have an adverse impact on population dietary intake e.g. a 92% fat free claim (currently prohibited under CoPoNC) may influence consumers' decision-making regarding fat containing foods, resulting in an excessive intake of fat (WA DoH, Monash Uni – N&D Unit, SA DoH, PHAA (supported by ACA));

- Regarding 'X% fat free' types of claims, many consumers may not draw the link that the product has 10% fat (Cadbury Schweppes);

- Consumer confusion as they're given misleading information if claims are not consistent across different foods (Sanitarium Health Food Comp.);

- Potential for consumers to be misled as compliance with CoPoNC is voluntary, therefore industry may use different defining criteria for different claims (NZFSA);

- If foods are making inappropriate claims, e.g. claiming to be 'low fat' when they are not, consumers may be lured into purchasing the food, to the detriment of their health and money. The proliferation of '% fat free' claims exemplifies the appeal of such claims to industry and their disadvantages to consumers (Diabetes Aust);

- Confusion created by disparity of claims (NSW DoH – N&PA Branch, NSW Food Authority, Tas DoH&HS); and

- Consumers receive inconsistent messages due to differences in messages from companies who comply compared with those who don't comply (Solae Comp.).

Costs associated with loss of consumer confidence from non-compliance were identified as:

- Non-compliance may result in a loss of consumer confidence, which may increase consumer resistance to food/nutrition health messages from reputable sources in the future (TCCA);

- The intangible cost of compliance and non-compliance with the CoPoNC is that of consumer trust. The Australian fruit, vegetable and nut industry has

built consumer trust in its products and believes acceptance of the role of these products in a healthy balanced diet is being eroded by inappropriate claims on competing products. The significant impact of products that ignore the CoPoNC is lack of consumer confidence in using the claims to help them to make sound food choices (Horticulture Aust.);

- The inconsistency of nutrition and health messages results in a subsequent loss of confidence in the food industry (National Starch);

- There is a loss in confidence in the ability of food industry to provide useful health information (a high cost) (Solae Comp.);

- Failures against CoPoNC, such as the '% fat free' claims, could result in a reduction in consumer confidence in the relevance of the claims, however figures given on page 87 of the IAR suggest that the failure rates between CoPoNC and the standard are approximately the same, therefore, a similar question should be asked of failure to comply with the various relevant standards (these are low risk claims) (DAFF);

- Consumers cannot have absolute confidence that the products meet the standard (ASA, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, Cadbury Confectionery, NZTBC, NZ Magazines); and

- Non-compliance may result in reduced consumer confidence in the system or on claims, which may detract from the effectiveness for industry in using such claims. It is important that industry promotes a high level of integrity in claims (Fonterra supported by Mainland Products).

Monetary costs of the price of food from non-compliance were identified as follows:

- Without adequate regulations, it is likely that there will be continued use of unapproved health claims. These products also demand a premium price, thus inflating the cost to the consumer without recognised benefits. (WA DoH, SA DoH);

- Consumers will pay more if they perceive that a food provides specific health benefits, although the consumption of foods that make inappropriate claims may be adversely affecting their health (GI Ltd); and

- There are potential monetary and health costs to consumers if they consume foods that fail to meet the requirements of CoPoNC. Consumers with specific health problems are usually willing to pay more for a food if they perceive it meets their particular requirements as they consider it a worthwhile investment in their long-term health (Diabetes Aust.).

Costs of claims (compliant and non-complaint) to consumers

A number of submitters commented that foods bearing claims cost more than foods without claims, although the products and/or benefits may be almost identical, e.g. products bearing the Tick versus those that do not (whether there is compliance or

not) (Dr R Stanton, SA DoH, Northland Health Dietitians). Packaged foods with claims may encourage consumers to purchase those products rather than loose unprocessed foods without claims e.g. fruit. This may lead to diets less consistent with Dietary Guidelines (WA DoH, Monash Uni – N&D Unit, SA DoH).

It was added that this raises issues in relation to equitable application of Policy where those on lower incomes have greatest burden of diet related disease (AIHW, 2004) yet if healthier foods are more expensive because of claims, they are less affordable to those who may need them most. Food Commission research in the UK has indicated that prices for foods marketed as 'healthy' are about 50% higher than for 'normal' products in the same category and some products were found to cost 10x the price of comparable food without the health claim (FSA, 2003) (SA DoH, WA DoH, Monash Uni – N&D Unit).

SA DoH predicted that properly regulated Nutrition, Health and Related Claims would create a segmented market with products with or without claims in each category. Products with approved claims will demand a premium price whilst the others will have to compete with other non-health related products.

Other submitters also noted influence on consumers by costs and by advertising (ASA, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, Cadbury Confectionery, NZTBC, NZ Magazines).

Other costs to consumers

Other costs to consumers that were identified were:

- Not being able to be informed truthfully about the nutritional benefits of foods (Dairy Aust.);

- Cynicism towards labelling laws in general and claims in particular, which detracts from the potential of claims to provide meaningful information (NSW DoH – N&PA Branch, NSW Food Authority);

- An uneven playing field (ASA, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, Cadbury Confectionery, NZTBC, NZ Magazines), which places consumers at risk of being misled (Griffins Foods);

- That consumers ultimately have to pay for costs to industry as these are recouped at point of sale. Any labelling is of cost to consumers therefore it is important that those paying for it get the benefit from the label (NZ MoH);

- That less expensive items are replaced with more expensive ones to substantiate a health or content claim (Nutra-Life H&F);

- Costs in information knowledge for consumers as many do not understand what ‘90% fat free’ means in terms of dietary requirements. (NCWA); and

- The need for knowledge to counter ‘fat free’ claims on foods not usually containing fat (NCWA).

It was noted that potential costs for consumers might be high as industry passes on costs of compliance, although consumers may be prepared to take on the costs for better information and goods (NCWA).

Nutrition Australia noted that non-compliant products might make unsubstantiated claims and provide products at a cheaper price to consumers. These products may provide a greater profit margin to the retailer and therefore get prime position on shelves at the expense of products that have committed the resources to providing well substantiated claims.

Costs to industry

A number of submitters noted that companies that choose not to comply may have an unfair marketing advantage over companies that do comply (Diabetes Aust., GI Ltd, Dr R Stanton, CML, Cadbury Schweppes, Sanitarium Health Food Comp., National Starch, NSW Food Authority, NSW DoH – N&PA Branch, SA DoH, WA DoH, Monash Uni – N&D Unit, Griffins Foods, Nestle, Unilever Australasia, Solae 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).

Other submitters noted this as an uneven playing field (PHAA (supported by ACA), ASA, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, Cadbury Confectionery, NZTBC, NZ Magazines, NZFSA).

CML felt that this would be a significant issue in some industry groups and Solae Comp noted that the costs of this in terms of dollars are high.

CMA gave the example of non-compliance with CoPoNC as imported 'sugar free' confectionary containing more than 0.2g sugar(s) per 100g, and use of variations such as ‘sugar (sucrose) free’ which is not in the spirit of the CoPoNC provisions and provides for consumer confusion. They noted the proliferation of claims due to lack of enforcement as CoPoNC is . This view 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.

It was added that the companies who don’t comply would also incur no penalties, and enjoy decreased initial production costs (GI Ltd, Diabetes Aust.). There are likely to be real advantages in not following CoPoNC, particularly for small manufacturers who want to maximise the perception of the nutritional benefits of their product for the least cost (Diabetes Aust.).

It was also noted that there are costs for industry in complying with the Code, as well as having to compete with those who don’t. The voluntary code creates a barrier for honest companies. There is no regulatory or self-regulatory check to ensure consistency (ASA, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, Cadbury Confectionery, NZTBC, NZ Magazines).

The publicity regarding an unfair advantage has sought to undermine both the value of claims in general and consumer confidence in the regulatory system. This has been

an issue for a period of years and it has still not been effectively addressed (Unilever Australasia). Nestle noted direct loss of sales because of perceived nutritional benefits that are communicated in an inappropriate way; and costs associated with communicating with companies about breaches of the CoPoNC (Nestle).

Maintaining competitiveness

Some submitters noted the need to maintain competitiveness as a cost to industry (PHAA (supported by ACA), SA DoH, Monash Uni – N&D Unit, WA DoH). They explained that manufacturers will make claims within the same line of food to maintain competitiveness, and this has been seen in a number of aspects of labelling, e.g. tomato sauce bearing a label 'no preservatives'.

It was considered that poor compliance with CoPoNC indirectly places costs on the industry who must either engage in prohibited practices in order to compete in the market place, or accept a reduced market share if unwilling to make claims on parity, by ASMI. They considered that this is reason why the food industry is unlikely to adhere to guidelines set for general claims if there is no legal underpinning (regulatory Option 2).

Costs of compliance to industry

Information was presented by GI Ltd and Diabetes Aust., who, from their own consultation with small local manufacturers on nutrition content claims demonstrated up to 2 hours advice per food item is needed, in contrast to large food companies that employ marketing/legal specialists to ensure claims are appropriate. They added that these compliance costs are incurred whether companies use consultants or employees.

The cost to National Foods for a tailored compliance program for Trade Practices legislation with the current CoPoNC provision was Aus$75K, which included initial costs for a customised software program and face-to-face training for a medium sized food company. This cost did not include the cost of on-going training (National Foods).

The cost to companies to comply in substantiation, and ensure that packaging and promotional material is accurate, was noted by CML.

Dr R Stanton submitted that if CoPoNC was monitored and enforced, costs to industry could include removing incorrect claims or making public retractions about incorrect claims. This has not occurred as little monitoring occurs.

GW Foods listed compliance costs as: product testing/analysis programs; monitoring packaging changes and updates and ACCC compliance training for staff. They added that the costs of compliance are the same whether claims are regulated by a standard or guideline (GW Foods).

Other costs of compliance listed were: testing costs, development costs, reduced time frames for development, increased number of trials etc. Ultimately these costs would be recovered in the wholesale price and increase the cost of goods to the consumer (Bakewell Foods).

CMA noted real costs associated with compliance to the CoPoNC including cost of truthful, accurate, compliant labelling, e.g. analytical testing. They believed the level of compliance should improve with general level claims in a government endorsed Guideline that in theory has more traction (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).

The cost of nutritional analysis was reported to be a minimum of $1,000 per product per annum. For micronutrients, several analyses may be required to represent seasonal variation and to provide an accurate average - $10,000 per product is not uncommon. Nutritional information based on calculation is less costly but the human resources to ensure accuracy and validate the paper work are significantly greater and more susceptible to inaccuracies. Other costs include staffing costs to review product and ensure accuracy in claims made and compliance to the code, printing costs and plate changes at least $1,000 per product (Nutrition Aust.).

It was believed that the more detailed the regulations the greater the costs to industry, by Nutra-Life H&F. They accepted that compliance costs are part of business.

Canterbury DHB suggested that the compliance costs for inappropriate claims are zero but for appropriate claims, the costs should not be high e.g. it is cheap to search literature on the Internet. They did not regard the cost of research to support a claim to be a compliance cost, but noted that there may be cost involved with registering a claim.

Economic costs to industry associated with the system have been similar to regulated costs for the vast majority who comply (Goodman Fielder, AFGC, MasterFoods Aust. NZ). Additional costs can occur as a result if requesting ACCC to act on a breach (AFGC, MasterFoods Aust. NZ, GW Foods, National Foods). One company indicated compliance costs in the order of $75,000 in drawing ACCC attention to breaches (AFGC, MasterFoods Aust. NZ). Most breaches were resolved in an efficient manner by the management committee of CoPoNC (AFGC, Goodman Fielder). National Foods support an active and responsive management system for the CoPoNC to resolve breaches.

Other costs to industry identified by submitters were:

- A lack of trust in food labelling (also a cost to government) (NHF Aust. supported by NHF NZ);

- For importers associated with relabelling for Australia/New Zealand market rather than having a multi-country label which adds to the cost of the product (Nestle);

- Not being able to communicate truthful information (Dairy Aust.); and

- As a result in loss of confidence by consumers in the claims being made, due to non-conformance with CoPoNC (Tas. DoH&HS).

Costs of changes to CoPoNC

Should some permitted claims by CoPoNC no longer be permitted, there would be costs to businesses including changes to packaging (GW Foods).

A manufacturer that makes a genuine attempt to gather and accurately assess evidence to make a general level claim but lacks the expertise to do so may find their claim must be withdrawn, reducing consumer confidence in their products (NSW DoH – N&PA Branch).

No extra cost

PB Foods stated that there is no extra cost to their company as they have been following the guidelines since the introduction in 1995. They added that the food industry has great interest in promoting high levels of integrity to ensure consumer trust.

Unable to quantify costs to food industry

Two submitters noted that they are not in a position to quantify the total monetary cost of compliance versus non-compliance for the food industry (Diabetes Aust., GI Ltd).

General comments

It was recommended that all associated costs should be absorbed by the manufacturers, not incurred by consumers (CHC). Auckland Reg. PHS supported this by stating that they would be concerned if costs incurred by manufacturers were to be passed on to the consumer - this is an equity issue and such a situation would not be supported by public health.

It was believed by CSIRO HS&N that the issue is one of net cost as they viewed health claims as point of sale differentiators which are viewed positively by industry, i.e. companies should be able to recoup their outlays with increased sales.

It was noted that as CoPoNC is not legally enforceable it is used and perceived as useful by some companies and abused by others, who risk enforcement by ACCC/TPA section 65. Measurement/claim of a single nutrient in isolation of a framework may be a useful marketing tool but in reality is meaningless unless related to other significant nutrients (Food Tech. Assoc. of Vic.).

Horticulture Aust. (HAL) noted that as fresh fruit and vegetables are not required to be labelled, CoPoNC does not affect many of the products produced by HAL member bodies.

NZFGC outlined that while CoPoNC does not apply in New Zealand, it received the support of the FGC (formerly the New Zealand Grocery Marketers Association) when it was developed in 1995. Member companies were requested to comply with CoPoNC. NZFGC went on to say that the FGC does not accept, as the Proposal P293 IAR states, that claims made without reference to a prior public health framework

have the potential to mislead and confuse consumers and that government enforcement agencies are unable to address products with non-compliant voluntary claims. Fair trading laws in New Zealand effectively address misleading and deceptive claims and compliance under fair trading legislation can be monitored and enforced whether a regulated or voluntary claim is in place. They stated that the costs of compliance and non-compliance with CoPoNC would be little different from costs of compliance with regulations.

Compliance to the CoPoNC has small insignificant costs to the industry and consumers. A new code with pre-approved health claims based on content should be voluntary (Nutra NZ).

Unable to quantify costs in general

Some submitters noted that there is little documented information regarding these costs, including Dr R Stanton who said that to her knowledge, costs associated with compliance/non-compliance with CoPoNC have not been documented. Others noted that there is paucity of published information regarding this as CoPoNC has not been formally evaluated, however it is known not all manufacturers abide by the Code (Choice 2004) (SA DoH, WA DoH, PHAA (supported by ACA)).

NCEFF also commented that these costs were not known.

Four New Zealand based companies stated that they are not well placed to comment (Naturalac Nutrition, Tegel Foods, NZJBA supported by Frucor).

Level of compliance with CoPoNC

A number of submitters commented on what they thought the level of compliance with CoPoNC was. Their comments are outlined below.

- There is significant non-compliance with CoPoNC and seemingly little enforcement under the current regime, which further highlights our concerns over a more permissive regime (TCCA).

- CoPoNC provides a framework for industry to make content claims, but this framework is not adhered to by all manufacturers. As a result, claims are being made currently which are outside this framework and CoPoNC is unable to enforce compliance (DAA supported by NZDA).

- It is ASMI's understanding that voluntary industry compliance to CoPoNC has been poor in the past.

Some of these submitters referenced the Williams P. et al (2003) study that reported that compliance with CoPoNC (voluntary) (14.7%) and the Food Standards Code (regulated) (13.3%) was similar (AFGC, MasterFoods Aust. NZ, DAA, NZDA, Goodman Fielder, Fonterra, Mainland Products, Unilever Australasia, Parmalat Aust., PB Foods). This suggests that enforcement is a major issue, regardless of which body sets the regulations (DAA supported by NZDA). AFGC also cited Caswell JA et al (2003) to support this point.

Other submitters stated that the vast majority of CoPoNC's criteria are complied with; the main exception being '% free' claims (F&B Importers Assoc., Goodman Fielder, National Foods, Unilever Australasia). It therefore remains effective co-regulation with optimal compliance (except for %fat free claims) (Williams et al, 2003). (National Foods). Some non-compliance with claims in CoPoNC that have not been revised in light of more recent nutrition knowledge and changes in regulation, was also noted by Unilever Australasia. They added that CoPoNC gave a level basis for claims and helped establish consumer confidence in reputable claims at the time when it was developed and implemented. Efforts to review and update CoPoNC have not been implemented as this was to be the subject of regulatory review back in 2000.

F&B Importers Assoc. inferred that the level of costs of complying with the CoPoNC would be equivalent to those complying with a regulation. This was supported by National Foods who submitted that the economic costs in complying with the regulation is the same, regardless of whether the legislation is a code of practice, co-regulatory or mandated. ABC didn't have data on level of compliance therefore could not quantify associated costs.

NHF Aust. (supported by NHF NZ) could not comment of the level of enforcement and compliance that the AFGC is able to achieve under CoPoNC.

Previous experience in the orange juice industry showed that industry compliance was greatly improved via self regulation using a "Code of Practice" (PB Foods).

CHC noted that that industry compliance with CoPoNC has been poor. They suggested CoPoNC be transformed into a legislative standard so that jurisdictions can ensure compliance; they added however that jurisdictional enforcement of food standards has been hindered by lack of resources and funding. Each jurisdiction has their own policies for dealing with breaches and there appears to be inconsistency in the application of penalties between jurisdictions. There appears to be reluctance to settle non-compliance issues due to high court costs, resources and risk involved. Effort is needed to ensure that the enforcement agencies can act efficiently, uniformly and timely with regards to any breaches of the new standards, which may require greater levels of funding for agencies so they can actively pursue meaningful enforcement of the FSC.

Dairy Aust. believed CoPoNC has been an effective guideline for the food industry to date, and with appropriate monitoring and regular reviews, best remains as a voluntary guideline. They noted the aims of the establishment of CoPoNC and that it has never been updated in the last 9 years.

It was felt that when introduced, CoPoNC was well accepted by industry, compliance was good and it was a useful tool for standardising nutrient claims and minimising the risk of consumers being misled. The challenge was that it was not enforceable by law and that imported products did not need to comply. Over time more and more products on the Australian market did not comply which diluted the Code's effectiveness. Industry that had complied became complacent and no longer saw the relevance of the CoPoNC. Anecdotal evidence shows that compliance to the code was stronger after its introduction until about 2000 and between 2000-2004 the number of

products available in the Australian market that did not comply with the Code or contained claims that were not addressed increased (Nutrition Aust.).

The effectiveness of CoPoNC was also covered by Nutrition Australia. CoPoNC has not been reviewed sufficiently which adds to the dilution of its effectiveness. The number and type of claims in CoPoNC do not reflect current industry trends or science, e.g. 'no fat claims'. New trends, such as GI are not captured any more quickly by a Code of Practice than they are within standards (Nutrition Aust.).

National Starch noted that CoPoNC is open to abuse and misinterpretation within industry, allowing for discrepancies with compliance.

Compliance is easier to verify with some claims than others, e.g. NIP allows content claims to be verified by analysis (Fonterra supported by Mainland Products).

Health assessment model

Two submitters recommended that health should be at the centre of the decision making process rather than an economic assessment where by a cost-benefit analysis underpins the decision making process (Auckland Reg. PHS, TCCA). FSANZ should consider a Health Impact Assessment model (TCCA).

Other comments from Nutrition Australia

Industry prefer to have minimal guidelines which provide marketing teams with the opportunity to be more creative with the way they communicate nutrition messages and is argued by food industry groups that this encourages innovation. It does not protect consumers from being misled or public health and safety -e.g. some products that carry the 'no fat' claim are equal in energy to products not making this claim.

A committee was established to review and encourage compliance with CoPoNC but was not highly active in enforcement and could not legally enforce CoPoNC. In practice ACCC needed to be involved and prosecute if a misleading or unsubstantiated claim did not comply with section 52 of the TPA, although this never occurred. Compliance was encouraged by legal action from competitors, which could run into thousands of dollars and is more viable for larger companies that dominate the market to take this action.

Other comments from National Foods

They strongly disagreed with the statement on p.19 of P293 IAR that "claims could have the effect of shifting consumption patterns from foods … to less health alternatives…", and provides an example of Vitasoy soy milk being a suitable dairy alternative for those with lactose intolerance.

They strongly supported the principle that consumers should be provided with clear and truthful information about the nutritional properties of food and that nutrient claims are reliable and substantiated.

They disagreed that government enforcement agencies are unable to address products with non-compliant claims as they believed that fair trading laws allow and support enforcement.

Question 2

What are the likely impacts on consumption patterns arising from a permission to make claims relating to nutrition and health? If there is a consequential risk to public health and safety, how significant do you consider this risk to be? Please provide any evidence you have to support your response to the extent of these risks.

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	30	17	4	2	53
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Consumers	2	-	1	-	2
Other	4	1	-	-	5
Total	**51**	**25**	**5**	**2**	**83**

Overview

Some submitters quoted evidence from the National Heart Foundation research, use of the GI endorsement and FSANZ quantitative research of a positive effect from existing nutrition claims. Others noted 'minimal' impact or provision of greater information, increased innovation resulting in more nutritious products – leading to better food choices in line with dietary guidelines and improved health. Some applicable research from the United States, the United Kingdom and Netherlands was referenced. Negative impacts included the potential for an increase in consumption, an imbalance in nutrient intake, an increase in consumption of processed, packaged and labelled foods at the expense of 'healthy' fruit and vegetables, and equitable application of policy.

Positive influence on consumers' food choices

A number of submitters commented as follows, on the likely positive influences on consumers' food choices of a permission to make claims in relation to health and nutrition.

- With the permission of health claims, there is the potential for assisting certain groups in the community to make better food choices. The groups more likely to be affected are carers such as parents, concerned with the health of their children and other health conscious groups such as people who participate in strenuous and sustained exercise or those who are chronically ill. If health claims are well regulated and enforced to ensure compliance, the risk to these groups would be low (DAA);

- For people requiring a gluten free diet the inclusion of the word 'coeliac' would give them more certainty in food choices (Coeliac Soc. of Aust.);

- Claims would give manufacturers the opportunity to produce foods for specific sectors of society and educate consumers about those foods. This could drive improved or healthier food choices (ABC);

- Consumers will have greater information to allow them to make more informed choices about the foods they eat – one of the primary objectives of the FSANZ Act (Cadbury Schweppes);

- There would be increased consumer awareness of healthier foods, and development of more (cheaper) private label products due to marketing advantages that can be gained (CML);

- From an economic perspective it should be beneficial to consumers since it would increase opportunity and therefore the competitive pressure of manufacturers to market the nutritional features of foods, and there would be a spread of information more effectively to a larger proportion of the population (Mathios & Ippolito, 1999) (Dairy Aust., Parmalat);

- There is potential to contribute to the achievement of public health objectives, but this relies on a motivated and educated public to make healthful choices. There is likely to be favourable impact on consumption patterns, as consumers will have more information at the point of purchase to foster informed food choices (Dairy Aust., Parmalat);

- Although unable to provide evidence to support their opinion, DSM Nutritional Products believed that pioneer products carrying health claims might influence consumer food consumption patterns initially. The impact of health claims on consumption patterns would diminish, as a wider choice of products became available (DSM Nut Prod.);

- Depends on what claims are permitted but better nutrition information should assist consumers to make in formed decisions (F&B Importers Assoc.);

- Wholemeal and mixed grain breads account for around 35% of all bread eaten in Australia so allowing claims about 'wholegrain foods' will help to encourage healthy eating through the increased consumption of these foods (Go Grains);

- The ability to make claims does not appear (from National Nutrition survey data) to adversely affect consumer eating patterns. Claims may possibly affect consumer choice within a food category e.g. lite yoghurt over full fat yoghurt, but that these changes are consistent with dietary guidelines. Proposed claims may promote healthy eating patterns, as consumers will have nutrition information available at point of purchase to help with buying decisions (National Foods);

- The desirable outcome from a permission to make claims would be that consumers preferentially select foods that may lead to improved health outcomes. Health claims would allow consumers to differentiate between products on the basis of nutrient content and health rather than packaging. This may lead to a preference for products that are healthier (Wyeth Aust.);

- Consumers will be influenced and make their choices on what they believe to be good for their health. There is a market shift towards healthy eating and with health and nutrition claims consumers will be better informed and empowered (ASA, Cadbury Confectionery, Naturo Pharm, NPANZ, Assoc. of NZ Advertisers, NZ Magazines, NZTBC);

- It is possible that consumers will shift consumption patterns towards products with claims if claims are relevant to their diet, although nutrition impact is only one factor of many that influence diet decisions. The greater level of health communications is more likely to have the effect of raising consumer awareness at a general level of the importance of the diet. Given that food is a group considered low risk, the only risk to health and safety is if claims sway consumers away from seeking medical help. If claims are balanced and substantiated, the risk of any claim is limited. Expanding the claim framework will increase the ability for the dairy industry to educate consumers on health effects and produce increasingly nutritious product, e.g. 1000's of products amended to get NHF Tick (Williams et al 2003). A net positive impact on health is therefore likely (Fonterra);

- There will be minimal impacts on consumption patterns (NZJBA, Frucor);

- It was considered unlikely that there will be any risk to public health and safety (AFGC, MasterFoods Aust. NZ, ABC, ANIC, GW Foods, Parmalat);

- There may be a risk to public health & safety but this is considered to be small, and not significant when compared to the risks associated with the current health problems of overweight & obesity, diabetes, cardiovascular & other serious diseases (CML);

- Consumers are provided with information that enables them to make an educated product choice. There should be minimal risk to public health, as only those claims appearing in Standard would be used (Nutra NZ);

- Various labelling options, which indicate the 'healthiness' of foods, can be helpful to consumers (NZ MoH);

- Impacts on consumption are unable to be stated until monitoring of these claims has been carried out, but theoretically there is potential for consumption of healthier food choices to increase (NZFSA);

- There would be longer-term impact as public perception about particular foods change, driven by public education, labels and wider marketing claims. There is ample evidence that consumption patterns of food can be effected by

association with health benefits, e.g. cranberry and urinary tract infections, may have resulted in lower public health costs (Horticulture & Food Research Institute of NZ);

- Improvement of consumption patterns would occur and consumers would be provided with health information that will assist in choosing a wide range of appropriate foods that will benefit their health. Do not expect to see a risk to public health and safety because of legislative changes (Nestle); and

- Permission will provide the necessary framework for the food industry to convey more information to consumers about foods, thus enabling more informed choices and improved health and nutrition outcomes (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).

Positive influences in relation to dietary guidelines

Allowing health and related claims is likely to assist consumers to achieve diets more consistent with the Dietary Guidelines, e.g. in the USA where nuts are allowed to carry a heart health related claim, nut sales have increased by 15% since the health claim was allowed. Influencing purchasing behaviour and dietary choices in this manner supports Dietary Guidelines that state "Legumes, nuts and certain seeds, along with other plant foods, have been shown to offer specific health benefits and their inclusion in the diet is recommended for everyone" and the NHF of Australia also recommends to 'snack on plain unsalted nuts and fresh fruit' as a strategy to managing blood cholesterol levels (NHF Lipid Management Guidelines, 2001) (ANIC).

Allowing nutrition and health claims on labels and in advertising will provide another forum for reinforcing well accepted public health nutrition messages (as proposed claims are in line with recommendations to increase consumption of fibre rich foods, fruits, vegetables, nuts, omega 3, folate) (ANIC).

Impact on total diet

As claims apply on individual foods, they are highly unlikely to impact on consumption patterns in the total diet. Permission to make claims related to nutrition and health for foods should mean that consumers make more informed individual choices in particular food or food groups rather than changing consumption patterns. Consumers are unlikely to change entire patterns of eating, though may change preferred choice if one option appears more 'healthy' than another. Claims may assist consumers to interpret the nutrition labelling information provided, as research has shown that although the nutrition information panel is mandatory, consumers find it difficult to interpret and use this information to make an informed choice (Unilever Australasia).

Evidence from consumer insights suggests that consumers at point of purchase do not consider whole of diet perspective in their choices. Nutrition and health claim

permissions will provide consumers with further information to assist decision process at point of purchase (GW Foods).

Research evidence suggests that consumers make purchasing decisions based on a product to product basis rather than a whole of diet approach so they do not believe, as stated in the IAR, there is a risk of consumers losing a whole of diet perspective with the introduction of health claims (quotes P293 IAR "claims could have the effect of shifting consumption patterns from foods such as fruit and vegetables to less healthy alternatives such as processed foods.")(Goodman Fielder).

FSANZ research indicates that consumers are aware of labels and what they mean and that they understand the need to put claims in context. Additionally, these claims are low risk claims (DAFF).

Market research on consumer purchasing decisions suggests that health and nutrition are often not top priorities. As a consequence, health claims are unlikely to influence consumption patterns at the expense of the whole diet (assuming sensible food composition criteria are set for making such claims) (Mainland Products).

Evidence from claims currently permitted

It is important to distinguish between existing nutrient claims, which represent current consumption patterns, from those claims that are not permitted. Claims currently not permitted are likely to improve consumption patterns, as consumer will have the information at point of purchase to help inform their decisions (AFGC, MasterFoods Aust. NZ, Parmalat).

It was noted that content claims and some health maintenance claims have been permitted in Australia since 1995 and there is no evidence of a negative impact on consumers' 'whole-of-diet' approach (Dairy Aust., Parmalat). Consumption patterns in relation to nutrition content and function claims should remain the same given their current permission (Nestle).

Nutrient claims have been in the market place for many years and therefore represent current consumption patterns. Considers that health claims which are currently not permitted but will be permitted under P293 are likely to improve consumption patterns as consumers will have the information at point of purchase to help inform their decisions (Goodman Fielder).

Claims are currently made, so revising the framework is likely to level the playing field and improve the quality of the claims (Fonterra).

Because product claims are not always a priority for consumers, sales of products carrying nutrition claims generally fail to outsell products without claims, e.g. sales of Trim Milk with no nutrition claim other than a standard calcium content declaration have exceeded sales of other milk products which carry more overt content claims. It was presumed that a general consumer awareness about the benefits of a low fat diet has driven sales higher. Nutrition claims have not unduly influenced consumption patterns, and that the introduction of health claims would have a minimal effect on the average healthy consumer (Mainland Products).

It is important to note that nutritional claims have been available for a considerable time and thus any risk to public health would have been apparent by now (NZFGC, NZJBA, Frucor). If the permission to extend the use of nutrition and health claims is granted, the FGC does not believe there will be a risk to public health and safety. The claims will be subject to substantiation and the types of food to which such claims can be made will be prescribed in the legislation (NZFGC, NZJBA, Frucor).

Increase in consumption

Some submitters noted that permission to make health and nutrition claims may result in an increase in consumption of certain foods, as outlined by the comments below.

- Consumers may not have the level of knowledge required to know when to take alternative products to a recommended dietary intakes. Current levels of obesity may be an indication that consumers do not understand recommended dietary intakes, although evidence is anecdotal (NCWA);

- Are not aware of any evidence that nutrition content claims have a positive effect on consumers' food choices and note that although there has been significant increase in products containing 'low fat' or '% fat free' claims since the introduction of CoPoNC, there has been increased prevalence of overweight/obesity of adult Australians over the age of 25yrs (AusDiab study) (Diabetes Aust.);

- The aim of industry in making a claim is to increase consumption of a product. If the claim is not accompanied by a cautionary statement limiting the intake of a particular food, that food may be consumed in excess in the mistaken belief that 'more is better' (Dr C Halais);

- Claims will tend to promote consumption of so called ‘functional foods’ that contain additives, which allow the claims to be made. This will send erroneous nutritional message that other foods are "non-functional" (Dr C Halais);

- Providing health claims sell products, this will either lead to (a) an increase in total consumption or (b) skew the diet towards foods that make health claims. An example is the introduction of fat-reduced ice creams, which led to an increase in the overall consumption of ice-cream, which is not in the public health interest (Dr R Stanton);

- There is good evidence that the consumption of certain foods may increase significantly when consumers become aware of certain health benefits, or perceived benefits (TGACC);

- The risks to include increased consumption of toxic substances/doses, expenditure on inappropriate products, a false belief in an ineffective therapy and diversion from appropriate therapy (Canterbury DHB);

- There is a slight risk of over consumption or concurrent use of therapeutic goods containing the same ingredients. This makes it important that adequate

and clear warning statements may be required in some circumstances (ASA, Cadbury Confectionery, Naturo Pharm, NPANZ, Assoc. of NZ Advertisers, NZ Magazines, NZTBC); and

- It is likely to increase consumption of products with valid and appealing health claims. Notes potential for over consumption of the RDI's of certain nutrients (NZ Dairy Foods).

The ASMI considered there is good evidence that the consumption patterns of certain foods may increase significantly with the introduction of nutrition and health claims. For example, a submission by the Australasian Soft Drink Association Ltd to the Productivity Commission Citrus Growing and Processing Inquiry (pages 9-10, 7 December 2001- attachment 1 to their submission) indicates the levelling out in the consumption of total carbonated beverages, with the main growth occurring in still water and energy drinks. The volume of the still water market for 12 months to 30th June 2001 was quoted as being 520 million litres showing a growth of 10% per annum. This highlights the attractiveness of formulating vitamins, minerals and other substances into still water and energy drinks, which provides a marketing advantage over other still water products and carbonated soft drinks (attachment 2 of their submission).

Data from Caputo and Mattes (1993) suggests that consumers might select higher fat diets in conjunction with the belief that they are consuming reduced fat items. Use of 'low' and 'reduced' fat foods can result in lower fat intakes but not necessarily lower energy intakes because consumers either compensate for reduced energy density of fat modified foods (Gatenby 1995) or because the fat modified products themselves are no less energy dense than the regular fat product (Crowe 2004) (PHAA (supported by ACA), SA DoH, WA DoH).

The 'American Paradox' was noted, whereby obesity rates are increasing despite the proliferation of reduced fat, sugar and energy products on the market, is testament to the likely effects of consumers acting on their beliefs about the composition of 'modified' foods (Allred, 1995) (PHAA (supported by ACA), SA DoH, WA DoH).

Concerns expressed by TCCA were that promoting increased consumption of energy-dense, high saturated fat, micronutrient-poor foods may increase the risk of consumers becoming overweight/obese, and consequently place them at greater risk of major chronic diseases associated with overweight/obesity, e.g. ischaemic heart disease, stroke, colorectal cancer and diabetes mellitus rank among the top ten leading causes of death in developed regions of the world and nationally within Australia (references given).

They went on to say that there is evidence that consumers are more likely to eat larger serves or higher quantities of products, which claim to be (and may well be) low in fat, which is of concern as these products can still be high in energy density (La Fontaine et al. 2003). They recommended that for FSANZ to meet it's statutory objectives, a regulatory framework that presents consumers with a balanced account of the overall health benefits of particular food products should be implemented, rather than emphasising isolated product features, and neglecting to give equal emphasis to other health-relevant attributes of that food.

TCCA further recommended that certain foods (e.g. energy dense, high fat, high sugar, or high sodium) should be ineligible to make health claims. This will help ensure consumers are not misled and efforts are made to protect their health. It would also mean that eligible, 'healthier' foods that make more well substantiated health claims could be promoted to consumers. This is likely to build greater consumer confidence in food-related health claims, than a context where there is a flood of general health claims on foods which could increase public scepticism about health claims on food in general, and result in lower perceptions of the credibility relating to more significant or substantiated claims.

Imbalance in nutrient intake

The following submitters discussed the possibility of consumers being influenced to choose certain foods with claims over other foods, thus resulting in an imbalance in nutrient intake.

- There is a risk that some consumers may misinterpret the nutrition/health information or believe that certain foods are better than others when they may not be or overindulge leading to other health problems (Cadbury Schweppes);

- A nutrition claim relating to a particular nutrient or ingredient may lead to consumers making poor choices in relation to possible imbalances in other nutrients/ingredients, e.g. low fat foods high in sugar. This system already occurs and there will always be some consumers who will take a short-sighted approach to their choices. The question is whether that risk is enough to warrant limiting the range of claims that may provide greater insight for consumer choice for the majority (Aussie Bodies);

- Health claims relating to isolated components of a food (e.g. low sodium) without reference to the potential health effects relevant to the full range of ingredients in that product, might encourage greater consumption of products we would wish to discourage consumption of from a public health point of view (e.g. foods high in fat or sugar) and over consumption of one type of food resulting in an unbalanced diet and nutritional deficiency (TCCA);

- A permission to make health claims may lead to imbalance in diet or have a variable impact. A significant change in a nutrient, e.g. fat, may lead to an increase in others, e.g. sugars, with adverse consequences (Food Tech. Assoc. of Vic.);

- It is difficult to know the likely impact or nutritional significance of these effects, but it may result in food choices that result in a diet that is inconsistent with dietary guidelines (SA DoH);

- Dietetic patients tend to consider a product 'healthy' if it carries a health claim, for example foods with '% fat free' claims which may be high in salt, sugar, low in fibre or have minimal nutritional value. Many people focus on an individual diet component rather than the concept of balance (Northland Health Dietitians);

- Consumption patterns are likely to become more unbalanced as consumers respond to claim on nutrition and health. Argues that claims relate to single nutrients and food whereas dietary patterns have been shown to have most substantial impact on health. Nutrient and health claims are likely to confuse the consumer (ref Vicky Scott) and to limit their use and interpretation of the NIP (Levy et al 1977) (Auckland Reg. PHS);

- Health claims on food would pose a substantial risk to these nutrition guideline messages, they have the potential to confuse or mislead consumers and influence consumers to focus on individual foods instead of the whole diet. The use of health claims that are not in the context of the total diet may mislead consumers into thinking there are "magic bullet" foods and distort the importance of balanced variety in food selection (Public Health South); and

- General fortification of food may lead to oversupply of some nutrients (Nutra Life H&F).

Regarding the halo and magic bullet effects mentioned in the IAR it was noted that it is difficult to know the likely impact or nutritional significance, but it may result in food choices that result in a diet that is inconsistent with dietary guidelines. Food choices can be strongly influenced by what consumers believe they are consuming (PHAA (supported by ACA), SA DoH, Monash Uni – N&D Unit). Consumer findings presented in IAR suggest there is little evidence that supports positive consumer benefit to be gained from allowing claims and a very real potential for them to be misused (e.g. halo and magic bullet effect) (NSW DoH – N&PA Branch).

Increase in consumption of labelled foods over unpackaged/foods without claims

Other submitters were concerned that consumers will choose foods that are packaged and labelled at the expense of loose foods such as ‘healthy’ fruit and vegetables, and made the following comments.

- Claims will tend to promote consumption of foods that are pre-packed. People induced into eating such foods will have to cut back on "loose" foods such as fresh fruit, vegetables, meat, fish, or face over-nutrition (Dr C Halais);

- The use of health claims may lead to the situation where it is likely that processed foods will increase at the expense of purchases of fresh products which are unlikely to carry health claims (Dr R Stanton);

- There is a great risk that consumers will select highly processed foods carrying impressive health claims over fresh fruit and vegetables, the majority of which do not carry labels (Horticulture Aust.);

- Claims are easier to make on packaging of processed products than on fresh produce. Consumers may be enticed away from non-packaged material to those that have sufficient packaging room to make a claims, in turn adversely affecting consumption rates of highly desirable fresh produce (NSW DoH – N&PA Branch);

- Greatest potential threat to public health is that there will be a shift from the 'total diet' perspective of healthy eating, to eating foods with the most/most impressive health claims (SA DoH, WA DoH) which are likely to be more highly processed foods, resulting in diets which are inconsistent with dietary guidelines (Monash Uni – N&D Unit, PHAA (supported by ACA), WA DoH). Food choices can be strongly influenced by consumers' beliefs about 'modified foods', e.g. low fat diet may result in diet higher in energy (Monash Uni – N&D Unit);

- Eating more F & V may be the single most important dietary change needed to improve health and reduce risk of disease and WHO has called for countries to have national campaigns, however majority of fresh fruit and vegetables do not carry labels (SA DoH, WA DoH);

- Health claims on packaged foods may disadvantage foods sold unpackaged such as fresh produce, meat and poultry (Northland Health Dietitians);

- Health claims would disadvantage foods that are not packaged such as fruit and vegetables and therefore may conflict with the recommendations of the NZ Food and Nutrition Guidelines (PHS); and

- Many forms of fruit and vegetables are unlabelled and hence may be seen as being less preferable because they will not be 'wearing' a health claim, whereas the processed forms may be. This may cause confusion and mislead the public that the processed form is a better food choice (NZ V&PG Fed/NZFG Fed.).

CHC submitted that consumption patterns of certain foods may increase dramatically when consumers are informed of particular health or nutritional benefits. There is a need to minimise consumer confusion and to allow them to readily distinguish the different between a health claims in the context of the daily diet and a therapeutic claim. Consumers must not be misled into believing their healthcare requirements can be solely obtained from eating specific foods. In the absence of their own knowledge and understanding of nutrition requirements, consumers may misinterpret claims and believe that their total health requirement are covered by a particular range of foods that have been marketed in the most favourable light possible. This may be a substantial risk (CHC).

GW Foods cautioned against a focus of claims on fresh produce, this may result in a shift from consumption of healthy 'processed' grain and cereal based products such as bread. They recommended there is a need to be realistic and work to encourage consumers to choose a combination of whole-foods, fresh produce and processed food alternatives.

Conversely, National Starch felt that given the experience of other countries there is minimal risk of consumers selecting diets skewed towards processed foods with health claims, at the expense of foods such as fruits and vegetables. A balanced perspective is achieved from product specific health claims that sit within a context of pre-approved generic health claims that are whole-of-diet related and in conjunction with dietary guidelines (National Starch).

Goodman Fielder and NZFGC also rejected the statement that processed foods are less healthy alternative foods as many processed foods are the nutritional equivalent of fresh foods and in some cases represent a safer alternative. Furthermore such statements detract from the fact that canned and frozen fruit and vegetables (regarded as processed foods) can be as nutritionally acceptable as the fresh varieties. Rather than a consequential risk to public health and safety the FGC believes public health will be improved (NZFGC).

Equitable application of policy

It was considered that foods bearing claims might be more expensive than nutritionally equivalent foods without claims. This raises issues in relation to equitable application of policy. Those on lower incomes have greatest burden of diet related disease yet if healthier food choices are more expensive because of claims, then they are less affordable to those who may need them the most (NSW DoH – N&PA Branch).

Minimising consumer public health and safety risks

Some submitters recommended ways to minimise the risks to public health and safety from the introduction of nutrition health claims, as outlined below.

- Provided nutrition and health claims are well-enforced, well-substantiated and have a comprehensive education strategy around them, the consumer public health and safety risks will be minimised. Well regulated claims can encourage improvement in food formulation, improve access to healthier food choices and ultimately improve the food supply (NHF Aust., NHF NZ);

- Research by Williams et al (2003) found 87% of labels complied with CoPoNC or the (old) FSC and the rate of non-compliance was similar amongst claims regulated through either the voluntary CoPoNC or legislated FSC. Legislative remedies exist for false, misleading or deceptive labelling or advertising through Fair Trading/Trade Practices legislation and ACC. A negative impact is likely to be minimal, as Policy Guidelines stipulate that health claims will need to be made in the context of the total diet, and be scientifically substantiated, therefore fostering truthful and non-misleading claims (Dairy Aust., Parmalat);

- Since claims will be required to be rigorously substantiated as to their claimed benefit, by encouraging consumers to select these foods, they can only have a positive impact. Foods carrying claims likely to have an adverse impact on public health will not be able to be substantiated (MLA);

- Nutrition and health claims are a public health issue but not a food safety issue. Claims need to be truthful and substantiated to minimise risk to public health (National Foods);

- Foods offer a much lower risk compared with complimentary medicine and hence data on the impact of complimentary medicines can be used to determine the upper risk level. Our consumer research indicates that food choice is very much determined by taste, freshness, convenience and prices and therefore health claims are just one of the criteria for food selection (PB Foods);

- Health claims have potential to increase development, marketing and consumption of healthier foods. Do not see there is any risk to public health and safety as long as the Code is legally enforceable which should minimise misleading claims (CSIRO HS&N);

- It is essential that all communication methods, from labelling to advertising, carry appropriate messages to ensure that the marketing/advertising of therapeutic goods is conducted in a manner that promotes the quality use of the food through safe and appropriate consumption, is socially responsible and does not mislead or deceive the consumer (CSIRO HS&N);

- The regulations must be robust enough to disallow any claims, which could result in the promotion of food products, which are low nutrient-high energy value. There must be adequate enforcement. Shortcomings in either the regulations, or the enforcement of the regulations could certainly mean increased consumption of low-nutrient-high energy foods, and displacement of important food groups in the diet (NZDA);

- Over-riding of dietary guideline and food selection guide is to 'enjoy a wide variety of nutritious foods' and claims on foods can be useful only when they are clearly put into this context (SA DoH);

- Care should be taken to ensure Nutrition, Health and Related claims do not mislead vulnerable sectors of the population such as pregnant women, lactating mothers, children and the elderly. Claims directed at specific population sectors should not be presented in such a way as to mislead the general population (SA DoH, Horticulture Aust.);

- Any unintended impact of Nutrition, Health and Related Claims on consumer dietary consumption patterns needs to be given due consideration. "…the likely consumer perception of the health claim 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 [Joint Health Claims Initiative] Code; all likely interpretations must comply" (SA DoH, Horticulture Aust.); and

- The use of health and nutrition claims runs the risk of having consumers choose products on the basis of these claims rather than on the basis of a balanced 'total diet'. National dietary guidelines and food selection guides recommend consuming a wide variety of nutritious foods and claims on food labels can be useful for consumers only when they are clearly put into this context. The extent of this risk depends on how the claims can be

made and in the way they are enforced. Therefore a process, by which claims must meet specific conditions and are fully substantiated and enforced, is needed (Horticulture Aust.).

The introduction of health and nutrition claims was supported because most consumers would link the physical consumption of foods to nutrition and health to some extent, and health claims would assist them in making healthy food choices. Successful marketing often involves an existing consumer perception between the food and the component/nutrient, for example calcium and milk. Health claim criteria should be based around these types of logical links. Individuals who perceive themselves as at risk of/or having a specific ailment should be able to choose products carrying health claims if: such claims are well founded; in a whole-of-diet context and relative to the whole category of comparable foods. The public may choose to ignore information if there was a huge proliferation of claims (Mainland Products).

Need for monitoring and evaluation programme

The need for a monitoring and evaluation programme was acknowledged by the following comments from submitters.

- An effective monitoring and evaluation program is required to monitor risk to public health and safety and for the prevention of misleading and deceptive practice (Nutrition Aust.);

- A National Nutrition Survey should be completed prior to the implementation of the system to regulate Nutrition, Health and Related Claims and will provide essential baseline information (Nutrition Aust., PB Foods). 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.);

- Claims on food products are predominantly based on this data and the dietary guidelines and consequently there is a low risk of a negative impact (PB Foods);

- Although unaware of quantitative evidence, there is anecdotal evidence that since CoPoNC was introduced there has been a significant increase in products carrying 'low fat' or '% fat free' claims. Another National Nutrition Survey may establish the effect of CoPoNC on food consumption patterns (GI Ltd);

- The likely impacts on consumption patterns are unknown and unable to be monitored in view of the lack of current Australian data on consumption patterns, food composition data and nutrient status. There is inadequate reference to any impact evaluation of the proposed health claims. One of the major public health concerns is that food consumption patterns could be significantly altered (for better or worse) and there is no capacity to monitor any change, as we have no recent baseline data on which to compare the impact of the introduction of health claims. The importance of extensive monitoring and evaluation of the introduction of a new system to

regulate Nutrition, Health and Related Claims cannot be underestimated (Tas DOH&HS);

- It will be very important to establish a comprehensive monitoring & evaluation process to determine the impact and outcome of P293 and to use the findings to improve the system over time (NSW DoH – N&PA Branch); and

- FSANZ should carry out a health impact assessment to inform any decision made concerning a preferred option (Auckland Reg. PHS).

Need for education

The need for education was noted by the following comments from the submitters below.

- It is government's responsibility to educate the consumer about claims, which will help increase consumer awareness. Industry may help this process by some nutrition education on the package with selected products that contain health claims (Bakewell Foods);

- Appropriate information needs to be provided to consumers to facilitate choice, which can be done in a number of ways including better education to children in schools or simple advertising messages in all forms of the media (Cadbury Schweppes);

- Appropriate education tools must be prepared for the implementation of the new regulations on health and related claims (PB Foods);

- There is no opportunity for intervention and advice at the point of sale other than the information on the label or package. Consumers will need to be educated on how to appreciate what the labelling means to them, in clear consumer friendly language (ASA, Cadbury Confectionery, Naturo Pharm Ltd, NPANZ, Assoc. of NZ Advertisers, NZ Magazines, NZTBC); and

- In terms of shifting consumption patterns from what is considered desirable to less desirable it is a matter for consumer education with respect to whole of diet, and therefore a broader understanding of the dietary guidelines. There are no good and bad foods, rather good and bad diets (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).

Lack of published evidence

Dr R Stanton, NCEFF and Nutrition Aust. noted that there is not a lot of evidence on this impact. Neither the USA or Sweden, where health claims have been permitted since 1990 and 1989 respectively, have undertaken any formal evaluation of the impact of the new health claims regime (NCEFF).

Overseas evidence

The following evidence on the impact on consumers from the introduction of nutrition and health claims was noted:

- There is a relatively low presence of health claims in the USA market. A representative survey in US supermarkets (carried out in 2001) (LeGault, L., et al., 2004) only 4.4% had a health claim. No comprehensive data on the use of permitted generic health claims in Sweden - only four products carry specific claims. Given the situation in these countries, NCEFF suggests that the 'visibility' of claims in Aust/NZ is likely to be low and therefore limited in its impact on consumer behaviour (NCEFF);

- A study in Netherlands (Van Assema P. et al., 1996) concluded that the evidence is insufficient to draw conclusions, but if there are impacts they will probably be only for a limited group of people (NCEFF);

- Since authorisation of the Soy Protein and Coronary Heart Disease (CHD) Health Claim there has been an increase in the use of soy protein in a variety of foods. Per capita consumption of soy protein increased from 0.78 g/day in 1998 to 2.23 g/day in 2002 (refer Appendix 2 attached to submission). Assuming soy protein intake doubled (increased 100%) as a result of the authorization of the proposed health claim, we estimate per capita soy protein intake would be 4.48 g/day (3.24-5.70 g/day for various age/gender groups). These intakes appear reasonable and present no safety concerns (Solae Comp.);

- A survey conducted in 2002 in UK found that few participants mentioned claims when discussing labelling elements they looked for on packaging, suggesting that they are not highly valued or useful to consumers. Other research indicated general distrust of claims and a view that they were largely viewed as advertising as opposed to nutrition education (NSW DoH – N&PA Branch);

- Overseas evidence suggests there is little short-term impact on foods displaying health claims (Horticulture & Food Research Instit. of NZ);

- Evidence from the US that shows that nutrition and health claims have the significant potential to increase consumer awareness of diet/health issues and to improve consumer dietary choice, especially for groups not reached by government (Mathios 1998). Submission notes a report from Federal Trade Commission (US) about health claims in the advertising and labelling of high fibre b/f cereals between 1985 and 1987 and the results in relation to reduced risk of colon cancer (Dairy Aust., Parmalat);

- There is a relatively low presence of health claims in the USA market. A representative survey in US supermarkets (carried out in 2001) (LeGault, L., et al., 2004) only 4.4% had a health claim. No comprehensive data on the use of permitted generic health claims in Sweden - only four products carry specific claims. Given the situation in these countries, NCEFF suggests that the

'visibility' of claims in Aust/NZ is likely to be low and therefore limited in its impact on consumer behaviour (NCEFF);

- Studies in the US (following introduction of a more liberalised approach to nutrition and health claims) confirm the potential for skewed dietary intakes, and underline the importance in Australia of regulation that defines eligible foods and claim criteria in standards. (See Legault et al, 2004 and Parker, 2003) (PHAA (supported by ACA), WA DoH, Monash Uni – N&D Unit, SA DoH);

- The Food Label and Package Survey (FLAPS) of 1,281 foods found health claims on 4.4% of food product labels, structure/function claims on 6.2%, and nutrient content claims on 49.7% (Legault et al, 2004). Of the foods with structure/function claims, meal-type beverages (47.1%) and baby foods (43.5%) had the highest sales-based percentage of products. Implied claims were found on a total of 10.2% of the products (SA DoH); and

- In a study on the use of nutrient content, health and structure/function claims in advertisements, Parker (2003) found that "…despite the USDA's recommendation that Americans consume products from this category sparingly, the highest number of advertisements was for products in the fats/sweets group, which accounted for 22.1% of the 1,320 advertisements (SA DoH).

Evidence presented by GI Ltd

Supporting evidence of substantial risk:

- The AusDiab study revealed an increase in overweight/obesity prevalence in Australian adults (25 + years), providing limited evidence that the introduction of CoPoNC nutrition content claims at the very least did not help prevent this health problem. (Diabesity and Associated Disorders in Australia 2000. The Australian Diabetes, Obesity and Lifestyle Study (AusDiab). International Diabetes Institute, Melbourne, 2001).

Supporting evidence of a positive influence on the food supply:

- NHF 'Tick' program research found that many manufacturers reduced the sodium/fat content of their products to meet NHF's nutrient criteria, demonstrating a positive influence on the food supply. (Young L. The influence of Pick the Tick on food formulation. National Heart Foundation of New Zealand. 1999) (supported by Diabetes Aust.);

- By mid-2004, GISP has grown to include nearly 70 food items carrying the Glycaemic Index (GI) Tested logo. Since 2002, annual surveys of Australian consumers revealed that 7 out of 10 consumers stated that they would be 'somewhat/very likely' to look for the logo, thus positively influencing consumer food choices (supported by Diabetes Aust.); and

- FSANZ's own quantitative consumer research determined that consumers trusted NHF's 'Tick' and the GI Tested endorsements more than any other label element, supporting the argument for health and nutrition claims to positively impact food purchasing decisions (Food Labelling Issues. Quantitative Research with Consumers. Evaluation Report series no. 4, FSANZ, 2003).

General comments

Care is needed to avoid using statements on risks to public health and safety purely based on assumptions of human behaviour (NCEFF).

Claims regarding the suitability of a product for a food-allergic consumer can jeopardise the safety of those individuals, e.g. claims regarding suitability of goat milk as milk replace for cow milk allergy suffers (Allergy NZ & Anaphylaxis Aust.).

Other comments provided but not in direct response to the question:

ANIC stated that nuts can make a significant contribution to general health, particularly in the area of heat disease, diabetes and weight control. By endorsing nut consumption by way of a high level claim, FSANZ is likely to alter consumer eating patterns. Research conducted by the industry shows consumers actually like nuts however they restrict consumption because of misplaced concerns about fat and cholesterol content. Research conducted by the Australian nut industry shows consumers and health professionals hold misconceptions about the role of nuts in health with 36.1% of consumers and 48% of GPs believing nuts have a negative impact on cholesterol levels (ref provided). This degree of misunderstanding means a message regarding the ability of nuts to reduce the risk of heart disease is likely to be educational and informative and have greater impact on public health as a result. Consumers enjoy the taste of nuts meaning the dietary changes required to have significant health benefits is likely to be well accepted by the community. Quotes a US report that found that taste is the most important factor influencing purchasing decisions (reference provided).

GW Foods rejects FSANZ's comments that "consumers are at risk of losing a whole of diet perspective on their food purchases" and "claims could have the effect of shifting consumption patterns from foods such as fruit and vegetables to less healthy alternatives such as processed foods". Rejects and is concerned by these statements as considers many processed foods are the nutritional equivalent of fresh foods and in some cases represent a safer alternative. In general foods carrying health claims would have been substantiated as to their claimed benefit, giving consumer confidence and certainty in selecting appropriate foods.

GW Foods were concerned about other FSANZ comments in relation to consumers interpreting health messages inappropriately, resulting in adverse health outcomes. George Weston Foods have reformulated products in order to meet strict nutrient criteria stipulated by endorsement bodies including the Heart Foundation's Tick program and the GI Symbol program. Certain products have been reduced in energy, salt, sugar and fat and increased in fibre to meet these requirements. They considered the FSANZ example of a high level claim and possible risk to public health if the food is high in sugar content and low in fibre, not to be appropriate example, as high level

claims require full evaluation by FSANZ before approval and if the food is substantiated regardless of its other components it is proven to deliver the claimed benefit.

GW Foods disagreed with FSANZ's comment that consumers may exclusively follow the advice of a claim on food and fail to seek or follow advice from a health professional. They considered the requirement for an advisory statement to the effect that a health care practitioner's advice is required, as recommended by the Ministerial Policy Guidelines for claims that refer to dietary management of a biomarker condition or disease, provides adequate risk management for consumers tempted to exclusively follow the advice of a claim on food.

Consumer's Institute of NZ considered consumers would not benefit if a broader range of claims are permitted. Primarily, they will be used by manufacturers for marketing purposes rather than for consumer information or education. Health claims may give a distorted view of food and accurate nutrition labelling should give consumers all the information they need.

Question 3

Would consumers in general (or specific consumer groups) benefit from a broader range of nutrition, health and related claims? If so, which claims?

Out of 147 submitters, 59.2% (87 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	31	19	4	2	56
Government	6	2	-	-	8
Public health	10	6	-	-	16
Consumers	2	-	-	-	2
Other	4	1	-	-	5
Total	**53**	**28**	**4**	**2**	**87**

Overview

Sixty per cent of submitters (52) believed or implied that consumers in general (or specific consumer groups) would benefit from a broader range of nutrition, health and related claims. Another 17 agreed, but only if certain conditions were met (e.g. education for consumers and the claim being made in the context of the total diet). The main benefits related to provision of information to assist with healthy food choices. Other claims that would be of benefit ranged from all types of claims to specific high level claims. Five submitters believed or implied that consumers in general (or specific consumer groups) would not benefit from a broader range of nutrition, health and related claims.

Consumers would benefit

Forty-seven submitters considered that consumers would benefit from a broader range of nutrition, health and related claims (Bakewell Foods, NZ Dairy Foods, DSM Nut. Prod., F&B Importers Assoc., Heinz Aust./Heinz Watties NZ, Nestle, Aussie Bodies, Horticulture and Food Research Instit. of NZ, NZJBA, Frucor, NZFSA, ABC, AFGC, MasterFoods Aust. NZ, GW Foods, NZFGC, Tegel Foods, Goodman Fielder, Parmalat Aust., Flour Millers Council of Aust., National Foods, DAFF, Cadbury Schweppes, CML, Go Grains, National Starch, Solae Comp., MLA, PB Foods, Sanitarium Health Food Comp., CSIRO HS&N, Fonterra, Mainland Products, Griffins, Nutra NZ, ANIC, Dairy Aust., 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 to support this belief were that:

- Consumers should have opportunity to make informed choices. If a range of claims can help, it is a benefit (Heinz Aust./Heinz Watties NZ);

- Consumers would only benefit from having more nutritional information to guide their choices and help them understand the benefits of particular foods, and will be of greater benefit to specific consumer groups, e.g. diabetics, coeliacs etc (Aussie Bodies);

- There would be more information and potentially lower disease risk as a result of increased consumption of certain foods. Availability of health and nutrition information about foods helps people make informed choices about diet and it may be a right for this information to be available (Horticulture and Food Research Instit. of NZ);

- Consumers are likely to benefit from claims with a direct public health benefit. There would also be more information available to consumers to assist them make an informed choice (NZFSA);

- The ability to use nutrition and health claims would present manufacturers with the opportunity to produce foods for specific sectors of society and educate consumer about those foods. This could be a driver for improved or healthier food choices (NZJBA, Frucor);

- A broader range of claims increases the information that can be conveyed to consumers about food, nutrition and health links. Benefits to consumers can only but accrue (NZFGC);

- Consumers should have the opportunity to make informed choices and if a broader range of claims helps consumers then it would be a benefit (Tegel Foods);

- Further information will be available at point of purchase (ABC, AFGC, MasterFoods Aust. NZ, GW Foods);

- The information will influence the purchase and focus consumers potentially toward healthier food choices (Goodman Fielder, Parmalat Aust.);

- Consumers will benefit from an increased choice of healthier foods. Health messages provided by public health and government can also be supported and reinforced at point of purchase. A broader range of claims, in particular pre-approved high level claim based on Dietary Guidelines would reinforce and support population nutrition guidelines for all Australians and New Zealanders (National Foods);

- Presenting the truth about the health benefits of products would benefit consumers in general (ABC, AFGC, MasterFoods Aust. NZ, Goodman Fielder);

- The increase in a competitive environment would also be a driver for improved or healthier food choices (AFGC, MasterFoods Aust. NZ);

- All claims proposed have potential to benefit consumers as they provide targeted information (GW Foods);

- Consumers will be provided with more information, and more choices. As consumers move away from convenience foods to health-conscious foods, this will become more and more important. Also there is real potential for health improvements through food choices, and averting serious diseases, which are linked to diet (DAFF);

- Consumers can benefit by access to wider choice via a broader product availability including nutrition, health and related claims (Flour Millers Council of Aust.);

- Consumers would benefit from greater knowledge of nutrition and health information (Cadbury Schweppes);

- The presence of any permitted claim on food will begin to educate consumers of the potential health benefits. Health professionals could also use these claims to educate consumers, consumer groups and patients. The initial focus of attention could be on any claims that are likely to have a positive impact on the top 10 causes of health care costs in Australia that are diet-related (CML);

- Nutritional needs of the population vary depending on age, sex, lifestyle etc and as such the scope for specific health messages and products will be of considerable benefit for both consumers and industry. Current restrictions on claims limit new product development and thereby act as an obstacle to consumers benefiting from innovative foods and beverages which provide meaningful health benefits for particular at-risk sub-groups (National Starch, Solae Comp.);

- Consumers in general and people managing specific diets could benefit from a broader range of claims as claims provide an opportunity to communicate and

educate consumers about dietary guidelines and public health recommendations (Sanitarium Health Food Comp.);

- A broader range of claims increases the information levels to consumers and raises consumer awareness of the importance of the diet (Fonterra);

- A broader range limits any bias created by only permitting a few claims, as consumers are aware of the nutrition and health attributes of a greater range of products (Fonterra);

- Truthful and appropriate claims will benefit consumers by providing them with information to make food choices. This will increase consumer awareness of healthy food options, forcing manufacturers to provide healthy options to remain competitive (Griffins Foods);

- Industry will be allowed to provide information on accurate and scientifically supported messages about nutrition and health at the point of sale. Research shows most consumers read labels (ANZFA qualitative research) and 24% state food labels as the most useful source of health and nutrition information (International, H.F., 2004). This research identifies the important and significant role health claims on labels and at point of sale can make to enhancing consumer education and understanding about the link between food and health (ANIC);

- Access to a wider range of nutrition, health and related claims, and the increase in a competitive environment would be a driver for improved or healthier food choices (Dairy Aust); and

- Overall benefit is likely to be from the combined efforts of food manufacturers being permitted to use diet-disease claims and education from government and non-government organisations (Dairy Aust.).

Dairy Aust. added that FSANZ qualitative research results that shows that consumers went from being sceptical about 'free claims' in 2001 to using them more extensively and favourably in 2003. Their submission noted WHO Global Strategy on Diet, Physical Activity and Health (2004), which states that providing information on the content of food items is conducive to consumers making healthy choices.

Another 17 submitters considered that consumers would benefit from a broader range of nutrition, health and related claims but only if certain conditions were met (PHAA (supported by ACA), Horticulture Aust., SA DoH, WA DoH, Monash Uni – N&D Unit, ASMI, NSW Food Authority, Northland Health Dietitians, Dr R Stanton, ASA supported by Cadbury Confectionery, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, NZ Magazines, and NZTBC).

These conditions were that:

- Consumers will only benefit from a limited number of nutrition, health and related claims that support the dietary guidelines and food selection guide (PHAA (supported by ACA), Horticulture Aust., SA DoH, WA DoH, Monash Uni – N&D Unit);

- Benefits are reliant on there being extensive consumer education on how to use nutrition, health and related claims when selecting food, in the context of the dietary guidelines (PHAA (supported by ACA), Horticulture Aust.);

- Nutrition and health claims must be real and tangible to be of benefit to consumers. Vague or misleading claims will lead to general mistrust of the food industry and increasing confusion over the validity of all health related claims (Horticulture Aust., SA DoH);

- There are safeguards to ensure that the claim in meaningful in context to the amount of ingredient in the product (ASMI);

- The claims meet the criteria of the overarching principles and to avoid potential misuse of claims, a substantial public education campaign is necessary to educate consumers in the principles behind the proposed Standard i.e. how to interpret different levels of claims, how to use products with claims in the context of the total diet etc (NSW Food Authority);

- Appropriate qualifying/disqualifying criteria for saturated fat, total fat, sugar and fibre are present for the following claims (see below) (Northland Health Dietitians);

- It is conveyed realistically. Groups that could benefit are those at risk of disease or suffering from a condition where targeted nutrition could be beneficial. Currently consumers are denied truthful information about food that would benefit their health (ASA supported by Cadbury Confectionery, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, NZ Magazines, and NZTBC);

- Claims are taken in the context of the total diet and only be approved for foods that do not have disqualifying features (Dr R Stanton); and

- The claims are scientifically substantiated. A problem is the inability of, e.g. fruit and vegetable producers to counter the many claims on products claiming fibre intake of their product is important for e.g. bowel cancer. Consumers require wider knowledge of nutrition and the role of nutrients in health and development (NCWA).

It was further explained that the folate health claim has been poorly communicated to consumers. A broader range of permitted claims would require more extensive consumer education. Jones (2003) advises that, "Consumer confidence must exist in health claims and the regulatory process through which they are generated if effective changes in nutritional behaviour of Canadians are to be maintained. Since behavioural

changes are complex and difficult to bring about on a population basis, emphasis should be placed on claims having major health impacts. Claims having little or no effect on health should not be allowed, as they may dilute consumers' efforts to modify their eating behaviour, and disrupt confidence in the regulatory process and the claims themselves." (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit). Horticulture Aust considered that the folate health claim has been poorly communicated to consumers and a broader range of claims requires more extensive (and expensive) consumer education.

Food Tech. Assoc. of Vic. commented that an increase in choice as a result of claims might lead to confusion without a parallel education programme.

Another five submitters implied that a broader range of nutrition, health and related claims would benefit consumers (NHF Aust., NHF NZ, TGACC, NZ V&PG Fed/NZFG Fed.).

Their comments were as follows:

- Such claims have the potential to extend the reach of nutritional messages. They may improve the food supply by creating competition between manufacturers to produce healthier food products (NHF Aust., NHF NZ); and

- The level of benefit and effectiveness of foods carrying health claims is not yet quantifiable. The introduction of a Standard will rectify and standardise the current market environment, which has existing problems with compliance with the general prohibition on health claims. The conformity achieved through this process will be of benefit to the consumer (TGACC).

Claims that would be of benefit

Some of the above submitters identified the types of claims that they considered would be of benefit to consumers as follows:

- General level claims (DSM Nut. Prod.);

- Health claims that are currently not permitted (Nestle);

- All justified claims (F&B Importers Assoc.);

- Examples - low level claims such as fibre and alleviation of constipation and high level claims regarding omega 3 fats, plant sterols and PUFA in preventing heart disease. general level claim such as 'high protein' may help appetite control and weight management; dietary fibre may help to promote laxation (CSIRO – HS&N);

- Dairy foods containing calcium link to reduced risk of osteoporosis; and probiotics link to enhanced immunity levels (Fonterra);

- Vegetables, fibre and cancers; dairy calcium and osteoporosis; dairy products and weight loss or weight maintenance, probiotics and gut health and immunity (Mainland Products);

- Claims that provide information on healthy eating in relation to heart disease, osteoporosis, high blood pressure, joint mobility, macular degeneration, diabetes, obesity, brain nutrition, gut health, mood, anti-inflammatory function (Nutra NZ);

- Health claims that address cardiovascular diseases – our no.1 killer (Solae Comp.);

- Calcium, iron and vitamin B status of women during different life stages; constipation and the elderly; those with higher risk of certain diseases (National Starch, Solae Comp.);

- Particularly in relation to general wellbeing (notes increasing consumer demand for info on general health and wellbeing and that facilitating the provision of well substantiated nutrition information will satisfy this demand and ensure that consumers receive accurate scientifically sound information) (MLA);

- Nutrient content linked to functional claims (ASMI);

- Low in saturated fat (with an explanation of its link with heart disease); wholegrain - relating to cancer risk reduction and heart health; and fruits and vegetables - relating to cancer risk (Northland Health Dietitians); and

- Claims that help the public change their eating behaviour could be of benefit e.g. claims promoting fresh fruit and vegetables, as could claims promoting foods/messages from the Australian Guide to Healthy Eating (Dr R Stanton).

Three submitters believed there is a need for a broader range of nutrition content claims (as opposed to health claims), in particular for the terms 'high protein' and 'low Carbohydrate' to be defined and regulated as nutrition content claims as they are currently being used on a range of food products in Australia due to Atkins diet (Diabetes Aust., GI Ltd, DAA). DAA explained that interest in low carbohydrate, high protein diets have been increasing in the community and industry is responding by producing foods with apparently reduced carbohydrates. However, as yet, there are no definitions as to what constitutes a low carbohydrate food and therefore there is the potential to mislead the consumer. In this instance, consumers would benefit from the introduction of definitions and recommended or allowed claims in relation to carbohydrates and protein (DAA).

ANIC believed consumers will benefit from a health claim related to the heart health benefits of nuts, in order of priority: whole or chopped nuts and heart disease; walnuts and heart disease; wholegrain foods and nuts and coronary heart disease/heart health; fruit, vegetables, nuts and grain products that contain fibre, particularly soluble fibre, and coronary heart disease (and variations of this claim); fibre containing grain products, nuts, fruit and vegetables and cancer; dietary saturated fat, cholesterol and

trans fat and coronary heart disease; Saturated fat and blood cholesterol; soluble gel-forming dietary fibre and blood cholesterol; omega-3 fats and factors affecting blood cholesterol and blood pressure, atherosclerosis; sodium and high blood pressure; folate and neural tube defects.

ANIC recommended nuts be specified in many of the health claims proposed that link wholegrains, fruits and vegetables with a reduced risk of coronary heart disease. Rationale for this is that because there is substantial, consistent scientific evidence demonstrating the heart health benefits of nuts (see petition attached to submission).

Go Grains considered that there would be benefit in broadening the range of claims to include those in relation to the wholegrain content of foods to assist in consumer education and to provide guidance to manufacturers by creating a level playing field. They commented that there is now substantial evidence to support the fact that consumption of wholegrain foods can lower risk of heart disease, type 2 diabetes and some cancers (refer to list of studies in Appendix 1 of submission). They also stated that research (refer to submission for references) shows people have difficulty identifying grain foods and think a 'wholegrain' claim would make this easier. They believes 'wholegrain' claims will enable consumers to make better food choices and prevent misleading and deceptive conduct as the wholegrain content could be reliably determined and substantiated. It was pointed out that encouraging the consumption of 'wholegrains' conveys a positive message in an environment where claims tend to be negative (Go Grains).

CMA stated that consumers would benefit from a broader range of claims that provide scientifically substantiated, truthful information about benefits that lead to improved nutrition and health outcomes. This would enable industry to inform consumers on levels that have not previously been permitted, including benefits about specific products, e.g. dental benefits of consumer 'sugar free' confectionary; nutrient rich chocolate which contributes protein, calcium, magnesium, iron and niacin as well as having other associated health benefits such as antioxidants, blood thinning properties, macronutrients, and fibre; and confectionary is a feel good food that may be enjoyed as part of a balanced diet (CMA supported Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA).

PB Foods commented that their consumer research has shown that there is growing interest in prevention of age related diseases, improving physical and mental well being above and beyond that of just staying free from disease. Claims on food products would supplement the information obtained from other media (e.g. Women's magazines), health professionals and health promotion campaigns by governments. Opportunities for product development will be dependent on changes to other standards – permissions to fortify, add vitamins, minerals and bioactives. Dairy foods have been associated with positive health benefits for osteoporosis, obesity, cancer, immunity and blood pressure. Future research will be determined by public health concerns. Allowing health claims also provides an opportunity for government to work with industry to direct research to areas of increasing health concern. Such partnerships are already occurring overseas, for example in the United States.

Cadbury Schweppes added that it is important to determine how the benefits of food can be identified while making sure that consumers are aware of the down sides (e.g. many benefits to chocolate such as calcium and other vitamins and minerals but it also has high levels of fat). It was also recommended that consideration should be given to how individual foods constitute a claim in the context of a specific dietary pattern (CSIRO – HS&N).

Dairy Aust. suggested that which claims to implement should be driven by their contribution to public health objectives, whilst considering consumers understanding and use by manufacturers, and that all substantiated claims have the potential to benefit consumers. They proposed a number of high level claims based on milk and other calcium rich dairy foods (refer to submission for substantiation) (supported by Parmalat Aust.). Each of these claims has the potential to improve public health and address the financial burden imposed secondary to these diseases/conditions (2000/01 $16.3 billion or 1/3 of total disease-related health expenditure costs (AIHW 2004). They acknowledged that FSANZ is working under time and resource constraints in approving the first round of high level claims therefore asks for a commitment from FSANZ to further review 5 high level claims per year, in order to maximise the effectiveness and compliance of the system (Dairy Aust.).

Concern was expressed by NZ V&PG Fed/NZFG Fed, who explained that most of the benefits of increasing fruit and vegetable consumption are in the prevention/protection of 'serious diseases'/high level claims. Because fruit and vegetables do not 'wear' a health claim the importance of being able to communicate substantiated information at a level that is of use to the consumer is paramount, consumers want to hear specifics. Groups promoting the whole category should be able to report (in websites, media, brochures etc) on scientific research, provided it is substantiated, without it being interpreted as a health claim. Freedom of speech issues must be considered. Using the above mediums enables full and comprehensive, detailed information to be presented - this needs to be defined as dietary advice. By contrast, messages on packaging must, by their very nature, be succinct and not able to present detailed explanation. The two situations are very different and need to be allowed for.

They went on to say that currently the legislation is all encompassing, if it is adhered to strictly it restricts the information able to be passed to the consumer to a level which is so general that it is not empowering in decision making. Consumers then seek information from other sources, e.g. media, women's magazines, diet books etc, which are not subject to legislation or responsible education strategies. Recommends the FSC should encourage the innovative education undertaken by reputable food industry groups who are intent on implementing the HEHA strategy, in line with the overall aim of P293 to enable the responsible use of scientifically valid nutrition. Currently Health Claims and HEHA appear to be in conflict. This creates huge frustration. Addressing this area of discrepancy would be most welcome ((NZ V&PG Fed/NZFG Fed.).

Would not benefit

Three submitters stated that consumers would not benefit from a broader range of claims (Dr C Halais, Auckland Reg. PHS, Public Health South).

Their comments were:

- This would encourage a proliferation of claims and could result in every packaged food bearing a claim, and greater confusion in consumers with respect to sound nutritional choices (Dr C Halais);

- The wider the range of claims the more potential for increased confusion (Auckland Reg. PHS); and

- There is no evidence that nutrition, health and related claims lead to improved public health. There would be a substantial risk to consumers if health claims were permitted. Health claims may confuse and mislead consumers and potentially influence a move away from a whole diet approach (Public Health South).

Another two submitters implied that they considered that a broader range of claims would not benefit consumers (Canterbury DHB, Nutra Life H&F) and made the following comments with respect to this:

- Do not believe the research substantiates that health claims will improve public health and safety, and propose that claims may do the opposite, with the potential to confuse the public more about appropriate food choices. General level claims have the most potential for confusion and misinformation, whereas well-substantiated high level claims, of any, are possibly of the most use from a public health perspective. Health claims are primarily marketing activities for the food industry, and are not recognised public health tools to improve health (Canterbury DHB);

- A health impact assessment of health claims rather than a cost benefit analysis should be conducted before the Draft Assessment Report to look at a wide range of potential public health issues e.g. reducing inequalities that are not adequately covered by a cost-benefit analysis (Canterbury DHB); and

- Health claims on foods may discourage consumers from seeking appropriate diagnosis or treatment for specific conditions, leading to further problems. Some health claims would contravene the NZ Medicines Act, which prohibits a range of conditions specified in Schedule 1 of the Act and its regulations (Nutra Life H&F).

Two submitters considered that consumers would not benefit from broader range of health claims, not including nutrition content claims (Diabetes Aust., GI Ltd). They explained that the evidence about the efficacy of health claims from overseas and evaluation of the Folate Health Claim Trial (Watson, M., Watson L., 2000) does not provide any compelling evidence to support the need for a range of health claims in Australia/NZ. They added that due to ambiguities in the current legislation food manufacturers are making implied health claims on foods, this issue needs to be addressed, most urgently those areas relating to cardiovascular disease, cancer and overweight/obesity.

Advantages and disadvantages of a broader range of claims

Some stakeholders submitted both advantages as well as disadvantages to consumers of a broader range of claims, as outlined below.

Foods with claims (largely packaged foods), may encourage consumers to purchase more of these products rather than foods without claims e.g. fruit which are more consistent with policy guidelines. Foods bearing claims may be more expensive to buy than nutritionally equivalent foods without claims, creating inequalities in access to the food supply (Nutrition Aust.).

Advantages are: that consumer awareness of nutrition is likely to be raised and thus on the whole consumers become better informed about nutrition and therefore make more appropriate choices; and wider range of foods available with improved nutritional profiles to meet the criteria and conditions to carry claims (this has been demonstrated by the NHF 'Pick the tick' program) (Nutrition Aust.).

Consumers would benefit for good health advice, but the concern is that food marketers may create a situation whereby the consumer is totally reliant on certain foods providing all their health benefits and these foods may contain sub-optimal quantities of nutrients (CHC).

There is limited evidence to indicate that health claims provide information to help consumers choose healthier diets and it is difficult to determine if any benefit would arise (Tas DoH&HS, NSW DoH – N&PA Branch, SA DoH, WA DoH). Evidence from FSANZ consumer surveys (Paterson et al, 2003a) and UK Food Standards Agency (2002) indicates that consumers are confused by health claims on food labels. The IAR highlighted problems with consumer interpretation of health claims (Tas DoH&HS).

Consumers would benefit from having clear, unambiguous, well-regulated claims that reduce the potential for misleading and deceptive conduct (Tas DoH&HS, NSW DoH – N&PA Branch, SA DoH, WA DoH).

Countries which have permitted health claims over the last 10 years such as the USA which allows health claims in relation to the reduction of risk of cancer or cardiovascular disease with low fat, saturated fat, high fruit and vegetable and soluble fibre or fibre containing grains have had no impact on markers of cancer and cardiovascular disease such as obesity (while recognising that disease is multi-factorial experience). Obesity levels have increased dramatically in the USA over the last 10 years (Centre for Disease Control, 2002) (references provided) (Tas DoH&HS).

General comments

Consumers would benefit from a wider education of healthy eating patterns rather than selective claims relating to specific components of foods, which may have proposed health benefits, but are claims that primarily function as marketing tools. There is a need for disqualifying/qualifying eligibility criteria for foods allowed to make claims, to ensure that products which might have one beneficial attribute, but

which in general terms are less healthy (e.g. 100% fat free Marshmallows), are not presented to consumers in a misleading light. Foods making claims may be able to detract from the negative attributes of the product if it is high in (saturated) fat, sugar, sodium, energy density, or contains alcohol (TCCA).

The nutritional value of unpackaged foods needs to be promoted to consumers as per Australian Guide to healthy eating. Whole food group claims are important (Tomox).

Further research is required as to what statements and claims are helpful to consumers before this can be adequately answered. Would like to see public consultation for all high level claims. Health professionals will then be able to consider the claims and not be presented with a fait accompli (NZDA).

It is unknown how effective health claims are in making a difference to food consumption behaviours. Claims could be used as a marketing tool by industry without proven benefits. Benefits are unknown until a system is put in place and subsequently evaluated. At a predetermined time, after introduction of new standard, there needs to be an independent review of whole claims process including how it provides health benefits for the population (NZ MoH).

Further comments from NCEFF:

- Considers that there is a case to be made that health and related claims on food provide another avenue for nutrition education. May be helpful to consider parallels to conventional nutrition education to determine the range of claims that could be made to the community. It seems illogical that statements on calcium and bone health are everyday practice in schools and community centre, when they cannot be made on food products;

- NCEFF suggested that cultural attitudes also impact on the management of claims. The USA system of qualified claims can be seen to provide information to consumers about the current level of scientific knowledge, whilst the more accommodating regulatory systems in some Asian countries reflect the cultural history of food use in health management. NCEFF questions Australia's position;

- Suggest that this policy increases the opportunity and the competitive pressure on companies to market the nutritional features of foods and facilitates cooperation between food manufacturers and nutrition education activities, thus benefiting the consumer (Calfee J,. et al. 1991; Mathios A., et al., 1998; Caffin N., 1998; McMahon K., 1998);

- The outcome of the NCEFF consultation meeting on potential pre-approved claims found that for dietary guideline claims, those with the following characteristics should be preferred:
    1. Consistently agreed quality of evidence for the claim
    2. Consistency with dietary guidelines (and other public health nutrition guidance policies such as Australian Guide to Healthy Eating and Eat Well Australia)

3. Potential population health impact in Australia and New Zealand (including the likelihood of potential dietary change)
4. Claims likely to be used by food marketers or health promotion organisations.
5. Existing consumer understanding, confusion or knowledge about the claim
6. Those that encourage new product development or reformulation

- It is likely that claims relating to new or unfamiliar nutritional information will have more influence on consumers than those about food/health relationships that are well understood and therefore may be the most beneficial. Finnish research reports that function claims were rated more highly by consumers than content claims for unfamiliar ingredients (Urala N., et al., 2003). Evaluations of the health claims about fibre and cancer in the USA in the mid 1980s and about folate and neural tube defects in Australia in the 1990s support this potential role of claims to assist in consumer education about new nutrition information (Ippolito P., et al., 1990; Watson M., et al., 2001); and

- They were uncertain about which type of claims Australian consumers would prefer. Research from other countries often has contradictory findings. Household interviews with main grocery buyers in Denmark, Finland and the USA found that health claims had a positive influence on consumers' perception of the healthfulness of foods, with prevention claims having more influence than physiological function claims (Bech-Larsen T., et al., 2003). The same preference was found in Scotland. Shoppers were more interested in information about nutrients that may contribute to chronic disease than to health maintenance (Tessier S., et al., 2000), contrary to a focus group study in Sweden that found consumers prefer claims that emphasise promotion of health rather than prevention of illness (Svederberg E., 2002).

Other comments provided but not in direct response to the question:

Campbell Arnott's Asia Pacific considered that substantiated health claims will help to improve consumer health by raising awareness and increasing nutrition knowledge, which will enable better informed healthy food choices to be made. They believed that balanced nutrition is an essential component for reducing risk of diet-related chronic diseases such as obesity, heart disease, stroke, high blood pressure, cancer, diabetes and osteoporosis. This belief is based on biomedical and nutritional science, in which scientific advances confirm that nutrition/food/lifestyle factors positively influence disease risk. In addition, a balanced diet assists in maintaining good health and overall wellbeing.

Kellogg's Aust. believed that scientifically substantiated information that is not misleading should be allowed in the labelling and advertising of food products promoted to the general public. They added that the use of claims on food labels is an important tool so that consumers may have ready access to responsible nutrition and health information, especially about the link between diet/role of foods and health/reducing risk of disease, so they can make informed choices about the foods included in their diet (Kellogg's Aust.). They support nutrition, health and related claims to allow effective consumer education.

Kellogg's aim to build awareness of the role of the diet in contributing to a healthy lifestyle and help to motivate and educate consumers to select a healthy diet to complement strategies to maintain and improve their health, and hopes these efforts will complement those of the Departments of Health in Australia and MOH in NZ in achieving public health objectives.

Consumer's Institute of NZ expressed concern that new permissions for health claims may not produce public health benefits unless tightly managed and regulated. If health claims mislead consumers towards unbalanced eating patterns, they consider this will have the potential to increase the incidence of health problems. They consider consumers need clear, accurate and useful information. This will allow them to choose foods that contribute to a balanced and nutritious diet. They do not believe health claims on food labels will provide unambiguous and useful information.

NZ King Salmon stated that if it is possible to make a HC for the heart with regards to Omega-3 DHA and EPA the consumer could be educated to a far greater extent and NZ health would therefore benefit. Few consumers are aware of the distinction between the different types of omega-3s. As CVD affects many people in NZ and Aus, this is an excellent opportunity to educate the public and help decrease the risk of obtaining the disease and also to hep reduce severity. They noted that CVD is the leading cause of death (40%) in NZ (reference provided). Sixteen New Zealanders die every day, or 1 in every 90 minutes as a result of CVD, with highest rates for Maori, followed by Pacific Island people so it is important that Omega-3 claims are able to be made in NZ.

They added that NZ King Salmon is the most easily accessible (year round) food product in the domestic market with a high natural source of Omega-3 EPA and DHA so it is important to the public that they are able to assert and publicise the claim. One 100g portion of NZ King Salmon contains approx 7.4g EPA and DHA (14) which would be more than sufficient to satisfy daily nutritional requirements for EPA and DHA (ISSFAL recommend 0.65g/day (11)). NZ King Salmon quoted that for cardiovascular health, a minimum intake of EPA and DHA combined of 500mg/day is recommend (13). 1 - 2 serves of NZ King Salmon per week would be adequate to satisfy Omega-3 requirements.

Question 4

What opportunities could industry take up in terms of product development and placement? Provide examples or data to show how significant the opportunities are to industry at present.

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	29	14	4	3	50
Government	3	1	-	-	4
Public health	6	2	-	-	8
Consumers	-	-	-	-	0
Other	2	-	-	-	2
Total	**40**	**17**	**4**	**3**	**64**

Overview

The opportunities that industry could take up in terms of product development and placement were identified as an increase in the range of functional foods, investment in research and development and innovation, reformulation, research and targeting specific segments of the population, and developing claims and products to support dietary guidelines. Some submitters noted that other standards, proposals and applications should be considered to answer this question. Current opportunities that were identified included enrichment of foods with sterols, increased sales of 'low fat' foods, and the impact on the food supply of the National Heart Foundation 'Tick' programme.

Opportunities – functional foods

The following opportunities relating to the development of functional foods were noted.

- Opportunity in the increase in the range and number of health and functional foods being developed by industry. Special health & functional food sections are already being created within supermarkets (CML);

- Industry would develop more functional and nutraceutical foods with a broader range of claims. They would be able to promote the benefits of whole foods e.g. those in dietary guidelines (Sanitarium Health Food Comp.); and

- Food will act as a delivery vehicle to the bioactive component, which is conveyed to the consumer through a claim. Industry can develop products that incorporate biologically active components in an easy to consume, pleasant tasting form. Will be able to open and expand market segments based on particular health claims for functional foods, as new scientific evidence becomes available (Nutra NZ).

It was predicted that the potential commercial benefits from marketing 'functional foods' would be significant. A 1998 survey, commissioned by the International Food Information Council (IFIC), of 1000 randomly selected U.S. consumers found: 95% believed that certain foods provide health-promoting or disease-fighting benefits beyond nutrition; and 91% were interesting in learning more about functional foods. It was added that 60% of U.S. adults are believed to select foods for health purposes (Milner, 2002 Br J Nutr 88(S2): 151-158). The consumer level of acceptance for functional foods may be similarly high in Australia and New Zealand. The opportunities for local industry to export to neighbouring Asian countries, where consumers are already familiarised with the concept of functional foods, are tremendous (DSM Nut. Prod.).

Nutrition Aust. noted that the prohibition on health claims has not prevented companies from developing products that could be classified as functional foods on a global market. Innovation in nutrition functionality has still occurred in Australia despite the regulations e.g. include the addition of phytosterols to margarines, use of resistant starch in a range of products. They added that Australian Food Statistics (2002,2003) (DAFF, 2004) support an increase in food product innovation and a greater commitment by Australian food companies to research and development including in the area of health and nutrition. The increased number of products promoting health on the Australian market and the fact that health products are no longer sold just in health food stores show that this is a growing and innovative market.

Research and development and innovation

Other opportunities were noted relating to research and development (R & D) and innovation (Unilever Australasia and submitters who commented below).

- More likely to make the R & D and other investments in developing relevant products, providing better choices for consumers (Aussie Bodies);

- Setting of nutrient criteria provides industry with a benchmark for new product development (Diabetes Aust., GI Ltd);

- Increased opportunities for many creative product developments and placements (CHC);

- Products may be able to carry health messages, which are currently not permitted, e.g., for sugar free products US FDA permits statements such as “Does not promote tooth decay”. New opportunities for industry may be taken up with innovation that supports changing consumer demography and wellness (William Wrigley Junior);

- Being able to make nutrition and health claims will encourage manufacturers to review their resistance to developing products because they may gain a competitive edge in being able to make a claim (Cadbury Schweppes);

- Broadening the claims to include 'wholegrain' could encourage innovation and provide an incentive for manufacturers to develop more wholegrain products

or increase the content of wholegrain ingredients in existing products (Go Grains);

- There will be an enormous impact on the willingness of companies to invest in product innovation and research because they will be able to market their products according to the real benefits they contain (Goodman Fielder);

- The Framework, which will allow factual claims to be made, opens up a reason and incentive for new product development to take place. This issue is also addressed through other policy guidelines, e.g. fortification of foods with vitamins and minerals (DAFF);

- Health claims will enhance the trend of product development. The inability to make validated claims will limit investment in nutrition research and reduce the competitiveness and innovation of the Australian Food industry internationally. The inability to make validated claims will also constrain progress in applied nutrition research, which can potentially make a positive impact on the health of segments of the population (CSIRO HS&N);

- Industry would be able to target products for specific health problems and identify new markets. There would be an opportunity to specialise and produce companion ranges for specific demographics (ASA, NZ Magazines, Cadbury Confectionery, Naturo Pharm, NZTBC, NPANZ, Assoc. of NZ Advertisers);

- Industry would be able to develop new products and brands to make health claims as well as reformulate or add claims to existing products. If claims could be made, NZ Dairy Foods believe sales would increase further (NZ Dairy Foods);

- Changing demographics and lifestyles, the increasing scientific knowledge being acquired in respect of the link between food and nutrition and the information being obtained from genomics opens up great opportunities to food processors. This provides food manufacturers with the opportunity to produce foods for specific sectors of society. It was anticipated that in the future an increasing number of foods would be produced to meet specific needs; the ability to make claims about such products will significantly advance their development (NZFGC);

- Industry could prepare foods specifically for special health issues (e.g. diabetes, allergy, heart) but these would be 'special medical purpose' foods. Several 'special food' standards already exist but these could be expanded (Nutra Life H&F); and

- Countless opportunities in terms of product development and placement. Products may be reformulated and with the proposed expansion of vitamin and mineral fortification, other opportunities will arise (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 noted potential claims for the confectionery industry: tooth friendly, calcium with reference to bones, GI/GL, antioxidants, carbohydrate and fibre. They recommended confectionery should be permitted to be a part of the food supply permitted to carry health claims. They stated that confectionery is already acknowledged for its benefits in the Australian Dietary Guidelines as a valuable supplementary food (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).

Product development to meet nutritional criteria

The following comments were made regarding the potential for claims to support national nutrition policies or dietary guidelines.

- Health claims will enable industry to support non-governmental organisations and government public health nutrition campaign (AFGC, MasterFoods Aust. NZ);

- Opportunities will be driven by public health objectives and consumer needs. Changing such food regulations paves the way for partnerships between industry and government and non-government organisations to maximise benefits to consumers (Dairy Aust.);

- One of the biggest identified opportunities for the horticulture industry is a co-ordinated approach to communicating the health benefits of eating the recommended number of fruits and vegetables and driving an appropriate change in consumer behaviour. This issue has been identified as a cross industry priority and HAL is working through the Australian Fruit and Vegetable Coalition to implement a national campaign (Horticulture Aust.);

- There are considerable opportunities to address Australia's most serious nutritional issues. Two thirds of teenage girls fail to meet their RDI for calcium. Prevalence of osteoporosis is predicted to reach 2.2 million by 2006 and 3 million by 2021, with 2000/01 health costs $1.9 billion rising accordingly. Industry development of segment-relevant products could be used to promote greater calcium intake directly to target groups via a health claim mechanism (National Starch, Solae Comp.);

- Opportunities include the clear marketing of products to the target group (see example below of dairy dessert for diabetics) (PB Foods);

- There are significant opportunities for industry product innovation outside of health claims, which will support national nutrition policy to reduce risk of diet-related disease and promote the community's health and wellbeing. Examples include making vegetables more convenient and appealing via pre-preparation for snacks and home-based meal preparation (SA DoH, WA DoH);

- Industry is more likely to develop healthier options including those targeting specific health issues. Health claims would allow industry to differentiate healthier products from standard ones (Griffins Foods);

- There would be opportunity for industry to label foods with health claims consistent with national food and nutrition guidelines, which could be desirable from a health point of view. This would mean various food categories would have to be defined by FSANZ and nutritional criteria developed to allow for making claims regarding particular food categories. These nutritional criteria would require regular review (NZ MoH); and

- Industry could support public health strategies by formulating products to meet criteria for carrying public health messages and assist public health agencies in communication the benefits of healthier dietary patterns for improved nutrition/public health (NHF Aust., NHF NZ).

Health claims regarding dairy foods

Research is currently being performed on the impact of food on bone, brain and heart health. Dairy foods have been associated with positive health benefits for osteoporosis, obesity, cancer, immunity and blood pressure. Future research will be determined by public health concerns. Allowing health claims provides an opportunity for government, health professionals and industry to collaborate to provide science based information in areas of increasing health concern, e.g. in the US the government has commissioned research into the nutritional deficiency and obesity epidemic in the US and is working with industry to improve the quality of food product in this respect (Fonterra).

Health claims regarding nuts and heart disease

Allowing a health claim for nuts and heart disease risk reduction will assist the nut industry to re-position nuts as a healthy snack, in line with NHF recommendation to snack on unsalted nuts as strategy to manage blood cholesterol levels. It will assist to address consumer and health professional misconceptions about the role of nuts in health. Research (Insights, C., 2003) shows <15% of consumers appreciate the positive impact nuts have on cholesterol levels and <18% of consumers appreciate that most of the fats in nuts are unsaturated. The nut industry would take full advantage of the marketing opportunity presented by being able to promote the heart and other health benefits of regular nut consumption (ANIC).

Consumer wants

Submitters identified that consumers rather than regulation, as outlined in the comments below, drive product development.

- Industry will respond to what are seen to be consumer needs and wishes (F&B Importers Assoc.);

- Product development, improvement and innovation are driven by consumer wants not regulations but the inability to communicate nutrition benefits can limit innovation (National Foods);

- Product development and innovation not driven by regulation but by understanding consumer needs, insights and issues (GW Foods); and

- Industry is driven by consumer demand and consumers are demanding healthier products, which have meant that industry's research and development platforms include platforms of health and wellbeing (Wyeth Aust.).

Wyeth Aust. added the concern that if the positive health outcomes of these products or nutrients cannot be communicated to consumers then this discourages industry from meeting this demand and putting resources into research and development. they noted that if a system of health claims is not developed, there is the potential for some food companies to make claims regardless. These claims may be unsubstantiated and result in benefits to the companies that make these illegal claims. In effect, companies would be rewarded for their non-compliance (Wyeth Aust.).

Opportunities at the expense of the consumer

- Industry would develop products to exploit the market opportunities created by allowable claims. These may not be of benefit and may lead to imbalanced diets in vulnerable groups, e.g. calcium added to foods may lead to magnesium deficiencies particularly in lactating women and breast-fed babies (Dr C Halais);

- Such industry opportunities could easily be at the expense of the consumer. Increased product development has the potential to create further confusion over food choices and redirect focus away from dietary patterns to individual products. Over the last few decades there has been a dramatic increase in the range of food products on the market. However, there is no evidence that this has led to improved food choices or better health (Auckland Reg. PHS).

Product innovation and link with medicines interface and other standards

A number of submitters commented that this question can only really be answered by taking into consideration the product breadth also captured in the consultations on at least one of the following: Food Type Dietary Supplements (P235), Formulated Beverages (A470), Non-culinary Herbs in Food (P260), permission to fortify with vitamins, minerals and bioactives in general (ASMI, Parmalat Aust., Fonterra, CHC).

ASMI added that the implementation of a health claims regime gives new and existing products on the interface with medicines a "home" and system of accountability, paving the way for new production innovation (ASMI).

CHC noted the relationship between P293 and P260 is extremely important. The inclusion of non-culinary herbs in foods allows for the opportunity for food marketers to tailor-make food for sale rather than for community health benefits (e.g. Echinacea

in a chocolate biscuit). CHC expressed concern that the P293 enforcement provisions may not be robust enough to handle the inevitable fact that food marketers will start inventing foods specifically to maximise claims under the new standard.

NZ Dairy Foods noted the scale of opportunities will rely on changes to other parts of the FSC such as Std 1.3.2 to allow for wider used of vitamins and minerals that are approved for health claims. Dairy Aust. agreed with this and added that this is an important consideration for FSANZ and one supported by industry.

More information needed to be able to answer the question

- Industry would like the opportunity to develop new products but initially requires knowing which claims will be permitted (Food Tech. Assoc. of Vic.);

- The answer to this question is dependent on the system that is eventually adopted. The more difficult it is for industry to make health claims because of regulatory burden, the less uptake there will be, e.g. the pre-approved high level claims are not 'marketable' and relevant to consumers. Changes to criteria for making nutrient content claims may inhibit opportunities to manufacture certain products (Nestle); and

- AFGC did not understand the use of the term ‘placement’ in this question. National Foods attributed the meaning 'category segmentation or positioning' to the FSANZ use of "placement" in the question.

Current situation – losses for industry

- ABC suggested FSANZ refer to the Allen Consulting Report (attachment has been provided). This report assesses the economic impact and loss to Australian beverage manufacturers due to the loss of market for fortified beverages for which nutrition claims may be appropriate;

- The current regulatory environment hampers innovation and limits what manufacturers can communicate about products (GW Foods).

Current opportunities - examples

- The ability to market foods according to their nutritional properties is obviously of benefit to food industry as evidenced by the large range of low fat/reduced fat foods on the market at present (Diabetes Aust., GI Ltd);

- The food industry has shown itself capable of being innovative with the introduction of thousands of new foods even without the impetus of health claims. Since the 1960's the food supply has increased markedly - estimates at 30 000 food items now (TCCA);

- Industry is already keen to enrich foods with resistant starch, plant sterols and omega 3 fats and develop foods that will assist weight control (CSIRO HS&N);

- Increase in consumption of calcium enriched milks such as Xtra and Mega Milk - this segment has grown at 18% from last year (NZ Dairy Foods);

- Inclusion of 'light', lite' and 'diet' have moved consumers towards lower fat dairy pressed, milk, yoghurt and cheese, e.g. supermarket sales of 'light' and 'lite' milk and cheese increased by 32% and 17% respectively, between 1999/2000 and 2003/2004. 'Light' and 'lite' dairy spreads also increased by over five fold (542%) for the same time period, and sales of yogurts with the term 'diet' on the label increased by 55%, (AC Nielson 2004) (Dairy Aust.); and

- The opportunity likely to be taken up by industry will be led by competitive innovation and driven by consumer insights and needs, so it is not possible to identify specific examples (AFGC, MasterFoods Aust. NZ).

PB Foods gave an example of their dairy dessert suitable for diabetics, produced several years ago, with the statement "Suitable for diabetics". They then developed a much better tasting product with inulin that was low in fat and sugar free, but could not state anymore that it is for diabetics and hence had to delete the product as people did not know the real purpose of it. Also truthful information on the caloric content was not in line with the FSC, as the code was outdated by not reflecting the caloric content of inulin and other soluble fibres. It took several years to amend the code with the appropriate data and testing method. This example shows that the standards must be very flexible to accommodate the rapid changes in the food industry and allow truthful information to consumers (PB Foods).

National heart Foundation 'Tick' Program

- A positive example is the NHF tick criteria for products used as a benchmark for developing products with a healthier profile. Although manufacturers pay to use the 'tick' licensing agreement on products, because this has product criteria that are specific to a category and quite stretching, they challenge food companies to meet these targets, and once met by one product, others tend to follow. The criteria are also regularly revised by comparing across the category, to ensure they remain relevant. Products and associated claims will only be developed where they meet consumer needs. The consumer must see a benefit for the claim on a particular product otherwise the product will not sell (Unilever Australasia);

- Providing benchmarks for food manufacturers has been demonstrated to provide an incentive for industry to improve formulation of its products. Over half of product in the NHF Tick program have been formulated or reformulated to meet guidelines for tick approval. Some manufacturers also use the guidelines to improve the nutritional profile of non-tick products (Williams et al, 2003). Tick program in New Zealand worked with food companies to exclude 33 tonnes of salt from the food supply achieved though reformulation of 23 products in three categories (Young L et al., 2002) (NHF Aust., NHF NZ); and

- Product development/improvement from the NHF's Tick Programme has caused significant changes in composition of food in certain categories, e.g. 19% of yoghurts, 27% of edible oils & spreads, 18% of b/f cereals, 14% of milk and milk substitutes, and 13% of breads have been modified (Williams et al 2003) (Dairy Aust., AFGC, MasterFoods Aust. NZ).

Comments from NCEFF:

- Providing information on nutrition is one way in which industry can differentiate their product from others to gain a competitive edge. Market research, based on sales trends and focus groups in which consumers indicate preferences, indicates that consumers are demanding food that is 'better for you' (Sloan, A., 2004);

- Functional foods is a terms that helps to identify foods in the 'better for you' category. The global market value is estimated at $US47.6b, with $US18.25b in the US, $15.4b in Europe and $US11.86b in Japan (Sloan, A., 2002). Opportunities lie in foods that target the extent of the lifespan (maternal health/infancy through to the elderly), and therefore follow topics found in textbooks on nutrition throughout the lifecycle;

- PASSCLAIM work in Europe (Asp, N., et al., 2003; Richardson, D., et al., 2003) identifies target conditions in which there is scientific evidence that supports the application of a claim. These are: diet related cardiovascular disease; bone health and osteoporosis; physical performance and fitness; body weight regulation, insulin sensitivity and diabetes risk; diet-related cancer; mental state and performance; and gut health and immunity;

- NCEFF identifies these areas, in market terms, as: foods supporting growth and development; foods with a role in the prevention and management of disease; foods that support mental health and wellbeing;

- There are fast evolving opportunities for industry to take up and the extent of development at the global level suggests the Australian food industry needs to keep up to remain competitive; and

- Case studies of successful functional foods indicate that the innovation usually occurs in smaller enterprises in the local context, for example, Yakkult in Japan, ProViva in Sweden, with international success resulting from a long term strategic commitment (Heasman, M., 2001). The regulatory framework may or may not inhibit the success of products depending on the claims made and approach to marketing. Translating this to the Australian context, a regulatory framework that enables innovation to gain a local foothold is likely to help companies succeed and take their products overseas.

Other comments provided but not in direct response to the question:

An increase in innovative products that compete on the basis of nutritional health benefit, in addition to packaging/promotions/price, would be a positive outcome (Campbell Arnott's Asia Pacific).

William Wrigley Junior stated that they have successfully developed and marketed chewing gum with a sugar free claim within the last 12 years, and more recently non-chewing gum sugar free confectionery. These products now comprise over 70% of their business within the pacific region sales and they have invested in excess of $125million in developing, promoting and growing this category. Sugar free confectionery business currently attracts $220 million in sales per annum, of which Wrigley sales account for approximately $150 million. The Wrigley Company markets sugar free products in over 150 countries worldwide, with sugar free chewing gum being the fastest growing confectionery item globally in 2001.

CHAPTER 2: FZANZ CLAIM DESCRIPTORS

2.1 GENERAL LEVEL CLAIM

Question 5

Do you think the working definition of a 'general level claim' captures all the possible types of claims, which would not reference a biomarker or serious disease or condition?

Out of 147 submitters, 63.9% (94 in total) directly responded to this question. The distribution of these responses was as follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	30	23	5	2	60
Government	7	2	-	-	9
Public health	12	4	-	-	16
Consumers	2	-	-	-	2
Other	5	2	-	-	7
Total	**56**	**31**	**5**	**2**	**94**

Overview

Almost 40% of submitters (36) believed that the working definition captured all possible types of claims, which would not reference a biomarker or serious disease or condition. However, more than half (51) stated that the definition would not capture all types of claims, or disagreed with the wording. Various comments and recommendations were made regarding the following terms: content claims, biomarker, non-serious disease or condition, serious disease or condition, function claims, enhanced function claims, risk reduction claims, and claims.

Submitter responses to whether the general level claim working definition captures all possible types of claims

Thirty-six submitters had agreed that the working definition of a general level claim captured all possible types of claims, which would not reference a biomarker or serious disease condition (NCWA, TCCA, DAA, NHF Aust, Nutrition Aust, PHAA (supported by ACA), DSM Nut. Prod, Food Tech. Assoc. of Vic, MLA, Wyeth Aust,

Tas DoH&HS, NSW DoH – N&PA Branch, NSW Food Authority, SA DoH, DAFF, WA DoH, Queensland Health – PHS, Monash Uni – N&D Unit, Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp, Auckland Reg. PHS, NHF NZ, ASA, Cadbury Confectionery, Functional Whole Foods NZ, Griffins Foods, NZ Dairy Foods, NZ Magazines, Nutra NZ, NZ King Salmon, NZTBC, Tegel Foods, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm Ltd, Heinz Aust./Heinz Watties NZ).

Fifty-one submitters either disagreed with the specific wording or believed that some claims would not be captured by the definition (Diabetes Aust, Dr R. Stanton, GI Ltd, NCEFF, Tomox, Aussie Bodies, ABC, AFGC, Bakewell Foods, Cadbury Schweppes, CML, CHC, Dairy Aust., GW Foods, Goodman Fielder, Horticulture Aust., National Foods, National Starch, Parmalat Aust, PB Foods, Sanitarium Health Food Comp, Solae Comp, Mandurah Aust, Kingfood Aust., CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, CM of SA, ASMI, CSIRO - HS &N, TGACC, NZDA, Fonterra, Hansells NZ, Mainland Products, Naturalac Nutrition, NZFGC, NZJBA, Frucor, Nutra-Life Health & Fitness NZ, CMA – NZ Branch, Beef & Lamb Marketing Bureau, MoH, NZFSA, Hort & Food Research Instit. of NZ, CMA, Masterfoods Aust. NZ., Nestle, Unilever Australasia, Palatinit GmbH, ICA). Many of these submitters had suggested modifications to the working definition.

Seven submitters did not clearly express whether or not they thought that the working definition captured all possible types of claims (Northland Health Dietitians, Crop & Food Research, ACDPA, Kidney Health Aust, NSF, Campbell Arnott's Asia Pacific, Kellogg's Aust.).

Fonterra considered the definition of general level claims to be far too wide. They stated that claims not specifically mentioned in the definition and which presumably fall under general level claims are those made in the context of the total diet to treat, alleviate or cure a disease or condition or the symptoms of these. They believed that there is little merit in attempting to exhaustively define or list all sub categories within the definition.

Comments regarding the term 'content' claims

One submitter believed that inclusion of the term *'content claims'* is acceptable (Nutra-Life Health & Fitness NZ) while 11 submitters believed that inclusion of the term *'content'* in the definition is important (CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, ICA, CM of SA, NZFSA). The majority of them considered that omission of the word *'content'* would leave unqualified inclusions of claims, which in turn would be likely to lead to confusion.

Six submitters recommended the removal of brackets (NHF Aust, NHF NZ, CHC, ASMI, TGACC, Griffins Foods), therefore implying that they support the inclusion of *'content'*.

However, Naturalac Nutrition expressed concern that the term '*content*' might be too all encompassing.

Twenty-seven submitters noted that the definition of a general level claim (section 5.4.2 of the IAR) was not consistent with the glossary definition of a general level claim (page 8 of the IAR), which clearly identifies a general claim as being related to 'nutrition' (ASMI, TGACC, Unilever Australasia, Nestle, CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, ICA, CM of SA, NHF Aust, NHF NZ, ABC, AFGC, Masterfoods Aust. NZ, Dairy Aust, Goodman Fielder, GW Foods, NZFGC, NZJBA, Frucor, Fonterra). They pointed out that this relationship underpins the requirement that any general level claim must have a context to nutrition in humans. Thus, they believed that the definition should be aligned with the definition of a general level claim in the glossary of the IAR:

> "…is a *type of nutrition, health and related* claim which does not reference a biomarker or serious disease or condition, and includes *nutrition (or nutrient)* content claims, function claims, and enhanced function claims and risk reduction claims that reference a non-serious disease or non-serious condition."

NZFGC believed, however, that the inclusion of references to *'content', 'function', 'enhanced function'* and '*risk reduction'* would create uncertainty.

Many of those submitters that recommended the use of the term *'nutrition* content claim' noted that these claims would be inclusive of biologically active substances, as defined in Standard 1.2.8 for 'nutrition claim' (Fonterra, PB Foods, NZJBA, Frucor, AFGC, Masterfoods Aust. NZ, GW Foods, Nestle, CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, ICA, CM of SA, Griffins Foods). Other submitters remarked that the term would permit biologically active substances to be included in general level claims (NZFGC), and in the guideline (Dairy Aust). Campbell Arnott's Asia Pacific agreed that health claims other than *'content claims'* could be made in relation to biologically active substances.

Nestle noted that the definition would include a reference to the characterising ingredient within a food, as this is essentially a 'content' claim relating to ingredient content rather than nutrient content.

Comments regarding the term 'biomarker'

Eight submitters believed that while the working definition appears to capture all the possible types of claims that would not reference a biomarker or serious disease or constitution, it is partly contingent upon having a precise definition for the term '*biomarker*' (PHAA (supported by ACA), SA DoH, WA DoH, Queensland Health – PHS, Monash Uni- N&D Unit, Tas DoH&HS, Horticulture Aust).

Several submitters had supported the inclusion of the following biomarkers in the definition of general level claims:

- Blood cholesterol (Fonterra, Diabetes Aust, GI Ltd);
- Blood glucose levels (Diabetes Aust, GI Ltd);
- Bone health indicators (Fonterra, NCEFF); and

- Hormones of satiety and mood (NCEFF).

Bakewell Foods suggested that the biomarker references Glycaemic Index 'GI' and National Heart Foundation 'Tick' symbols should not be classed as high level claims as they are well known and frequently used in industry already, and they are promoted as a healthier option as opposed to being a direct health claim

Diabetes Aust and GI Ltd. considered that the rationale for the utility of many content claims is due to their perceived effect on biomarkers, and that evidence linking certain key nutrients to the maintenance of many important biomarkers is very strong, for example:

- 'low cholesterol' or 'low saturated fat'...blood cholesterol and triglycerides;
- 'low sugar'...glucose levels.

They believed that reliance on surrogate claims like 'low fat' when consumers are most likely concerned with weight or cardiovascular health has caused unnecessary confusion and has failed to impact health outcomes. Thus, they questioned the need for biomarker associated claims to be classified as high level claims.

NCEFF noted that the approach to 'capturing all types of claims' that do not reference biomarkers, diseases and/or conditions is itself problematic, and probably not feasible. They suggested the working definition of general level claims might be better placed to address the support of growth, development and wellbeing, and biomarkers would be required to demonstrate the evidence of this support. They felt that this category of claims would logically reflect those used in community nutrition education programs, nutrition curriculum materials and food guidance systems.

Fonterra believed that reference to some biomarkers would not be confusing to consumers and should be permitted in general level claims (e.g. 'cholesterol' and 'bone density' are likely to be well understood by consumers). Fonterra considered that public health could benefit from consumer awareness of the impacts of foods on biomarkers and recommended a list of acceptable biomarkers be developed by FSANZ.

CSIRO – HS&N considered that the use of a biomarker does not necessarily imply serious disease and suggested rewording the definition to:

> '…a claim which does not reference a serious disease or *biomarker of a serious disease or condition*…'

They believed that the latter part of the proposed general level claim definition in the IAR is confusing and ambiguous.

Dairy Aust noted that if Policy for categorising biomarker claims were to change, appropriate amendments would need to be reflected in the definition of general level claims.

TCCA agreed that biomarker claims (e.g. 'calcium increases bone strength,' as bone density is measurable and therefore a biomarker) should be classed as high level

claims, as they believed consumers would interpret such claims as being at a high level of reliability and influential on health status. In addition, they recommended a list of acceptable biomarkers be developed by FSANZ in consultation with health agencies.

Comments regarding the terms 'non-serious disease or condition' and 'serious disease or condition'

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) recommended clarification of the overall definition to confirm whether or not general level claims must reference a '*non-serious disease'* or '*non-serious condition'*.

Eleven submitters considered that while the working definition appears to capture all the possible types of claims that would not reference a biomarker or serious disease or constitution, but it is partly contingent upon having a precise definitions for the terms '*non-serious disease or condition'* and *'serious disease or condition'* (PHAA (supported by ACA), SA DoH, WA DoH, Queensland Health – PHS, Monash Uni-N&D Unit, Tas DoH&HS, Horticulture Aust, CHC, ASMI, TGACC). In addition, the TGACC believed that these definitions should remain consistent with those definitions found in therapeutic goods legislation.

NZFSA recommended that the words *'or condition'* be removed from the definition, as this should be included in the discussion regarding the definition of *'serious disease'*. They noted that the term *'non-serious disease'* should also be defined.

The Solae Comp. and National Starch recommended that some changes might be required to what is defined as a *'serious disease'*. They suggested that *'disorders, defects or conditions'* should not be included in the definition of *'serious disease'*, which would mean by default that they would be included as general level claims (e.g. constipation is a disorder or condition in which the assistance of an 'enhanced function' from a high fibre food could be categorised as a general level claim). MoH agreed that a non-serious disease such as constipation could be a symptom of a more serious condition (e.g. an obstruction), and that many diseases could usually be considered on a continuum. They believed that careful consideration should be given to the definitions of '*serious disease'* as opposed to *'non-serious disease'* and should be clearly defined by a schedule included as part of the FSC.

Although Aussie Bodies believed that the working definition was a good descriptor, they questioned whether *'non-serious condition'* captures various states of health that are generally not regarded as a *'condition'* (e.g. tiredness, poor concentration, excessive hunger). Furthermore, they were concerned about 'grey area' conditions that might be interpreted differently by health authorities in different jurisdictions as to whether or not they are serious conditions.

Naturo Pharm Ltd noted that TAPS views references to a 'condition' as a therapeutic or implied therapeutic claim (e.g. words such as 'pain', 'fever', 'chilblain', 'cold sore', 'influenza ('flu)' cannot be used in relation to a specific product). Naturo

Pharm Ltd strongly recommended that the interface between TGA and FSANZ jurisdiction be clearly defined.

Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp agreed to the working definition provided the proposed definition of *'serious disease or condition'* is adopted.

Mainland Products considered the word *'condition'* to be superfluous and too open to interpretation.

Dr R. Stanton believed that the definition of *'serious disease'* would always be open to question and dispute.

Cadbury Schweppes queried whether the descriptor indicates that general level claims must reference a *'non-serious disease or condition'*, and suggested that clarification is required as to whether this is mandatory. They noted that the definition of a *'serious disease or condition'* assists in the descriptor but queried whether the list is definitive.

NSW DoH – N&PA Branch supported the development by FSANZ of a list of non-serious disease or conditions to ensure that this is applied consistently.

Comments regarding the terms 'function claims', 'enhanced function claims' and 'risk reduction claims'

Horticulture Aust. considered that the terms *'function claims', 'enhanced function claims'* and *'risk reduction claims'* required further clarification.

MoH agreed with the working definition, although they stated that it could be argued that an *'enhanced function claim'* is ultimately a high level claim since it may involve 'risk reduction' and if included in this category, should require rigorous substantiation.
They considered that enhanced function claims could imply reduction of risk factor exposure and hence could be considered similar to high level claims since they are implicitly promoting the idea of disease prevention.

TCCA suggested that FSANZ develop a list of appropriate and permissible function claims and enhanced function claims to accompany this definition (e.g. the Canadian example shown in Attachment 5 'International Regulations', where a list of approximately 25 pre-approved function claims and the associated qualifying criteria are specified, should be given consideration).

NZDA reiterated DAA concerns with regard to the interpretation of '*prevention*' and '*risk reduction'*. They argued that the concepts of relative and total risk reduction are not familiar to consumers. Consumers might believe that by consuming a food with a risk reduction claim they are now protected from developing that particular condition or disease. Additionally, the efficacy of risk reduction would be relative to the quantity and frequency of consumption of the protective nutritional component. NZDA considered that these concepts might not be able to be clearly communicated to the consumer and therefore their inclusion in general level claims is questionable.

DAFF considered these claims to be redundant, even in FSANZ's own proposed substantiation process, and believed that they would only serve to further confuse industry and potentially consumers (with the possible exception of content claims, should the FSANZ process for substantiation go ahead).

Nutra-Life Health & Fitness considered function claims to be acceptable, however they believed that risk reduction claims for *'non-serious disease or condition'* go beyond a general level claim.
ASMI questioned whether there is a potential for risk reduction claims to be made as general level claims where the condition is considered 'non-serious', and whether this is appropriate.

Comments regarding classification of specific claims

Eight submitters considered that the working definition appears to capture all the possible types of claims that would not reference a biomarker or serious disease or condition, but it is partly contingent upon having a precise definition for the term '*claim*' (PHAA (supported by ACA), SA DoH, WA DoH, Queensland Health – PHS, Monash Uni- N&D Unit, Tas DoH&HS, Horticulture Aust.).

Of these, six submitters noted that the definition does not reference claims such as 'detox', 'healthy eating', 'super food' or 'eat smart', and believed that consideration should be given to the classification of these types of claims (PHAA (supported by ACA), SA DoH, WA DoH, Queensland Health – PHS, Monash Uni- N&D Unit).

Fonterra noted that statements such as 'tasty', 'fresh' or other descriptors and marketing terms might be viewed as claims, suggesting that the definition of '*claim*' should be clarified.

Dr R. Stanton stated that the definition seems good but may not cope with claims that are trite or vague, or those unable to be documented, such as 'detoxification', 'boosting the immune system', 'energy boosters', 'stress relief', 'vita boost', 'recovery food' and more - all of which the submitter noted are present in the marketplace and are likely to increase.

National Foods submitted that a general level claim is not a food quality claim and should not include the use of the terms 'organic', 'natural', 'Halal', 'Kosher' and other related terms.

Sanitarium Health Food Comp believed that coeliac disease and lactose intolerance should be covered as general level claims. They noted that if products claim 'gluten free' for example, manufacturers should state on the packaging the product is suitable for people with coeliac disease, so that people without coeliac disease can understand that the claim refers to a benefit for a specific group of consumers and not the whole population.

Hansells NZ considered that the definition should be extended to allow foods that claim suitability for inclusion in a diet restricted by certain diseases, for example:

- Low sugar/sugar free foods as 'suitable for diabetics';
- Gluten free foods as 'suitable for coeliacs'.

They noted that while these claims name a serious disease (as defined by Section 5.4.5 of the IAR), they do not make an enhancement or risk reduction claim. Therefore, they considered that substantiation for this type of claim should be made within the scope of a general level claim. They noted that there is currently no provision in the Code for this type of claim, as Standard 1.1A.2 prohibits any reference to a disease or physiological condition.

With regard to the general level claim definition in the glossary of Attachment 4 of the IAR (The Substantiation Framework for Nutrition, Health and Related Claims), NZFSA believed that the definition would need to reference *'performance'* and *'wellbeing'* claims if these are going to be permitted as per the Policy Guidelines.

Hort & Food Research Instit. of NZ recommended that the word *'defect'* be included in the definition. In addition, they recommended that general level claims include explicit allowance for specific claims targeted at wellness, wellbeing, mood and performance, not just disease conditions (e.g. boost immunity, improve gut health).

In relation to antioxidants, Crop & Food Research questioned where activity claims would sit (e.g. antioxidant activity, where it relates to the food itself but is separate from a biomarker). They noted that it is to some degree a content claim but also more than that, and stated that although foods can contain antioxidants, research has demonstrated that they might not show good antioxidant activity. Crop & Food Research assumed that this would be a function claim, although in many respects is a higher level of content claim. They recommended clarity in this popular area given that 'claims' are being made.

Crop & Food Research noted the issue of bioavailability claims in addition to straight content claims and questioned where these would sit. They stated that this is an important issue, especially with regard to some biologically active substances (e.g. in the US, a 'fat free' soup was promoted for its carotene content. Crop & Food Research noted, however, that carotenoids are fat-soluble. Unless fat is consumed with the meal, little carotenoids would be absorbed). They queried whether or not there is an avenue for foods to promote particular components being more bioavailable because of the formulation or particular delivery.

Tomox questioned where overweight and obesity fit would in and noted that these are not mentioned in disease states and BMI is presumably not a biomarker under the definitions. They questioned whether helping to maintain a healthy body weight is a general level claim.

Other specific comments regarding the working definition

Although CML considered the overall wording to be satisfactory, they recommended some minor changes as follows:

> "…is a claim, which does not reference a biomarker or a serious disease or condition, *and/or* [content] claims, *and/or* function claims, enhanced function

claims and risk reduction claims that reference a non-serious disease or non-serious condition".

CML believed that if this is a complete list of claims, then the word [includes] is not needed

General comments and recommendations

Although NZ Dairy Foods agreed that the working definition captures all the possible types of claims, they also suggested that tightening up of the definition surrounding general level claims was warranted.

Three submitters believed that it was vital that the wording of all general level claims convey the correct meanings are not misleading to consumers (TCCA, ACDPA, Kidney Health Aust). TCCA suggested that FSANZ prescribe the exact wording of claims based on agreement amongst health professionals and the testing of claim interpretation with consumers.

Food Tech. Assoc. of Vic recommended a user guide, which would list the possible/specific claims, as the current definition is too broad and open to individual interpretation.

The ASA (supported by Cadbury Confectionery, NZ Magazines, Naturo Pharm Ltd, NPANZ, Assoc. of NZ Advertisers, NZTBC) noted that the definition should make it clear that a general level claim should include the ability to support normal function and good health.

ASMI and TGACC identified that it is not clear whether the context of general health claims is for assisting in 'nutritional deficiency' or a compromised health status of the individual, or whether the health claim is intended to convey a benefit to a consumer with no health problems.

Twelve submitters suggested that the requirement for general level claims other than content claims to be made in the context of the following, should be included in the working descriptor:

- The total diet (Cadbury Schweppes, Fonterra);
- The 'appropriate total diet' (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).

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) recommended that reference be made in the definition that it is a requirement of the Standard for general level claims (other than content claims) to be made in the context of the appropriate total diet, unless this is defined by way of conditions in the Standard. Moreover, they sought clarification with respect to such

claims being made in the 'context of the appropriate diet' versus the 'context of the total diet'. Processed foods, including bread and confectionery were thought to be appropriate foods.

NZ MoH noted that 'whole of diet' claims should be clearly defined in the claim descriptor category.

Fonterra recommended that FSANZ give consideration to possible exceptions to the claim regulation framework. This is consistent with the principle behind other legislation, such as the Securities Act, which reduces the information requirements for investors who are considered to have greater understanding of investment. Fonterra submitted that claims made in a non-retail context should be excluded from the framework. They noted that such claims might include those made to other companies, health professionals or in forums, which are unlikely to be targeted to the end consumer.

Hort & Food Research Instit. of NZ stated that it would be difficult to capture all possible types of claims, although the working definition would probably capture most. They recommended that it is important the current form allows realistic and worthwhile general level claims.

Tas DoH&HS noted that definitions should clarify implied claims and how they fit into general level claims and high level claims.

Dr R. Stanton believed that to prevent a plethora of indefinite, misleading claims, it might be preferable for some general level claims to be pre-approved.

NSW Food Authority believed the working definition probably captures all the types of claims, although they questioned the need for it to do so. They recommended a more simple, all encompassing definition that is based on the definition of the high level claims. general level claims would then be defined as those that are not high level claims.

Nestle noted an alternative to having a definition for general level claim is to sufficiently define therapeutic claim and high level claim. A general level claim is then a nutrition, health and related claim that is not a high level claim or a therapeutic claim.

DAFF noted that if the claim does not reference a serious disease or biomarker, then it is a general level claim. It is the definition of *'serious disease'* and *'biomarker'* that are important.
Moreover, they stated that it would not be the case of needing 'increasing degrees of regulation' as one moves along the spectrum. Instead, they felt that all claims should be substantiated, requiring more evidence as the complexity of claims increased. DAFF believed that this proposal did not represent increasing degrees of regulation, and would not need the sub-categories to be achieved.

Northland Health Dietitians questioned whether the public's response and understanding of general level claims would differ from high level claims. They believed that how the public differentiates between the two and interprets them is

more important than how claims are categorised. They also questioned whether the public would distinguish a difference between 'reduces blood cholesterol levels' and 'good for the heart'.

Other comments provided but not in direct response to the question

CHC strongly advised that consideration should be given to developing legally enforceable advertising principles along the lines of the Therapeutic Goods Advertising Code, so that food manufacturers and marketers have a clear guidance document of what is acceptable as a health or nutrition claim. It would give greater assurance regarding compliance requirements were met which in turn would reduce jurisdictional enforcement activities.

Diabetes Aust. stated that they did not see any difference between biomarker maintenance claims or biomarker enhancement claims.

The ACA stated that pictures and graphics must also be included in the definition of health claims as they can convey a health benefit as well as any written claim. They noted that this is consistent with other areas of the Food Standards Code that state that a label must not carry pictures or graphics that imply the presence of ingredients when that ingredient is not in the product.

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

Comments regarding the terms 'claim' and 'health claims'

Beef & Lamb Marketing Bureau stated that the definition of *'claim'* is too broad and threatens to stifle the distribution of highly valued nutrition resources used by a range of health and fitness professionals in the education of consumers in a whole diet context. Communication of substantiated information should not be restricted. Dairy Aust supported this view and commented that the current definition of *'claim'* in the IAR is substantially broader than the scope of regulation in Standard 1.1A.2 (which specifies advertising and labels for food), and it appears to include <u>all</u> communication in relation to food whether or not of a public nature, including:

- Advice from health professionals to patients;
- All communications from Dairy Australia to members of the public (including educational materials, websites and ph advice lines); and
- Communications from Dairy Australia to health professionals, including a science-based education newsletter.

Dairy Aust considered that this could prevent them communicating about nutrition science that mentions any serious disease or biomarkers other than those with approved dairy-related high level claims, even if substantiated. They stated that this accounts for approx 75% of their activities to health professionals and consumers, and considered that this restriction would not strike an appropriate balance between the provision of information and consumer protection, and would hinder the responsible use of scientifically valid nutrition, health and related claims. It also opposes a

number of Ministerial Policy Principles. Dairy Aust believed that the definition of *'claim'* would have significant implications for:

- Information/communication programmes by other similar organisations (e.g. Meat and Livestock Australia);
- Research and development corporations (e.g. Grains, Horticulture and Fisheries); and for
- Non-government organisations (e.g. National Heart Foundation).

They noted that many programs might require clearance in advance by FSANZ, which will impose a major bureaucratic burden and cause delays.

SA DoH pointed out that the definition of *'claim'* in the IAR is different to that in the Ministerial Council Policy Guideline, and that there is no explanation for this. They believed that the definition must be stated or implied as in the definition in the Policy Guidelines. Furthermore, SA DoH questioned whether the definition is consistent with that used by Fair Trading and/or the TGA. They believed that the definition should cover verbal, visual and audio marketing and advertising, food, food ingredients and components, symbols and vignettes, all media including electronic, and all possible forms of advertising.

ACDPA stated that the definition of '*health claim'* should be tightened. They believed that it is critical that this definition does not lead to health education (e.g. a university lecture on the link between diet and chronic disease), or materials published in evidence-based clinical guidelines and accompanying consumer material by organisations such as the Australian Government and ACDPA member organisations being regarded as health claims, as it appears possible under the current definitions. NSF held a similar view to ACDPA.

GW Foods did not consider that a separate definition of a *'health claim'* is needed, as it is already defined under nutrition, health and related claims. In addition, they did not consider it necessary to further divide general level claims by introducing health claims into the framework (page 37 of IAR). Although GW Foods did not support sub-categorising claims in the claims classification framework, they agreed that inclusion of claim descriptors in the guidelines would be helpful to industry.

Kellogg's Aust. recommended that with current legislation (e.g. Fair Trading), FSANZ should focus on ensuring clarity of definitions and structure of the framework to reduce the number of possible interpretations and provide for uniform treatment to allow for effective enforcement. In addition to the reasons listed above, Kellogg's Aust. supported well-defined descriptors to allow effective communication of claims.

2.2 HIGH LEVEL CLAIM

Question 6

Do you think the working definition of a 'high level claim' captures all the possible types of claims, which would reference a biomarker or serious disease or condition?

Out of 147 submitters, 59.2% (87 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	21	4	3	56
Government	7	2	-	-	9
Public health	11	4	-	-	15
Consumers	2	-	-	-	2
Other	5	-	-	-	5
Total	**53**	**27**	**4**	**3**	**87**

Overview

Nearly 40% of submitters (34) agreed that the working definition of a 'high level claim' captures all the possible types of claims, which would reference a biomarker or serious disease or condition. However, a small majority of submitters (48) either disagreed with the specific wording or believed that some claims would not be captured by the definition.

Submitter responses to whether the high level claim working definition captures all possible types of claims

Thirty-four submitters had agreed that the working definition of a high level claim captured all possible types of claims which would reference a biomarker or serious disease condition (Auckland Reg. PHS, NZDA, ASA, Cadbury Confectionery, Functional Wholefoods NZ, Griffins Foods, Naturalac Nutrition, NZ Dairy Foods, NZ Magazines, Nutra NZ, NZ King Salmon, NZTBC, Tegel Foods, NPANZ, Assoc of NZ Advertisers, Heinz Aust./Heinz Watties NZ, NCWA, TCCA, DAA, Dr R. Stanton, PHAA (supported by ACA), Nutrition Aust., DSM Nut. Prod., MLA, Sanitarium Health Food Comp., Wyeth Aust, NSW DoH - N&PA Branch, Tas DoH& HS, DAFF, Queensland Health – PHS, Uni of Adel. & Uni of SA – Nutrition Physiology Research Grp, NHF Aust., NHF NZ)

Forty-eight submitters either disagreed with the specific wording or believed that some claims would not be captured by the definition (Fonterra, Mainland Products, NZFGC, NZJBA, Frucor, MoH, NZFSA, CMA, Mandurah Aust., Kingfood Aust, Palatinit GmbH, CMA- NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, CM of SA, Nestle, Masterfoods Aust. NZ, ICA, William Wrigley Junior, Diabetes Aust, GI Ltd., NCEFF, Tomox, Aussie Bodies, ABC, AFGC, ASMI, Bakewell Foods, Cadbury Schweppes, CML, CHC, Dairy Aust., Food Tech Assoc. of Vic., GW Foods, Goodman Fielder, Horticulture Aust., National Foods, National Starch, Parmalat Aust., PB Foods, Solae Comp, NSW Food Authority, SA DoH, WA DoH, CSIRO – HS&N, Monash Uni – N&D Unit, TGACC).

Four submitters did not clearly express whether or not they thought that the working definition captured all possible types of claims (Northland Health Dietitians, Naturo Pharm Ltd, ACDPA, Kidney Health Aust). One submitter did not support high level

claims except if the food is designated for a 'special medical purpose' (Nutra-Life Health & Fitness NZ).

Nutra-Life Health & Fitness NZ stated that the evidence and substantiation must be provided to support claimed benefits.

Comments and recommendations regarding the overall definition

National Foods requested consistency between the definition for high level claim, which includes the words *'risk reduction claims which reference…',* and the definition for general level claim, which says *'risk reduction claims that reference …'.*

CML suggested that a comma be inserted after the first appearance of the word *'condition'*.
CSIRO – HS&N suggested rewording the definition as follows:

> "…is a claim which references a serious disease or condition *or a biomarker of such* or and (includes) biomarker maintenance claims, biomarker enhancement claims and risk reduction claims which reference a serious disease or condition."

Fonterra recommended that the high level claim definition should be linked to further definitions of content and health claims by including the phrase:

> "…a *type of content or health* claim…"

Nineteen submitters (NZFGC, NZJBA, Frucor, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, CM of SA, ICA, Nestle, Unilever Aust, ABC, AFGC, Dairy Aust, ASMI) noted that the definition of a high level claim (in Section 5.4.3 of the IAR) is not consistent with the glossary definition (page 8 of the IAR), and recommended that the definition should be prefaced with:

> "…a *type of nutrition, health and related* claim…"

Twenty submitters (CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, CM of SA, ICA, Nestle, ABC, AFGC, Dairy Aust, ASMI, GW Foods, CHC, TGACC, NHF Aust., NHF NZ) recommended the removal of brackets from the word [includes], therefore implying that they support the inclusion of *'biomarker maintenance claims', 'biomarker enhancement claims'* and *'risk reduction claims'* in high level claims.

Goodman Fielder supported this modified definition if the term *'biomarker maintenance claims'* remain.

ASMI noted that the definition for general level claim in the glossary clearly identifies a general level claim as being related to 'nutrition', which underpins the requirement that any high level claim must have a context to nutrition in humans. TGACC supported this view and expressed concern about the potential for certain

high level claims to be 'generalised' in order to escape pre-market evaluation, as they felt that it is unclear how a consumer would easily differentiate between a high level claim and a general level claim.

Comments regarding the terms 'biomarker', 'biomarker maintenance claims' and 'biomarker enhancement claims'

Nine submitters considered that the definition requires clarification of the term *'biomarker'* (Horticulture Aust, Tas DoH&HS, NSW DoH - N&PA Branch, SA DoH, PHAA (supported by ACA), WA DoH, Queensland Health – PHS, Monash Uni – N&D Unit). Queensland Health – PHS noted that the definition of *'biomarker'* has varied from that provided in the Ministerial Council guideline. Horticulture Aust. requested further clarification of the terms *'biomarker maintenance claims'* and *'biomarker enhancement claims'*.

Bakewell Foods agreed with the working definition with the exception of some biomarker claims, which they believed should be included in general level claims (e.g. Glycaemic Index 'GI' and NHF 'Tick').

Many submitters considered that *'biomarkers'* (Fonterra, PB Foods, Nestle) or *'biomarker maintenance claims'* (NZFSA, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, CM of SA, ICA, Nestle (supports AFGC and Dairy Aust), Masterfoods Aust. NZ, Unilever Aust, Diabetes Aust., GI Ltd., AFGC, Goodman Fielder, National Foods, National Starch, Parmalat Aust., Solae Comp, Unilever Australasia, Goodman Fielder, National Foods, National Starch) should be considered as general level claims and not high level claims for the following reasons:

- For some biomarkers there is a general level of consumer understanding or awareness (Fonterra, PB Foods);

- If all biomarkers are included in high level claims, the situation might arise where biomarkers for *'non-serious disease'* would be under greater regulatory control than the mention of a *'non-serious disease'*, which would fall under general level claim regulation (Nestle);

- *'Biomarker maintenance claims'* are about maintaining healthy levels of an appropriate marker for disease (CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, CM of SA, ICA, Nestle, Masterfoods Aust. NZ, Unilever Australasia, Diabetes Aust., GI Ltd., AFGC, National Starch, Parmalat Aust., Solae Comp, Goodman Fielder, National Foods);

- *'Biomarker maintenance claims'* are not high risk (Solae Comp, National Starch); and

- *'Biomarker enhancement claims'*, not '*biomarker maintenance claims'*, should be classified as high level claims, as the former are promising therapeutic benefits for consumers (Diabetes Aust., GI Ltd).

FSANZ notes that Diabetes Aust. also stated that they do not see any difference between biomarker maintenance and biomarker enhancement. In their comments, Diabetes Aust. suggested that prevention versus therapy only (slightly) changes the target audience for the claim, and not the level of 'seriousness'. They also believed that use of both terms might potentially cause confusion with respect to interpretation and regulation.

Three submitters recommended the removal of the terms 'biomarker' (National Foods), *'biomarker maintenance claims'* (National Foods, GW Foods, NSW Food Authority), and *'biomarker enhancement claims'* (National Foods, NSW Food Authority) from the definition of high level claim. NSW Food Authority questioned the need to include the mention of the types of biomarker claims in the high level claim definition. They favoured a simpler, all encompassing definition, based on the definition of the high level claims. general level claims would then be defined as those that are not high level claims.

Other submitters supported the inclusion of biomarker references in high level claims (J. Seal – PH Nut, TCCA)

Dr R. Stanton considered the definition is reasonable but stated that there should be clear listing of acceptable biomarkers.

Masterfoods Aust. NZ stated that the inclusion of 'biomarker of disease risk' in the high level claim definition is scientifically unjustified and that there is evidence of use of such claims in the US and related claims in Australia and New Zealand (e.g. 'helps to control cholesterol levels', and 'helps to maintain blood glucose control'). They considered that the Ministerial direction to include reference to biomarkers in high level claims was ill advised and should be reconsidered, with claims that refer to 'biomarkers of disease risk' be reviewed to define appropriate substantiation, and reclassified as general level claims.

Parmalat Aust. opposed the restriction from high level claims of biomarkers that do not reference a *'serious disease'*; in other words, they favoured the use of biomarkers that reference a *'non-serious disease or condition'*.

NCEFF considered the reference to biomarkers is problematic given that high level claims that reference biomarkers should be qualified to relate to serious disease. They considered that the distinction between general level claims and high level claims should relate to the need (or not) for consumers to seek the advice of health professionals based on the relative seriousness of the health issues and the consequences of not seeking this advice. Moreover, they noted that general level claims should also reflect concepts of health and wellbeing rather than just disease risk.

Dairy Aust recommended that biomarker claims should be managed as general level claims and high level claims according to the estimated risk to public health and safety. They recommended that if the Policy is amended to reflect such a change, the definitions must also.

Comments regarding the terms 'non-serious disease or condition' and 'serious disease or condition'

Several submitters believed that the definition requires clarification of the following terms:

- *'Serious disease or condition'* (Horticulture Aust, Tas DoH&HS, NSW DoH - N&PA Branch, SA DoH, PHAA (supported by ACA), WA DoH, Queensland Health – PHS, Monash Uni – N&D Unit, Griffins Foods, Food Tech. Assoc. of Vic);

- *'Non-serious disease or condition (*Tas DoH&HS, NSW DoH - N&PA Branch, SA DoH, PHAA (supported by ACA), WA DoH, Queensland Health – PHS, Monash Uni – N&D Unit); and

- *'Reference… (*(PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit, Horticulture Aust)…*to a serious disease or condition' (*NSW DoH - N&PA Branch).

Griffins Foods suggested that the definition of the term *'serious disease'* includes examples of serious diseases.

Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp agreed to the working definition provided the proposed definition of *'serious disease or condition'* is adopted. Fonterra recommended that the definition should also stipulate a *'serious condition'*.

Mainland Products believed that the term *'condition'* is ambiguous and unhelpful. They recommended using the term *'serious disease'* alone in this definition.

The NZFSA considered that the words 'or condition' should be removed from the definition, as this should be included in the discussion regarding the definition of *'serious disease'*.

Aussie Bodies believed that the high level claim working definition is generally in the right direction but felt that there may be considerable difference in interpretation of '*serious*', particularly the working definition of a condition needing diagnosis and treatment by a qualified health care professional. They noted that different states have differing arrangements relating to who is a qualified health care professional (e.g. TCM certification in Victoria). If 'qualified health care practitioner' includes those under the National Health Training Package, then a herbalist or naturopath may have differing interpretations about conditions to allopathic doctors.

ASMI considered that it was not necessarily clear where chronic conditions fit within this definition (e.g. chronic *'non-serious conditions'* such as eczema). CHC recommended the definition include a reference to non-serious chronic conditions, such as the one given in the example above. Both submitters questioned whether claims for assistance in managing or reducing the severity of eczema with a food product high in Omega-3-fatty acids would be regarded as a high level claim.

Comments regarding the term 'risk reduction claims'

Horticulture Aust. considered that the definition for *'risk reduction claims'* requires clarification.

ASMI members questioned whether there is considerable scope for consumer confusion between a *'risk reduction claim'* and a *'prevention claim'*.

Five submitters stated that claims that relate to '*function/biomarker depreciation'* and/or '*risk increase'* (which may be required for use in nutrition education efforts of health professionals for instance) are not captured (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit).

MoH considered that the *enhanced function* claim category that is included in the general level claim definition is more similar to a high level claim.

Distinction between high level claims and therapeutic claims

Five submitters believed that it is important to note how the *'references to a biomarker or a serious disease or condition'* could be made; that is, not as a therapeutic reference (e.g. prevent, treat, alleviate or cure). They believed that more appropriate wording would be helpful, such as *'may reduce the risk of'* instead of *'may prevent'* (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit).

William Wrigley Junior recommended that there is clarity on the distinction between high level claims and therapeutic claims.

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) were concerned that some high level claims will overlap with therapeutic claims, so it is paramount that the two types of claims are clearly defined. This requires alignment of the therapeutic claim definition adopted by FSANZ with that of the TGA and the Standard must be written to eliminate any confusion between the requirements of both agencies, FSANZ and TGA.

SA DoH believed that the definition should include words that indicate high level claim cannot refer to the diagnosis, prevention, treatment, alleviation or cure of a disease, ailment, defect or injury to reduce confusion and increase consistency between the definition of high level claim and Therapeutic claim. They believed that the definition should also include ailment, defect or injury for reasons above.

Cadbury Schweppes raised concerns that some high level claims will infringe into therapeutic claims and considered that there is a need to clearly distinguish between the two types of claims and products.

The ASA (supported by Cadbury Confectionery, NPANZ, Assoc. of NZ Advertisers, NZTBC, NZ Magazines) agreed that it captures all possible types of claims but care needs to be taken that the definition of a high level claim does not impinge on what is considered a therapeutic claim as defined in the Therapeutic Goods legislation. They noted controversy and potential for grey area (as already exists in NZ) at this interface, which could be exploited and cause consumer confusion. If it is not addressed firmly and sensibly this will almost certainly be the area of the greatest health risk. Great care needs to be taken with biomarker enhancement claims as these are very close to the definition of therapeutic purpose and there will be confusion for the regulators. The ASA recommended that there is a link to Therapeutic Goods legislation to clearly define what will be permitted for foods in this area. They suggested that it would be possible to use a self-regulatory method of pre vetting advertisements to ensure that the claims did not exceed what is permitted, and help to keep advertisers honest.

General comments and recommendations

Seven submitters considered that the working definition appears to capture all the possible types of claims that would reference a biomarker or serious disease or condition, but it is partly contingent upon having a precise definition for the term '*claim*' (Tas DoH&HS, SA DoH, PHAA (supported by ACA), WA DoH, Queensland Health – PHS, Monash Uni – N&D Unit).

Tas DoH&HS considered that the definitions also needed to clarify implied claims and how they fit into general level claims or high level claims.

Dr R. Stanton and Tomox queried whether obesity or body weight would be biomarkers or diseases, with Tomox noting that if obesity were a disease or condition then it would be a therapeutic claim.

PB Foods believed that the working definition for high level claims was not appropriate, and suggested that it is reworded to reflect that high level claims are those where there is potential harm if someone does not scrutinise the basis of the claim, or where there is a need for a higher level of evidence.

Food Tech. Assoc. of Vic. stated that the current definition for high level claims is too broad and requires examples for clarification.

NSW DoH - N&PA Branch considered it preferable to provide a list of each of these terms (claim, biomarker, serious disease or condition, non-serious disease or condition) rather than just the definition, to make it easier & clearer for industry and reduce duplication of effort as manufacturers try to determine what is appropriate to include under each of these definitions.

Fonterra considered that the definition of a high level claim should to be limited to situations where a significant risk to the public may arise through use of a claim on food. They noted a way to achieve this is would be to offer scope for a regulatory body to provide a list of biomarkers, diseases and conditions, which are generally understood by the public, and which might not be regulated under the general level

claim framework, despite prima facie being captured by the high level claim definition.

Fonterra considered that it was strange that the claim framework, proposed to address concerns with regards to public health and safety, did not seem to reference this. Fonterra noted that it appears that 'high level' claims are those where there is potential harm if someone does not scrutinise the basis of the claim, or where there is a need for a higher level of evidence. Is unclear how this rationale has resulted in the proposed definition. Claims not specifically mentioned in the definition but which presumably fall under high level claims are those made in the context of the total diet to treat, alleviate or cure a serious disease or serious condition or the symptoms of these.

Twelve submitters recommended that the requirement for high level claims to reference the whole diet should be incorporated into the definition, unless by way of conditions/criteria in the Standard (CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA – NZ Branch, CMA – NSW Branch, CMA – Qld Branch, CMA – Vic Branch, CM of SA, ICA, William Wrigley Junior, Cadbury Schweppes).

Three submitters believed that it is vital that the wording of all high-level claims conveys the correct meaning to consumers and is not misleading. Suggests that FSANZ prescribe the exact wording of claims based on agreement amongst health professionals and the testing of claim interpretation with consumers (TCCA, ACDPA, Kidney Health Aust).

If it references a 'serious disease' or 'biomarker', it is a high level claim. It is the definition of *'serious disease'* and *'biomarker'* that are important. The subcategories within the definition do not appear necessary and are unnecessarily complicating (DAFF).

Other comments provided but not in direct response to the question

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

Naturo Pharm stated that there was significant potential for increased confusion and inequity of treatment between foods and therapeutic products. They argued that food and medicines exist on a continuum in a similar manner to the health spectrum, and considered it equitable and logical that products which claim to do (or do) a similar job should be treated alike, largely irrespective of the nature of the product (foods, dietary supplements and therapeutics). In their view, all products should be classified by claim and ingredient and not by whether they have been historically understood as foods, dietary supplements or therapeutics.

ASMI believed that to state that a health claim is not a therapeutic claim is an unnecessary semantic exercise and facilitates FSANZ and TGA working with two different definitions of therapeutic use. They considered that the definition makes it clear that the claim is based on the 'consumption of food', which differentiates it from medicinal use. They believed that this is acceptable provided the health message has appropriate dietary context.

Northland Health Dietitians questioned whether the public's response and understanding of general level claims would differ from high level claims. They believed that how the public differentiates between the two and interprets them is more important than how claims are categorised. They also questioned whether the public would distinguish a difference between 'reduces blood cholesterol levels' and 'good for the heart'

TGACC believed that promotion/advertising of general level claims/high level claims will result in the use of extended marketing claims, which will be worded differently to any claims specified in the Standard. This would be acceptable, provided a suitable mechanism of national advertising control (preferably a co-regulatory arrangement, such as the advertising controls for therapeutic goods) is implemented in the food industry for health claim-related advertising above nutrition content claims. Consider that this works in the consumer's best interest by ensuring truthful advertising and offering a transparent complaints resolution procedure that does not burden the compliance capacity of the State jurisdictions.

Judy Seal supported the inclusion of biomarkers as high level claims.

2.3 THERAPEUTIC CLAIM

Question 7

Are there any circumstances not adequately captured by the proposed wording of FSANZ's working definition of a 'therapeutic claim'?

Out of 147 submitters, 51.7% (76 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	20	4	2	49
Government	5	2	-	-	7
Public health	10	3	-	-	13
Consumers	2	-	-	-	2
Other	5	-	-	-	5
Total	**45**	**25**	**4**	**2**	**76**

Overview

More than 20% of submitters (16) stated that there were 'no circumstances' not adequately captured by the definition of 'therapeutic claim' or that they supported the working definition as it was presented in the Initial Assessment Report. Other submitters expressed concerns that related to the inclusion of [outside the context of the total diet] and the terms 'may prevent' and 'helps reduce' etc being used to avoid classification as a therapeutic claim. There were also concerns regarding confusion

with the terminology used in the high level claim definition and the need to align the definition with the Therapeutic Goods Act definition.

All circumstances adequately captured

The following eight submitters stated that there were no circumstances not adequately captured by the definition: NCWA, Tomox, Auckland Reg. PHS, Naturalac Nutrition, NZ Dairy Foods, NZ King Salmon, DAA, NZDA.

However, it was added that 'prevention' and 'risk reduction' have similar meanings and should be defined in the standard to avoid confusion (DAA, NZDA). NZDA further expressed concern with the use of the word prevention, explaining that the cause and effect relationship, which is at the core of prevention of disease or conditions, is unable to be substantiated for a single food.

Other submitters agreed with the working definition as it was presented in the P293 IAR (TCCA, Diabetes Aust., GI Ltd, Sanitarium Health Food Comp, NZJBA, Frucor, Tegel Foods, Heinz Aust./Heinz Watties NZ).

Circumstances not adequately captured

The remaining submitters did not expressly state that circumstances were not adequately captured but noted the issues below, apart from DSM Nut. Products who noted that there were some circumstances not adequately captured but did not provide details.

Removal of the term 'outside the context of the total diet'

Eleven submitters recommended removal of [outside the context of the total diet]. (NHF Aust., NHF NZ, NZFSA, Horticulture Aust., NSW DoH – N&PA Branch, WA DoH, Griffins Foods, PHAA (supported by ACA), SA DoH&HS, Monash Uni – N&D Unit)

Reasons provided for this by submitters were that:

- No therapeutic claims should be permitted inside or outside the context of the total diet, as there are no foods or diets that will cure a disease (NZFSA);

- Claims to the effect that a food will prevent, treat, alleviate or cure a disease, ailment, defect or injury, should be considered therapeutic whether expressed within the context of the total diet or not (NHF Aust., NHF NZ);

- Including the wording within the claim makes it possible to remove it from the therapeutic classification (Griffins Foods);

- These concerns have been raised in the IAR (p31) which suggests that inclusion of these words would permit claims that are made in the context of the appropriate total diet but that which refer to the prevention, treatment, alleviation or cure of a disease, ailment, defect or injury (PHAA (supported by ACA), SA DoH&HS); and

- Using the proposed wording, for example with the therapeutic claim provided, 'This food is high in iron for the treatment and prevention of anaemia' could be easily modified to a high level claim by inserting words such as "in conjunction with an appropriate diet". Hence, in this case, there would be little difference between a therapeutic claim and a high level claim (PHAA (supported by ACA), SA DoH&HS, WA DoH, Monash Uni – N&D Unit).

Dr R Stanton stated that the words 'outside the total diet' might be misleading or confusing for the food industry. The definition needs to clearly state that no claims may say that a food (or foods) can prevent, treat, alleviate or cure a disease, ailment, defect or injury.

It was considered that 'whole of diet' or as 'part of the diet' need to be defined as the mechanics of these statements have not been adequately described. The inference is that because a high level claim is made about food in relation to that food used in the diet as a whole it is not a therapeutic claim, even though it mentions a serious disease. Confusion will arise unless the wording of Standard is clear (Cadbury Schweppes).

Inclusion of the term 'outside the context of the total diet

Ten submitters recommended that the definition of a 'therapeutic claim' should include the term 'outside the context of the total diet' (AFGC, MasterFoods Aust. NZ, ABC, National Foods, NZFGC, Nestle, Goodman Fielder, Dairy Aust., Fonterra, Mainland Products).

Reasons provided for this by submitters were that:

- This is as indicated in the Ministerial Guidelines (AFGC, MasterFoods Aust. NZ, Goodman Fielder);

- As claims referring to disease are to be regulated as high level claims, then FSANZ will be in a position to determine whether or not a claim 'within the context of an appropriate diet", which refers to the prevention, treatment, alleviation or cure of a disease ailment, defect or injury, is sufficiently substantiated to be permitted on foods (AFGC, MasterFoods Aust. NZ);

- It is highly unlikely that any single food item would be capable of being substantiated for a claim within the context of the appropriate total diet, which refer to the prevention treatment, alleviation or cure of a disease, ailment, defect or injury (AFGC, MasterFoods Aust. NZ); and

- The definition implies that the claim that 'a food containing iron may be used to treat anaemia' would not be permitted, but that the claim 'a diet high in iron may be used to treat anaemia' would be permitted. The inclusion of these terms is supported as it encourages use of the total diet context and balanced

claims, and also limits therapeutic claims to those where the claim is made to prevent persons self-medicating or self-treating a particular condition (Fonterra, supported by Mainland Products).

It was considered that the definition of a therapeutic claim is unclear and suggested that the user guide clarifies the distinction between therapeutic claims and health and nutrition claims. Using the therapeutic claim example listed, the assumption is that a general level claim would be permitted if additional wording indicated that it applied in a 'total diet' context (Parmalat Aust.).

Nutrition Aust. was not sure whether to recommend removal of the words [outside the context of the total diet] from the definition of a therapeutic claim because this may further obscure the difference between a therapeutic claim and high level claim. They noted the concern that with the proposed definitions the therapeutic claim could be easily converted to a high level claim by inserting the words 'in the context of the total diet' or 'in conjunction with an appropriate diet' (Nutrition Aust.).

CML recommended that all claims made (irrespective of type) should be in the context of the total diet.

Confusion with high level and general level claim definitions

There were a number of comments based on confusion with general level claims and also with high level claim definitions in particular.

NSW Food Authority stated that the difficult area of implied claims might not be adequately captured by the proposed definition.

A therapeutic claim has the potential to confound general level claims, particularly with respect to interpretations of 'ailment', 'defect' and 'injury' as these are general terms not formal medical terms in the context of health claims. The working definition needs qualification to address the need to seek professional advice where appropriate. Further to this the language used in claims needs to reflect consumer usage rather than formalised scientific usage. The language used in the substantiation framework needs to reflect the formalities and rules of the scientific discourse (NCEFF).

The distinction between high level and therapeutic claims is a fine one. It is interesting to note that while high-level claims refer to "serious" diseases and conditions, therapeutic claims do not. It is essential the definitions be clear and unambiguous (NZFGC).

The definition for high level claims must be modified to stipulate that the following words cannot be used in relation to claims on foods; prevent, treat, alleviate, cure in relation to a disease, ailment, defect or injury (Horticulture Aust., NSW DoH – N&PA Branch, WA DoH, PHAA (supported by ACA), SA DoH, Monash Uni – N&D Unit, Nutrition Aust.). Since these claims must be pre-approved, FSANZ can

take account of the wording where claims have the potential to be implied therapeutic claims (Nutrition Aust.).

Careful monitoring of distinction between high level claim and therapeutic claims is needed, as a high level claim may be considered therapeutic. There is widely varying individual responses may reduce the efficacy of consumer research to clarify the distinction. Industry may wish to use consumer research in high level claim pre-approval submissions to confirm consumer understanding of a claim is not therapeutic (National Starch, Solae Comp.).

CSIRO - HS&N believed there to be an overlap between the two because the use of the word 'prevention' in a therapeutic claim is the same as a risk reduction in a high level claim e.g. the purpose of lowering cholesterol with sterols is to prevent heart disease either primarily or secondarily. Lowering cholesterol is not an end in itself, it is for disease prevention. They pointed out that omega 3 fats also fall into the treatment category and have dosage implications but believes they can be useful food components that should have health claims.

Further to this they suggested that 'therapeutic' should not be based on action (other than cure) but on nature i.e. what is not normally consumed as part of the diet, i.e. statins from fungi are not normal part of the diet although they occur in nature whereas sterols are a normal part of diet.

It was suggested that impacts of food on certain biomarkers such as blood pressure or cholesterol might be interpreted as therapeutic, and believed that these beneficial effects should not be disallowed. The health potential of certain nutrients applies to treatment/prevention of various chronic health conditions, and as an adjunct to drug therapy (Nutritional Phys. Research Group.)

The definition needs further work for clarity. An interpretation of 'defect' is required and it was assumed that in this context it is a life-threatening defect (Nutra NZ).

The definition of a therapeutic claim is unclear, largely as a result of using inconsistent terminology to the previous definitions. This includes the need for clarity on whether prevention, treatment, alleviation or cure refers to the disease, ailment, defect or injury only, or may include the symptoms (Fonterra, Mainland Products).

Fonterra noted that it will be difficult to substantiate that a product will prevent something, especially where the statement is not qualified by limiting its effect to those who are not genetically predisposed to a condition or who do not have a history of it. They assumed that ‘aliment, defect or injury’ related to types of conditions and that other types of conditions fall into the GL or high level claim categories. Wording should be adjusted to clarify this.

Regarding serious diseases or ailments, defects or injuries, Fonterra recommended that consistent with the perceived risk distinction between GL and high level claim categories, the definition of a therapeutic claim should be limited to 'serious’ diseases, serious ailments, serious defects or serious injuries. They suggested a user guide to clarify the above and to state the principle behind the definition, which is presumably

to prevent the risk of not seeking professional help where required. Mainland Products supported comments made by Fonterra.

CMA noted that general level claims might be made about non-serious diseases/conditions, high level claims about serious diseases/conditions and therapeutic claims about prevention and cure of diseases. They recommended a definite requirement to clarify the boundaries of general level claims, high level claims and therapeutic claims both within the FSC and in alignment with the TGA to avoid confusion. This may trigger amendment to TGA. They added that there is a need for clarification to be made with respect to 'may prevent' and 'helps reduce' phrases and whether or not this triggers a therapeutic claim, as opposed to the high level claim, which illustrates the blurring between various levels of claims and what is and isn't permitted (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 recommended that the definition be expanded to include interference with physiological processes rather than just relying on disease, ailments, defects of injury, i.e. add "or influencing, inhibiting or modifying a physiological process". This would capture such claims as weight loss, hair growth, erectile dysfunction, menopause, hangover etc, all of which are likely to be targeted as potential markets for health claims on food, and are not in themselves diseases, or ailments, but part of normal physiological process for many people (ASA, Cadbury Confectionery, NZTBC, NPANZ, Assoc. of NZ Advertisers, NZ Magazines).

A high level claim might include the ability to reduce the risk of, or support the normal operation of, such functions, but should not relieve symptoms of or modify the process in some way that would be considered interfering with the normal operation of that process. The food should have a demonstrated nutritional advantage for such processes, in that it supports the body's optimum response to these conditions, as there will be a point where food alone will not be enough and an intervention with a therapeutic product may be necessary (ASA, Cadbury Confectionery, NZTBC, NPANZ, Assoc. of NZ Advertisers, NZ Magazines).

It was recommended that if therapeutic claims were to remain, clear definitions for disease, ailment, defect or injury would be required (CML).

Use of the words 'may', 'could', 'may prevent' and 'helps reduce'

The following issues were raised with respect to the use of these words in claims.

The word 'management' should also be included in the working definition of a therapeutic claim for clarification, even though it is probably covered by treatment (Nutrition Aust.).

The interface is with the word 'prevention'. There is potential for confusion in relation to a high level risk reduction claim that uses 'may prevent' or 'helps reduce' (Nutrition Aust.).

There was concern that the terms 'may' and 'could' prevent, treat etc, will be used by manufacturers to avoid classification of the claims as 'therapeutic' and therefore the definition should include words such as 'that a food will, or possibly will, prevent…' (NHF Aust., NHF NZ).

'May prevent' and 'helps reduce' terminology needs to be clarified. There is no guarantee that any therapeutic good will actually cure any disease and yet these terms are often applied to therapeutics. This does necessarily mean that they are, or should be, exclusive to therapeutic goods (Cadbury Schweppes).

It was recommended that a clear distinction be made between 'prevention' and 'risk reduction' and that these terms should not be treated as interchangeable (AFGC, MasterFoods Aust. NZ).

Fonterra had concerns regarding prevention versus risk reduction. They presumed that prevention is simply a stronger level of risk reduction, but the distinction is not clear. Claims made outside the context of the total diet to reduce risk, as opposed to prevent a disease, ailment, defect or injury, are assumed to be in the general level claim or high level claim categories (depending on seriousness). There does not appear to be a justification for disallowing the use of the word prevent where it is substantiated. Mainland Products supported this.

Nutra Life H&F believed the definition suggests 'risk reduction' can be considered part of 'prevention' making 'risk reduction' part of a therapeutic claim.

The term 'prophylactic' needs to be defined, i.e. preventative as opposed to 'therapeutic', i.e. curative (Food Tech. Assoc. of Vic).

Therapeutic Goods Act definition

Ten submitters recommended that this definition should align with the Therapeutic Goods Act (TGA) definition (Food Tech. Assoc. of Vic., NZ MoH, Bakewell Foods, DAFF, Wyeth, Cadbury Schweppes, TGACC, Fonterra, Mainland Products, CHC) and made the following comments with respect to this.

- What is TGA's definition and approach to this proposal, as alignment with TGA is vital to prevent grey areas, confusion and possible legal challenges/areas of responsibility etc (Food Tech. Assoc. of Vic.);

- The definition needs to be consistent with other legislation including the FSC and the TGA currently under review (NZ MoH);

- The definition should be very clear and align with Therapeutic Goods Act (Bakewell Foods);

- The definition agreed to by FSANZ should be consistent with the definition under the Therapeutic Goods Act, so that health claims and therapeutic claims would be synonymous. This would allow similar regulatory mechanisms to exist for foods making therapeutic [health] claims as for medicines as recommended in the "Report of a review of Advertising Therapeutic Goods in

Australia and New Zealand", Nov 2002. The advantage of a similar regulatory mechanism means there is equity in the regulatory treatment of a claim and enables clearer food-medicine interfaces to exist (Wyeth Aust.);

- The FSANZ definition is different to TGA definition, which may cause confusion. The Therapeutic Goods act does not adequately define what a therapeutic claim is or the conditions under which such a claim can be made. TGA need to amend this, it is not necessarily the responsibility of FSANZ to define it in the Code (Cadbury Schweppes);

- The relevant definitions under the future Joint Therapeutics Agency and those in the Joint Food Code should align to allow a seamless transition from one regulatory regime to the other (Fonterra supported by Mainland Products); and

- CHC strongly advocates that there must be consistency across FSANZ and TGA with regard to key terms such as food, therapeutic product and therapeutic claim.

TGACC explained that many high level claims and general level claims are synonymous with therapeutic claims, except for the requirement that the claim be framed in context of total diet. Because of this, the TGACC expressed strong concerns at having the different legislative definitions for therapeutic use for foods and medicine when the intended health outcome may in fact be the same. In such cases, the primary distinctions between a food and medicine making similar claims will be based on the presentation of the product and the manner in which it is used in context of diet.

The TGACC added that because the intended health outcomes may be shared across the food-medicine interface, it is essential that foods making claims in excess of nutrition content fulfil comparable requirements:

- For substantiation for claims;
- For quality/manufacturing principles to ensure the product is capable of delivering the claim;
- On compliance measures for labelling and advertising.

This was supported by CHC who noted there should be equity with complementary medicines in relation to the above points. They added that manufacturers and marketers of foods must clearly understand the difference between a therapeutic and health/nutrition claim (CHC).

It was noted that the proposed FSANZ definition for a therapeutic claim does not encompass all of the definition of therapeutic use under the Therapeutic Goods Act (Wyeth Aust.). The Therapeutic Goods Act 1989 was referenced for therapeutic use definition and it was noted that exclusion of subclause (b) (that is "Therapeutic use means use in or in connection with: (b) influencing, inhibiting or modifying a physiological process in persons or animals the replacement or modification of parts of the anatomy in persons or animals.") from the FSANZ definition is problematic as it creates a difference in interpretation under the Therapeutic Goods Act and the Food Standards Code about whether a claim is a therapeutic claim or not (Wyeth Aust.).

Wyeth Aust. added that subclause (b) captures function claims (e.g. 'calcium aids in the development of strong bones and teeth') and enhanced function claims (e.g. 'A high fibre diet may help to improve bowel function.'). Therefore they questioned what is a health claim that is not a therapeutic claim?

CMA noted a great deal of concern currently within the food industry with regard to FSANZ and TGA definitions for therapeutic claims (supported by Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA – NZ Branch, CMA-NSW Branch, CMA – Qld Branch, ICA, CMA-Vic Branch, CM of SA).

Dairy Aust. noted that this definition would align with the Policy Guidelines and Codex definition for therapeutic (prophylactic and curative) claims.

Comments regarding the Policy Guideline

It was submitted that the Policy Guideline, which suggests that 'a therapeutic claim for a food, or food component, may influence, inhibit or modify a physiological process', is broad and ineffectual e.g. a thirst quenching drink may be captured by this definition (National Foods).

It was recommended that the words 'a statement about dosage is an implied therapeutic claim and is therefore not permitted on foods' should be amended to include 'where excepted by the Food Standards Code' as dosage or portion information may be required by consumers, e.g. foods containing plant sterols, meal replacements (National Foods).

This submitter also noted that the Ministerial Policy Guideline indicates that therapeutic claims are not permitted, except where permitted by the FSC. They recommended this information be located with the drafted definition of a therapeutic claim as amended.

General comments

TCCA added that they supported the position that therapeutic claims are not permitted on food labels.

The Coeliac Society of Australia expressed concern that because a gluten free diet is the only treatment for coeliac disease, the linking of gluten and coeliac disease on a food label may be a therapeutic claim.

According to a number of dictionaries, therapeutic has the principle meaning of 'used in treating disease – but involving or used in the treatment of disease or disorders'. (AFGC, MasterFoods Aust. NZ).

The wording of claim appears to be based on non-food items; and an item is either a food or a therapeutic good, but not both (CML). CML believed that therapeutic claims for food should not be permitted (unless covered by TGA as a therapeutic good). In contrast it was commented that disallowing therapeutic claims would deny consumers

further information on benefits of functional foods (Nutritional Phys. Research Group.).

Unilever Australasia supported the inclusion of the phrase 'outside the context of the total diet' in this definition.

Question 8

Should the definition of a therapeutic claim explicitly include claims that can be interpreted as medical advice or is this already implied in the definition? Or should such claims be treated separately?

Out of 147 submitters, 50.3% (74 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	16	4	2	48
Government	6	2	-	-	8
Public health	8	3	-	-	11
Consumers	2	-	-	-	2
Other	4	1	-	-	5
Total	**46**	**22**	**4**	**2**	**74**

Overview

Almost 20 percent of submitters (14) recommended that the definition should explicitly include claims that can be interpreted as medical advice, whereas 35 per cent submitters (26) stated or implied that the inclusion of claims that can be interpreted as medical advice was already implied in the definition. Another six submitters stated that claims which could be interpreted as medical advice should be treated separately.

Should explicitly include claims that can be interpreted as medical advice

Fourteen submitters recommended that the definition should explicitly include claims that can be interpreted as medical advice (TCCA, Dr R Stanton, NCEFF, PHAA (supported by ACA), Nutrition Aust., Tas DoH&HS, SA DoH&HS, WA DoH, Monash Uni – N&D Unit, Horticulture Aust., NSW DoH – N&PA Branch, NSW Food Authority, Heinz Aust./Heinz Watties NZ).

Further comments from these submitters were as follows:

- It could be argued that consumers could interpret some claims currently referred to as high level as therapeutic or medical advice (TCCA);

- Examples of words or phrases that may be interpreted as medical advice should be included (Dr R Stanton);

- Relying on implications is risky. The explicit definition of claims would be more helpful to users of the standard (NCEFF);

- The more explicit the definition of a therapeutic claim the better, to reduce confusion and misinterpretation (PHAA (supported by ACA), Nutrition Aust., Tas DoH&HS, SA DoH&HS, WA DoH, Monash Uni – N&D Unit, Horticulture Aust);

- The UK Joint Health Claims Initiative (2001) Code of Practice lists words and phrases which may imply or which are unlikely to imply prevention, treatment or cure of disease. It may be necessary to consider such an approach within the Australia/New Zealand standard (PHAA (supported by ACA), SA DoH&HS, WA DoH, Monash Uni – N&D Unit);

- This would assist in clarifying the definition (NSW DoH – N&PA Branch); and

- Prefer the standard is as clear as possible (Heinz Aust./Heinz Watties NZ).

PB Foods commented that claims that can be interpreted, as medical advice should not be included in the standard as this criteria would be difficult to enforce. They questioned whose judgement should be used.

CHC considered that claims that can be interpreted as medical advice should not be allowed on foods. This should be clearly defined within the health and nutrition claims standard.

Another recommendation was that there should be some guidance either within the definition or as a guideline to avoid ambiguity as to what would be considered medical advice. If this were done there would be no need to treat these claims separately (NZFSA).

Already implied in the definition

Fifteen submitters stated that the inclusion of claims that can be interpreted as medical advice was already implied in the definition (DAA, NZDA, Tomox, CML, Solae Comp, National Starch, Parmalat Aust., DSM Nut. Prod, Griffins Foods, Horticulture and Food Research Instit. of NZ, Nestle, Cadbury Schweppes, F&B Importers Assoc., Dairy Aust., Auckland Reg. PHS).

Another 11 submitters implied this by stating that it was not necessary to explicitly include claims that can be interpreted as medical advice within the definition (ABC, AFGC, MasterFoods Aust. NZ, National Foods, Goodman Fielder, GW Foods, Fonterra, NZFGC, NZJBA, Frucor, Nutra NZ). DAA and NZDA also stated this in addition to their support as above.

Further comments from these submitters were as follows:

- There may be situations where a claim could be interpreted as medical advice even if it would not be necessary for a health professional to give the advice. The reference to health professionals is targeted sufficiently to address any risk, and a reference to medical advice will increase ambiguity. It is preferred that the definition be limited to situations where there is perceived to be a significant risk for consumers (Fonterra);

- A therapeutic claim is a claim that implies medical advice and Cadbury's believe that this is well understood without having to include a reference (Cadbury Schweppes);

- No, the definition of therapeutic claim covers medical advice (F&B Importers Assoc.);

- The amended definition adequately captures claims interpreted as medical advice and does not warrant a separate claim/definition (Dairy Aust.);

- Some claims currently referred to as 'high level' could be interpreted by consumers as therapeutic or medical advice (Auckland Reg. PHS); and

- This should be addressed under high level claims (Nutra NZ).

DAFF commented that there could be confusion over this term, given that all nutrition, health and related claims could be viewed by some as medical advice. It is unnecessary, and could put high level claims at risk.
It was felt that providing the definition of a therapeutic claim is clear and delineates between therapeutic goods and foods, this should be sufficient. For further clarity, it was recommended that there was reference to claims of an implied medical nature. It is understood that therapeutic claims are not made in the context of the total diet (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).

Such claims should be treated separately

Six submitters stated that claims that could be interpreted as medical advice should be treated separately (NCWA, Canterbury DHB, Mainland Products, Diabetes Aust., GI Ltd, Food Tech. Assoc. of Vic.).

Comments made in support of this were:

- To ensure that health professional endorsement issues are covered adequately (Diabetes Aust., GI Ltd);

- Don't believe it is adequately expressed in the proposed definition e.g. is the claim "Drs recommend eating a folate rich diet" considered as medical advice? (Sanitarium Health Food Comp.); and

- Medical claims should be aligned with TGA definition and guidelines etc (Food Tech. Assoc. of Vic).

CSIRO HS&N highlighted another overlap in that lowering cholesterol with sterols (or increasing fibre to manage constipation) can be construed as medical advice, in the sense of providing a possible medical benefit as opposed to advice from Doctors. They don't believe 'medical' advice is useful for discrimination as the idea of 'health' claims is to use nutrition as a preventative, which can be construed as 'medical' even though it does not necessitate consultation with a Doctor.

Other comments or recommendations

The TGACC and ASMI thought that a distinction would probably need to be made between nutritional/dietary advice versus medical advice. As medical advice is likely to appear in advertising, this highlights the need for a comparable system of advertising control to be implemented in the food industry.

The TGACC went on to say that the food industry should be aware that under existing arrangements of the Therapeutic Goods Advertising Code (TGAC), capacity already 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 good (i.e. based on 'dosing' advice, presentation, claims). If such a complaint was upheld by the CRP a recommendation could be made to either a State health authority or would be made to the TGA so that the good be declared an unregistered/unlisted Therapeutic Good under Section 7 of the Therapeutic Goods Act 1989 and compliance action enacted at a federal level.

It was noted that under the proposed Joint Therapeutic Agency, the term "medical advice" will be defined, along with the groups to whom this information is given. Nutra Life H&F understood that when used in conjunction with a product such as a food, this information can be considered to be a therapeutic claim if it meets FSANZ's proposed working definition.

A recommendation was made that the existing definition under the Therapeutic Goods Act should be adopted in the Standard for health claims to ensure consistency across different product types (Wyeth Aust.).

The ASA noted that it would be necessary to cover off the likelihood of using medical advice to add credibility to a product. While this should be allowed generically for food ingredients, it should be prohibited from product labelling and promotion, either directly or indirectly as in putting this advice in an editorial content which then includes advertisements for branded foods that would be given extra credibility by the association. They suggested one way to cover this off is to include this as a prohibition in any advertising rules, e.g. a 'Code for Advertising Food' similar to the Code for Therapeutic Products, where testimonial and endorsement can be covered adequately. The proposed Joint Agency code for Therapeutic Advertising based on the ASA Code is a good template. The ASA already has a Code for Advertising Food, which would need to be revised in light of P293, but which could easily be adapted to the proposed system (supported by NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, NZTBC, NZ Magazines).

NZ Dairy Foods commented that they were unsure.

NZ MoH said that consistency of definition in law is needed.

Question 9

Does the terminology of 'disease, aliment, defect or injury' in the definition of a therapeutic claim, in contrast to the high level claim definition which centres on disease, conditions or biomarkers, cause any specific problems?

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	24	16	4	2	46
Government	4	2	-	-	6
Public health	7	2	-	-	9
Consumers	2	-	-	-	2
Other	4	1	-	-	5
Total	**41**	**21**	**4**	**2**	**68**

Overview

Nineteen per cent of submitters (13) considered that the difference in terminology in the definition of a therapeutic claim in contrast to the high level claim definition did not cause any specific problems. Another 12 per cent of submitters (8) implied that they did not see any problems with the difference in terminology because it helps differentiate 'therapeutic claims' from 'health claims'. However, 20 per cent submitters (14) stated that there were problems as a result of the difference in terminology, including confusion, lack of consistency and cross-over of therapeutic claims to general level claims.

Does not cause any problems

Thirteen submitters considered that the terminology of 'disease, aliment, defect or injury' in the definition of a therapeutic claim, in contrast to the high level claim definition which centres on disease, conditions or biomarkers, does not cause any specific problems (NCWA, DAA, NZDA, Tomox, F&B Importers Assoc., GW Foods, Horticulture Aust., Auckland Reg. PHS, DSM Nut. Prod, Goodman Fielder, Wyeth Aust., Unilever Australasia, TCCA (with exceptions)).

Comments in support of this view were:

- Consumers will be able to distinguish a high level claim from a therapeutic claim given that the former refers to reduction of disease risk via the maintenance/enhancement/reduction of recognised biomarkers and the latter refer to the prevention/diagnosis/cure of diseases (DSM Nut. Prod.);

- There isn't an issue with the current terminology; it actually helps differentiate the 'therapeutic claims' from 'health claims' definitions (Goodman Fielder); and

- At this stage, do not see that this difference in the terminology of the definitions for therapeutic claim and high level claim causes any problems, if anything it helps to differentiate the claims for the different types of products that are to be controlled by different regulations (Unilever Australasia).

TCCA considered that the difference in terminology is unlikely to cause specific problems if FSANZ develops and applies the following as a part of the standard:

- A list of serious diseases as used in the TGA Act 1989;
- Prescribed wording for all possible high level claims;
- A specific list of acceptable biomarkers for each specified serious disease/condition; and
- Prescribed wording for all high level claims referencing a biomarker (if different from above) (TCCA).

Wyeth Aust. added that there appears to be a significant crossover between the definition of a therapeutic claim and a high level health claim, e.g. 'disease' in the definition of therapeutic claims versus 'serious disease' in the definition of high level health claims. The word 'disease' is less specific and could encompass both serious and non-serious diseases and conditions. Under the current definitions, there is an area of debate regarding what constitutes a high level health claim and a therapeutic claim. For example, a claim that an ingredient in a food 'may assist in preventing' a particular condition could be classified as either a risk reduction claim under the definition of a high level health claim, or as a prevention claim, which falls under the definition of a therapeutic claim. More clarity is required.

Eight other submitters noted that this difference in terminology helps differentiate 'therapeutic claims' from 'health claims' (NZJBA, Frucor, Nestle, ABC, AFGC, MasterFoods Aust. NZ, National Foods, Dairy Aust.).

Dairy Aust. added that it is the terminology that relates to 'food/constituents' versus 'whole of diet' and 'to treat, prevent, alleviate or cure' versus 'reduce the risk' that distinguishes therapeutic from high level claims (Dairy Aust.).

It was added that there might be some unintended consequences that may become apparent at the draft assessment stage (AFGC, MasterFoods Aust. NZ, Nestle). Supports food industry 'road testing' claims and definitions to ensure a robust system (National Foods).

It was considered the terminology in the two definitions (therapeutic claim and high level claim) is not mutually exclusive and all parameters within a 'High Level Claim'

are valid in context of a 'Therapeutic Claim', the difference being dietary context (ASMI, TGACC). CHC agreed that all parameters within a 'high level claim' are valid in context of a 'therapeutic claim' (CHC).

Does cause problems

Fourteen submitters noted or implied that the terminology of 'disease, aliment, defect or injury' in the definition of a therapeutic claim, in contrast to the high level claim definition which centres on disease, conditions or biomarkers, does cause problems (Diabetes Aust., GI Ltd, Fonterra, Mainland Products, NZFGC, Nutra NZ, NZ MoH, NSW DoH – N&PA Branch, NSW Food Authority, PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit).

Additional comments provided by some of these submitters were:

- The omission of 'serious' (preceding disease) may potentially confuse stakeholders and that where possible, terminology should be consistent (Diabetes Aust., GI Ltd);

- The definition results in ambiguity. The implication is that "ailment, defect or injury" is a subset of "condition". Definition as it stands encompasses items that would otherwise fall in the general level claim category (Fonterra);

- There is a problem with the sudden proliferation of different terminology. Recommend using one descriptor or finite collection of descriptors consistently throughout all definitions (Mainland Products);

- The reference to "condition" in a high level claim and "ailment" in the therapeutic claim could cause confusion (NZFGC);

- A defect may be interpreted as trivial, e.g., a lack of vitamins, through to serious disease (heart failure). 'Defect' needs to be defined (Nutra NZ);

- Some benefit is offered re disease prevention in high level claims and is very similar to a therapeutic claim (NZ MoH);

- Preferable to use same terms for both therapeutic and high level claims to provide consistency and reduce confusion. Suggests using the terminology of 'disease, conditions or biomarkers' that is used to define high level claims (NSW DoH – N&PA Branch); and

- It would be preferable to have consistency across definitions (NSW Food Authority) so that there is less confusion and potential for misinterpretation (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit).

Other similar comments were that the current definition is ambiguous. There are areas of overlap where therapeutic claims could encompass a general level claim irrespective of the different terminology. Suggest that the user guide clarifies the distinction between therapeutic claims and health and nutrition claims. Using the therapeutic claim example listed, the assumption is that a general level claim would

be permitted if additional wording indicated that it applied in a 'total diet' context (Parmalat Aust.).

As it currently stands, ‘seriousness’ does not appear to be considered in therapeutic claim definition whereas this is the basis of differentiating high and general level claims for foods. Therefore it would be appropriate to include a reference to ‘seriousness’ in the therapeutic claim definition (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni – N&D Unit).

It will be necessary to spell out that normal life stages such as menopause or ageing are not 'defects' (Dr R Stanton).

There is potential for consumers to view some high level claim as having a therapeutic benefit; that is, an 'implied therapeutic claim'. Consumer research could be used on a case-by-case basis to clarify understanding (National Starch, Solae Comp.).

Recommends the term ‘defect’ be added to the definition. Notes area of ‘nutrigenomics’, which aims to develop foods and diets customised for individuals based on genetic makeup and environmental effects so in the future some foods may be recommended for people with specific genotypes or ‘defects’’ (Hort & Food Research Instit. of NZ).

CMA noted that general level claims may be made about non-serious diseases/conditions, high level claims about serious diseases/conditions and therapeutic claims about prevention and cure of diseases. They recommended the definition for a therapeutic claim clarifies the breadth of claim including serious and non-serious disease/conditions. This combined with a definition of what constitutes a serious versus not serious disease/condition would be helpful. Suggests clarification of therapeutic claims in the standard of the parameters around disease, aliment, defect or injury may also help the segregation of claims (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).

The explicit definition of claims would be more helpful to users of the standard (NCEFF).

Consistency with other legislation

Cadbury Schweppes would like greater clarity in the definitions to avoid any confusion or misunderstanding by manufacturers and consumers. Any definitions used must have the same meaning in the TGA as the Code. Food Tech. Assoc. of Vic also recommended coordination with the TGA otherwise problems are envisaged. NZFSA also supported this by stating that if therapeutic claim is intended to be the same as therapeutic purpose then the definition used in other legislation should be used to ensure consistency between all relevant legislation e.g. Therapeutic Goods Act (Australia) and Medicines Act (NZ) and any new trans-Tasman codes or agreements.

General comments

Nutra Life H&F agreed with the definition although believed it may need to be clarified for some elements of the food industry.

CSIRO HS&N believed they are indistinguishable. They don't believe a biomarker statement constitutes a high level claim as it depends on what condition the biomarker is surrogate. They do not believe there is any contrast as health claims are defined as those that deal with risk reduction while therapeutic claims relate to prevention, treatment and cure (Griffins Foods).

All terms would need to be defined before comments could be made (CML). NZ Dairy Foods are also unsure.

ASA noted that the problem lies with what claims are permitted for the disease, conditions or biomarkers. Currently you cannot mention these without making an implied claim, so by allowing mention of them creates the risk that what is permitted to be said is making a therapeutic claim by implication. The definition of a therapeutic product is "a product that is represented in any way to be, or that is, whether because of the way in which the product is presented or for any other reason, likely to be taken for a therapeutic purpose" and in light of the definition for a therapeutic claim, this will make it very difficult to make a high level claim for food without implying that the food has a therapeutic purpose and is in fact a therapeutic product. This needs to be remedied so it is clear to Industry (supported by NPANZ, Assoc. of NZ Advertisers, NZTBC, Cadbury Confectionery, NZ Magazines).

Other comments provided but not in direct response to the question:

The definition of serious disease and therapeutic claim should be consistent with terms used in the Therapeutic Goods Administration Act. The wording [outside the context of the total diet] should be omitted. The inclusion of these words would permit claims that are made in the context of the appropriate total diet but that which refer to the prevention, treatment, alleviation or cure of a disease, ailment, defect or injury. If the phrase [outside the context of the total diet] was included it would be possible for "therapeutic claims" to be made as "high level claims". This would be inconsistent with the Therapeutic Goods Advertising Code. The definition of therapeutic claim should preferably be consistent with the TGA advertising code so that there is less confusion and potential for misinterpretation. However as the inclusion of biomarkers is in addition to the wording for high level claims this should reflect the therapeutic claim, with the addition of biomarkers (Tas DoH&HS).

A clear statement is required that therapeutic claims and prophylactic claims will not be permitted under the Code and that the definition should be harmonised with that in the Therapeutic Goods Act to provide a clearly defined boundary between a high level claim and a therapeutic claims. The statement in the current definition 'outside the context of the total diet' could be interpreted to mean there is no need to consider the 'context of the total diet' (Queensland Health – PHS). ASMI strongly advised against FSANZ and the TGA operating on different legislative definitions of therapeutic

claim while both under the responsibility of the Commonwealth Department of Health and Ageing.

2.4 SERIOUS DISEASE

Question 10

Should a reference to 'disorders, conditions or defects' be included in the definition of serious disease?

Out of 147 submitters, 60% (88 in total) directly responded to this question. The distribution of these responses was follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	32	19	3	2	56
Government	7	2	-	-	9
Public health	10	6	-	-	16
Consumers	2	-	-	-	2
Other	5	-	-	-	5
Total	**56**	**27**	**3**	**2**	**88**

Overview

Almost 60 per cent of submitters (52) supported the inclusion of 'disorders, conditions or defects' in the definition of serious disease. Thirty per cent (26) opposed the inclusion. Many submitters commented that reference to disorders, conditions and defects should be included as this is consistent with the Therapeutic Goods Act definition of disease. Several submitters suggested it would be helpful to provide examples of professional groups considered to be suitably qualified health care professionals to diagnose and treat conditions.

Discussion of submitter responses

Fifty-two submitters supported the inclusion of 'disorders, conditions or defects' in the definition of serious disease (NSW Food Authority, NSW DoH - N&PA Branch, Queensland Health - PHS, SA DoH, Tas DoH&HS, WA DoH, MoH, Aussie Bodies, ASMI, Bakewell Foods, CHC, Horticulture Aust., Sanitarium Health Food Comp, Wyeth Aust., NCWA, Diabetes Aust, DAA, Dr R. Stanton, GI Ltd, Nutrition Aust, PHAA, ACA, Tomox, TCCA, Monash Uni - N&D Unit, TGACC, Uni of Adel. & Uni of SA – Nutrition and Physiology Research Grp, Auckland Reg. PHS, Canterbury DHB, NHF NZ, NZDA, ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes, Griffins Foods, Naturalac Nutrition, NZ King Salmon, Nutra Life Health & Fitness NZ, Nutra NZ, NZ Magazines, Heinz Aust./ Heinz Watties NZ, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA).

Twenty-six submitters did not support the inclusion of 'disorders, conditions or defects' in the definition of serious disease (ABC, AFGC, Cadbury Schweppes, Dairy

Aust, DSM Nut. Prod, F & B Importers Assoc., Food Tech. Assoc. of Vic., GW Foods, Goodman Fielder, Kellogg's Aust., MLA, National Foods, National Starch, Parmalat Aust., PB Foods, Solae Comp, NCEFF, NZFSA, Fonterra, Frucor, Mainland Products, NZ Dairy Foods, NZFCG, NZJBA, Nestlé, Unilever Australasia)

Many submitters commented that reference to disorders, conditions and defects should be included as this is consistent with the TGA definition of disease. (Tas DoH&HS, WA DoH, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA, Diabetes Aust, GI Ltd, Monash Uni- N&D Unit, ICA).

Cadbury Schweppes are concerned that FSANZ would be looking to broaden the definition of "disease" outside the strict medical definition, even though this were to include disorders, conditions, or defects. FSANZ, which is responsible for food products, should not be creating any definitions that do not currently exist in accepted medical text nor which is not approved and documented by the TGA.

WA DoH and Monash Uni- N&D Unit also comment that as the Oxford Dictionary definition of disease is inclusive of disorder, condition that it may not be necessary to make reference to them.

NZFSA comment that reference not required as believes that the definition of disease is all encompassing. The Oxford Dictionary defines disease as 'a disorder in a human, animal or plant, caused by infection, diet or by faulty functioning of a process'.

The definition needs to be clear and precise and inclusion of the reference to disorders, conditions and defects will help to remove ambiguity (Queensland Health - PHS, Wyeth Aust). Queensland Health - PHS gave an example of confusion over the definition of condition meaning physical condition.

Several submitters considered it would be helpful to provide examples of professional groups considered to be suitably qualified health care professionals' to diagnose and treat conditions (NSW DoH - N&PA Branch, CML, Dairy Aust, NHF Aust, NHF NZ, PB Foods, Fonterra). NHF Aust and NHF NZ consider that "suitably qualified healthcare Professional" should read "suitably qualified medical practitioner".

NHF Aust and NHF NZ believe that the definition of serious disease should include the concept of a condition that is of public health significance - so that would include obesity. "Public health significance" may be able to be defined in terms of the proportion of population affected, or a condition that has been identified by government as a key health priority for the population.

Dairy Aust considers that attention needs to be given to the table of diseases, disorders, conditions provided in the Initial Assessment Report. There is considerable variance in the degree of 'seriousness' or severity to the consumer. For example, skin diseases can range from acne through to nappy rash and eczema; respiratory diseases from asthma through to emphysema; and, diseases of the joint and bone from inflammation through to a broken bone to rheumatoid arthritis. They can be mild through to severe. To account for these differences diseases should be ranked for their

severity, and then assigned to being general level or high-level claims. Terms such as 'mild' asthma and 'moderate' hypertension could be introduced. This would then be consistent with the substantiation process that reflects the varying degrees of impact to the consumer. Food Technology of Australia, Kellogg's Aust., National Starch, Solae Comp, NCEFF, Mainland Products, and GW Foods agree that inclusion of these terms makes the definition too broad and the lack of clarity blurs the distinction between high and general level claims. Fonterra comment if disorders and defects are not included in the definition of conditions, they could be included, if anywhere, in the definition of general and high level claims.

MLA considers a reference to disease manifestation may make it easier to categorise diseases into serious and non-serious disease.

'Life stages' should be defined in the glossary (National Foods, Dairy Australia)

The term 'conditions' in the definition of serious disease needs to be differentiated in the user-guide from the definition of the term 'condition' as per the glossary on page 8 of P293. One refers to medical condition, the other the conditions that a claim must comply with (National Foods, Unilever Australia).

Several submitters made comments pertaining to allergies and serious disease and the implications around of food claims in relation to allergens (Nutra-Life Health & Fitness NZ, Tegel Foods, Heinz Aust/ Heinz Watties NZ).

Question 11

Would it be useful to include a list of serious diseases/conditions in a guideline document? Do you have any questions about the proposed list of serious diseases conditions?

Out of 147 submitters, 61.2% (90 in total) directly responded to this question. The distribution of these responses was follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	31	17	5	3	56
Government	7	2	-	-	9
Public health	14	4	-	-	18
Consumers	2	-	-	-	2
Other	4	1	-	-	5
Total	**57**	**24**	**5**	**3**	**90**

Overview

Eighty-six per cent of submitters (77) supported the inclusion of a list of serous diseases/ conditions, of which 30 specified that the list should be part of a user guide.

One submitter categorically stated that they did not support the inclusion of a list. Seven submitters inferred that they did not agree with the inclusion of a list in either a user guide or in the Standard. One submitter felt it would be difficult to find a list that is fully comprehensive. Another stated that a list of common ailments (not considered serious disease) should be provided in the Standard.

Discussion of submitter responses

Seventy-seven submitters supported the inclusion of a list of serous diseases/ conditions (DAFF, NSW Food Authority, NSW DoH - N&PA Branch, Queensland Health - PHS, SA DoH, WA DoH, Aussie Bodies, ABC, AFCG, ASMI, Bakewell Foods, Cadbury Schweppes, CML, Dairy Aust, DSM Nut. Prod, Flour Millers Council of Aust, F & B Importers Assoc, Food Tech. Assoc. of Vic., GW Foods, Goodman Fielder, Horticulture Aust., Lazarus Scientific Research, MLA, National Foods, National Starch, Parmalat Aust., PB Foods, Sanitarium Health Food Comp, Solae Comp, Wyeth Aust, NCWA, DAA, Dr R. Stanton, NCEFF, NHF Aust, Nutrition Aust, PHAA, ACA, Tomox, TCCA, CSIRO – HS&N, Monash Uni- N&D Unit, Uni of Adel. & Uni of SA – Nutrition & Physiology Research Grp, MoH, NZFSA, Auckland Reg. PHS, NHF NZ, NZDA, Northland Health Dietitians, ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes, Fonterra, Frucor, Griffins Foods, Mainland Products, Naturalac Nutrition, NZ Dairy Foods, NZFGC, NZJBA, NZ King Salmon, Nutra NZ, NZ Magazines, Hort. & Food Research Instit. of NZ, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA, Nestle, Unilever Australasia).

Of those in support of the provision of a list, 30 specified that the list should be part of a user guide (AFGC, ABC, CML, Dairy Aust, DSM Nut. Prod, Flour Millers Council of Aust, GW Foods, Goodman Fielder, Lazarus Scientific Research, National Foods, National Starch, PB Foods, Sanitarium Health Food Comp, DAA, Nutrition Aust, ICA, Fonterra, Frucor, NZJBA, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA, Unilever Australasia). Nine submitters thought the list should be in a standard (Cadbury Schweppes, NSW DoH - N&PA Branch, Queensland Health - PHS, Tas DoH&HS, WA DoH, Horticulture Aust., NHF Aust, PHAA, ACA, TCCA).

One submitter categorically stated that they did not support the inclusion of a list (Coeliac Society of Aust.), whilst seven submitters inferred that they did not agree with the inclusion of a list in either a user guide or in the standard. One submitter felt it would be difficult to find a list that is fully comprehensive (CHC) one submitter preferred that a list of common ailments not considered serious disease should be provided in the standard (Heinz Aust/ Heinz Watties NZ).

Considerations to be made in determining a list of serious diseases included:

- Prevalence of the disease or burden in the population (Queensland Health - PHS, WA DoH, PHAA, ACA, Monash Uni- N&D Unit);
- Substantiated link between diet and disease (Queensland Health - PHS, Tas DoH&HS, WA DoH, DAA, Nutrition Aust, PHAA, ACA, Monash Uni- N&D Unit);

- List determined in consultation with health professionals (CML, Food Tech. Assoc. of Vic., NZFSA). What is a health professional? (Northland Health Dietitians);
- Would like a list of diseases not waffling paragraphs that create a whole load of confusing implications (Mainland Products);
- List should not be exhaustive and should be regularly up dated (Aussie Bodies, ASMI, Dairy Aust, DSM Nut. Prod, National Foods, Uni of Adel. & Uni of SA – Nutrition & Physiology Research Grp, NZFSA, Fonterra);
- Limit the diseases listed to those in the NHMRC dietary guidelines (Horticulture Aust.) based the list on national dietary guidelines (PHAA, ACA, Monash Uni- N&D Unit);
- Terminology used to describe these diseases should reference standard medical practise rather than every day expression (NCEFF);
- Obesity should be considered as serious disease (NHF Aust, NZH NZ).

Several submitters made reference to the TGA definition of serious disease and conditions: Some considered the TGA list is too broad and that a FSANZ list would have to be more specific (DAFF, NSW DoH - N&PA Branch) other commented that the experience with TGA has shown that a list of serious diseases has significant limitations (Diabetes Aust, GI Ltd, TGACC). Comment was also made that FSANZ consideration of serious disease should be inline with that of the Joint Therapeutic Agency (ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes, NZ Magazines, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA).

A variety of submitters commented on the difficulty of determining what constitutes a serious disease and what separates it from non-serious disease – particularly with reference to the list provided in the IAR. In addition some submitters consider that non-serious disease can be a subset of serious disease:

- Note that difficult to make distinction between serious and non serious disease (Dr R. Stanton, NHF Aust, NHF NZ);

- Consider that within the list of disease outlined in IAR the degree of severity varies – skin diseases could include acne, which is not serious. This needs attention so not to cause confusion. (GW Foods, Monash Uni- N&D Unit, CSIRO – HS&N, NZFSA, Fonterra, NZFCG);

- Medical conditions should be differentiated from physical conditions (National Foods, AFGC, GW Foods);

- Do not believe that the current definition allows adequate interpretation (Coeliac Society of Aust); and

- General category of disease will include both serious and non-serious diseases; it will be essential to specify disease or condition (Tas DoH&HS, WA DoH).

Several submitters recommended a general prohibition on making claims less they are listed (WA DoH, Tas DoH&HS, PHAA, ACA, Monash Uni- N&D Unit).

Several submitters commented that there is confusion over the categorisation of allergies as a serious or non-serious disease and that this needs to be clarified (Fonterra, NZFCG, Heinz Aust/ Heinz Watties NZ).

One submitter thought that it would be preferable to avoid all mention of serious disease in respect to foods except in "foods for special medical purposes" and when identifying foods suitable for use by those who have a specific disease or condition, for example suitable for diabetics on medical advice (Nutra-Life Health & Fitness NZ).

One submitter preferred that the standard provide a list of common ailments that are not considered serious disease (Heinz Aust/ Heinz Watties NZ).

Question 12

Should claims in relation to cancer be permitted in food regulation?

Out of 147 submitters 53% (79 in total) directly responded to this question. The distribution of these responses was follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	24	19	3	-	45
Government	5	2	-	-	7
Public health	12	6	-	-	18
Consumers	2	-	-	-	2
Other	5	2	-	-	7
Total	**48**	**29**	**3**	**-**	**80**

Overview

More than 70 per cent submitters (58) supported permissions for health claims relating to cancer. Two submitters implied they supported health claims pertaining to cancer and nineteen per cent of submitters (15) did not support health claims referring to cancer. Several conditions (e.g. level of evidence, claim wording, claims around

specific rather than generic cancer) were considered necessary before a cancer claim could be made. Many submitters commented on the level of evidence for a relationship between particular/specific foods and cancer(s) and the difficulties in undertaking research proving a protective effect.

Discussion of submitter responses

Fifty-eight submitters supported permissions for health claims relating to cancer (AFGC, CML, CHC, F & B Importers Assoc, GW Foods, Goodman Fielder, Lazarus Scientific Research, National Foods, National Starch, Parmalat Aust, PB Foods, Sanitarium Health Food Comp, ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes, Frucor, Griffins Foods, Mainland Products, Beef & Lamb Marketing Bureau, NZJBA, Nutra NZ, NZ Magazines, NZ V & PG Fed/NZFG Fed, Tegel Foods, Cancer Society NZ, Cancer Society NZ – Rotorua Branch, Cancer Society NZ –Waikato/Bay of Plenty Div, Hort & Food Research Instit. of NZ, NZF & V Coalition, Griffins Foods, PHAA, ACA, NZFGC, NSW DoH - N&PA Branch, Aussie Bodies, AFGC, Dairy Aust, Flour Millers Council of Aust, F & B Importers Assoc, CSIRO – HS&N, Fonterra, Nutra-Life Health & Fitness NZ, NSW Food Authority, Tas DoH&HS, WA DoH, CML, ABC, Goodman Fielder, GI Ltd, DAA, Diabetes Aust, MLA, Monash Uni. – N&D Unit, Uni of Adel. & SA – Nutrition & Physiology Research Grp, MoH, Food Tech. Assoc. of Vic., Nutrition Aust).

Two submitters implied a yes (NZ King Salmon, Horticulture Aust.).

Fifteen submitters did not support health claims referring to cancer (Auckland Reg. PHS Service, Canterbury DHB, NZ Dairy Foods, ACDPA, Dr C. Halais, Dr R. Stanton, Kidney Health Aust, NCEFF, TCCA, DAFF, DSM Nut. Prod, Wyeth Aust, Cadbury Schweppes, Solae Comp, NCWA).
The majority of submitters approved of claims pertaining to cancer; some equivocally approved, others considered that there should be conditions around the approval. There were several reasons cited for permitting cancer health claims:

- Claims relating to Cancer were not specifically prohibited by ministers so should be permitted (DAFF);

- Consider that cancer is serious health problem where good diet can minimise risk, thus claims should be permitted for risk reduction. (ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes);

- Believe that diet is a well recognised risk factor in the development of many cancers (Heinz Aust/ Heinz Watties NZ);

- A number of claims pertaining to Cancer have been validated internationally with rigorous frameworks (Unilever Australasia);

- Any disease that is diet related and which has a significant cost to the society in terms of medical and social costs should be permitted (DAFF); and

- Public health professionals at the Functional Foods Centre of Excellence workshop ranked cancer claims relating to grains, fruit and vegetables as first priority (DAFF).

Many conditions (level of evidence, claim wording, claims around specific rather than generic cancer) were considered necessary before a cancer claim could be made - including:

- Assurance that wording on products should not take advantage of the consumer (Aussie Bodies);

- So long as the consumer will not develop unreasonable expectations about cancer prevention from the consumption on a single product or food source. (ASMI, CHC);

- The claim meets the criteria and evidence required for a high level claim (NSW Food Authority, Tas DoH&HS, Diabetes Aust, GI Ltd, Fonterra, Griffins Foods, NZJBA, Frucor, NZFGC, Hort & Food Research Instit. of NZ, NZFSA, CSIRO – HS&N, Monash Uni- N&D Unit, TGACC, Cadbury Schweppes, Food Tech. Assoc. of Vic., Lazarus Scientific Research, Heinz Aust/ Heinz Watties NZ);

- The claim is around risk reduction not cancer cure (NZ Magazines, NZ V&PG Fed/NZFG Fed, Tegel Foods);

- Individual risk and body of evidence for claims relating to cancers should be for specific cancers rather than cancer as a whole (Tas DoH&HS, MLA, Wyeth Aust, DAA, Dr R. Stanton, Beef and Lamb Marketing Bureau, Nutra NZ, Monash Uni- N&D Unit, Unilever Australasia);

- Cancer is a multi-factorial disease state with the cancer nutrition evidence only clear in some specific areas (Canterbury DHB);

- Claims relating to non diet related cancers and/or rare cancers should be prohibited (Tas DoH&HS, WA DoH, Monash Uni- N&D Unit); and

- No food should be identified or suggested as treatment for cancer (Nutra-Life Health & Fitness NZ).

Several submitters discussed the relationship between fruit and vegetable consumption and cancer prevention. NSW DoH - N&PA Branch consider that the restriction of claims in regards to cancer would limit the opportunities for fresh produce and grain products to make high level claims – both of these foods groups are regards as ones that need to be specifically encouraged for consumption in Australia. The National Branch of Cancer Society NZ and supporting branches considered that claims concerning cancer should not be permitted with the possible exemption for fruit and vegetables. They believe that health claims should be permitted around increased fruit and vegetable intake and the prevention of some cancers, so long as qualifying and disqualifying criteria are met (Cancer Society NZ, Cancer Society NZ – Rotorua Branch, Cancer Society NZ – Waikato/Bay of Plenty Div).

A few submitters did not agree with cancer health claims and citied some of the following reasons:

- TGA advertising code does not currently permit references to cancer on the labels of non-prescription medicines such as fibre tablets. Consistency across the standards should be encouraged (Tas DoH&HS, Wyeth Aust, NZ MoH);

- Do not believe that there is enough hard evidence to make health claims relating to cancer (NZ Dairy Foods);

- Cancer and other serious disease claims increase the risk of sufferers relying on specific foods as a cure. (Dr C. Halais);

- There is not enough evidence to convincingly support an association between cancer and specific nutrients or food components (Kidney Health Aust, ACDPA, TCCA);

- Cancer is a serious disease and requires specialist medical treatment (NCEFF).

Many submitters commented on the level of evidence for a relation ship between particular/specific foods and cancer(s) and the difficulties in undertaking research proving a protective effect:

- Nestlé and Nutrition Aust. commented that while there is debate over the specific dietary factors involved with cancer there is a clear association between a healthy diet and physical activity and lower cancer incidence;

- NCEFF considered that claims could relate to the support of immune function and maintenance of adequate nutrition;

- While there are a number of contributing factors to cancer, diet is an important one in relation to some of the more common cancers such as bowel cancer. (Mainland Products);

- Solae Comp commented that the type of studies required for high level substantiation is impractical for cancer and that intervention studies in cancer would take years and are not financially feasible. They do not consider that it is justifiable to shelter the public from evidence that certain dietary components may be protective from cancer. They point out that the FDA allows claims on cancer based on epidemiological studies that are supported by animal studies and in vitro investigations;

- TCCA considers that the relationship between diet and cancer is complex and the greatest efficacy for cancer prevention is through decades of appropriate dietary practice. They recommend dietary recommendations based on a whole for diet approach and on the NHMRC dietary guidelines; and

- ACA believe that claims regarding cancer should not be permitted until a substantiation of cause can be made, as many consumers do not understand the difference between a risk factor and a cause.

The NZ MoH stated that if cancer is not included as a potential health claim there should be a clear rational as to why it is different from other serious diseases.

Wyeth Aust note that they consider public health to be more interested than industry in permitting health claims pertaining to cancer. However ASMI gave an example of where they consider industry is already making a health claim in relation to soy and cancer prevention.

National Foods recommend flexibility of wording for high level claims regarding cancer as with other high level claims.

2.5 NON-SERIOUS DISEASE

Question 13

Is there a need to define 'non-serious disease' in the Standard for nutrition, health and related claims?

Out of 147 submitters 59% (86 in total) directly responded to this question. The distribution of these responses was follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	30	17	4	3	54
Government	7	2	-	-	9
Public health	11	4	-	-	15
Consumers	2	-	-	-	2
Other	5	1	-	-	6
Total	**55**	**23**	**4**	**3**	**86**

Overview

Seventy per cent of submitters (60) agreed or implied that there is a need to define 'non-serious disease'. Twenty-three submitters did not support the inclusion of the definition. Opinion was spilt as to whether the list should go into a standard or a guideline. Regardless of the opinion on the inclusion of a definition for non-serious diseases, the majority of submitters made comment on examples of non-serious diseases either in the guideline document or in the Standard.

Discussion of submitter responses

Fifty-seven submitters were of the opinion that there is a need to define 'non-serious disease' (WA DoH, NSW DoH - N&PA Branch, Queensland Health - PHS, ACA, NCWA, ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes, NZ Dairy Foods, Nutra NZ, NZ Magazines, Tegel Foods, Diabetes Aust, DAA, GI Ltd, NCEFF, Nutrition Aust, Tomox, TCCA, NHF NZ, NZDA, NZ MoH, NZFSA, TGACC, Monash Uni -N&D Unit, Aussie Bodies, ABC, ASMI, Bakewell Foods, CML, Cadbury Schweppes, CHC, DSM Nut. Prod, Food Tech. Assoc. of Vic., Horticulture Aust., MLA, National Starch, Sanitarium Health Food Comp, Solae Comp, Wyeth Aust, Heinz Aust/ Heinz Watties NZ, Nestle, SA DoH, WA DoH, Canterbury DHB, Beef & Lamb Marketing Bureau, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA).

Three implied a yes response (PHAA, ACA, Flour Millers Council of Aust)

Twenty-three submitters did not support the inclusion of the definition (DAFF, NSW Food Authority, Hort. & Food Research Inst. of NZ, Frucor, Mainland Products, Naturalac Nutrition, NZJBA, Dr C. Halais, CSIRO- HS&N, Uni of Adelaide & Uni of SA –Nutrition & Physiology Research Grp, AFGC, F & B Importers Assoc, GW Foods, Goodman Fielder, National Foods, Parmalat Aust, PB Foods, Unilever Australasia, Dr R. Stanton, Fonterra, Griffins Foods, NZFGC, Dairy Aust).

Many submitters thought the inclusion of a definition of non-serious disease would help avoid misinterpretation and confusion (ACA, WA DoH, Heinz Aust/ Heinz Watties NZ, Nestle, TGACC, ICA, Nutrition Aust, TCCA, Flour Millers Council of Aust, Horticulture Aust.).

Some thought that the definition should be in a guideline document (Queensland Health - PHS, ASA, Assoc. of NZ Advertisers, Cadbury Schweppes, NZ Magazines), others thought the definition should be part of the standard (Horticulture Aust., CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA, Sanitarium Health Food Company).

Reasons given for supporting a definition included:

- Consistency with definitions of serious disease (NSW DoH - N&PA Branch);
- The more defined and explicit the easier it would be to enforce (NSW DoH - N&PA Branch, GI Ltd, AFCG)

Many submitters were also of the opinion that if definitions of serious disease and biomarker claims are clearly defined, the remainder are general level and will not need defining (DAFF, NSW Food Authority, Unilever Australasia, CSIRO – HS&N, Hort. & Food Research Instit. of NZ, Fonterra, Frucor, Griffins Foods, Mainland Products, Naturalac Nutrition, NZFGC, NZJBA, Dairy Aust, F & B Importers Assoc, National Foods, PB Foods).

Dr R. Stanton is of the opinion that definition of non-serious disease may be more appropriate than the definition of serious disease.

It was considered the that definition of non-serious disease also needs to clarify the likes of conditions such as overweight and obesity and mineral/vitamin deficiencies (Beef and Lamb Marketing Bureau)

Regardless of the opinion on the inclusion of a definition for non-serious diseases the majority of submitters commented on providing a list of examples of non-serious diseases. Several submitters thought that a list citing examples of non-serious disease should be included in the standard (NHF Aust, PHAA, ACA), others considered that a list in a guideline document would be more appropriate (Unilever, Monash Uni- N&D Unit, Nutrition Aust., TCCA, AFCG, Dairy Aust. GW Foods, 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, Parmalat Aust).

Several submitters commented that whilst definition is not required a list in a guideline document may be helpful in order to clarify borderline cases. (Fonterra, Frucor, Griffins Foods, NZFGC, NZJBA)

Dairy Aust. and National Foods commented that any list should regularly reviewed n order to maximise its value. It was also proposed that a list should include exceptions to the definitions (National Foods).

PHAA (supported by ACA) consider that there should be a general prohibition on those claims not included in a list in the standard.

Several submitters thought that a list should be developed in consultation with TGA (CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA-NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA, Cadbury Schweppes).

In addition to opinions as to the inclusion or not of a definition or list of non-serious diseases several other issues where raised. Tas DoH&HS considered that there might be a need to be a warning statement similar to that used on over the counter medications – if symptoms still exist seek medical advice. Canterbury DHB considered that the definition of appropriate health care professional was required.

Question 14

Can you provide examples of what may constitute a non-serious disease or condition?

Out of 147 submitters 48% (70 in total) directly responded to this question. The distribution of these responses was follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	26	14	4	3	47
Government	5	2	-	-	7
Public health	8	3	-	-	11
Consumers	1	-	-	-	1
Other	3	1	-	-	4
Total	**43**	**19**	**4**	**3**	**70**

Overview

Submitters provided an extensive list of over 60 non-serious diseases ranging from constipation, irritable bowel syndrome, overweight, migraines and heart burn to bruises, coughs, headaches and acne. There was much discussion and comment surrounding the wide spectrum of severity of disease and the difference of disease severity according to individuals. It was noted that health professionals treat some non-serious diseases or conditions. In addition, there was concern that non-serious diseases may also become serious or be indicative of serious disease for some individuals.

Discussion of submitter responses to specific issues raised in question

The following diseases were listed by submitters as being a non-serious disease or condition:

Constipation	ABC, AFGC, ASMI, Dairy Aust, GW Foods, Goodman Fielder, Lazarus Scientific Research, National Foods, National Starch, Parmalat Aust, Sanitarium Health Food Comp, Solae Comp, Wyeth Aust, ASA, Assoc. of NZ Advertisers, Cadbury Schweppes, NZ Magazines, NZ Dairy Foods, Nutra NZ, NHF NZ, CSIRO – HS&N, Nestle, Unilever Australasia
Irritable bowel syndrome	ABC, AFGC, Dairy Aust, Goodman Fielder, National Foods, Unilever Australasia
Diarrhoea /Traveller's diarrhoea	ASMI, Lazarus Scientific Research, Sanitarium Health Food Comp, NZ Dairy Foods
Flatulence	ASMI, Parmalat Aust, NSW Food Authority
Bloating	Parmalat Aust.
Tummy upsets	AFGC, Dairy Aust, Goodman Fielder, National Foods, ASA, Assoc. of NZ Advertisers, Cadbury Schweppes, NZ Magazines, NPANZ, Nestle, Unilever Australasia, Parmalat

	Aust.
Dehydration	Parmalat Aust, Sanitarium Health Food Comp.
Indigestion	ABC, AFGC, Dairy Aust, GW Foods, National Foods, Wyeth Aust, NZFGC, Unilever Australasia
Heart burn	Wyeth Aust, NZ Dairy Foods
Indigestion	Goodman Fielder, Parmalat Aust, NSW Food Authority
Minor aches and pains	ABC, AFGC, National Foods, Unilever Australasia
Bruises	AFGC, National Foods, Nutra NZ, Unilever Australasia
Minor trauma	AFGC, National Foods, Unilever Australasia
Acne	ABC, AFGC, Dairy Aust, GW Foods, Goodman Fielder, National Foods, Parmalat Aust, Mainland Products, NZ Dairy Foods, NZFGC, Unilever Australasia
Eczema	ASMI, NZ Dairy Foods, Nutra NZ
Dandruff	Nutra NZ Ltd
Body Lice	Nutra NZ Ltd
Fungal infection/thrush	ASMI, Dairy Aust, National Foods
Nappy rash	Goodman Fielder, Nestle
Minor skin irritations	Parmalat Aust.
Cold sores	Parmalat Aust.
Allergies	ASMI, Wyeth Aust, Heinz Aust/ Heinz Watties NZ (possibly)
Minor Allergies	ASA, Assoc. of NZ Advertisers, Cadbury Schweppes, NZ Magazines
Lactose intolerance	Sanitarium Health Food Comp.
Colds and flu	ASMI, National Foods, Wyeth Aust, NZFGC, NHF NZ
Common cold	Goodman Fielder, Lazarus Scientific Research, NZFGC, Nutra NZ Ltd, CSIRO – HS&N
Coughs	NZFGC
Rhinitis / Hay Fever/ Sinusitis	ASMI, Wyeth Aust.
Congestion	ASMI
Sore throats	ABC, AFGC, National Foods, Wyeth Aust, Nutra NZ, Unilever Australasia
Gut Health	Nutra NZ
Vomiting	NHF NZ
Halitosis	ASMI, ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes, NZ Magazines, Nutra NZ, CMA, Mandurah Aust, Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA
Tooth decay	Nutra NZ, NHF NZ, NSW Food Authority, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA.
Signs of Aging	NZ Dairy Foods
Menopause	NSW Food Authority
Pregnancy	NSW Food Authority
Menstrual Pain	Nutra NZ
Anxiety/ Nervous	ASMI

tension /Mood swings	
Stress	ASMI, Dairy Aust, National Foods, Parmalat Aust.
Migraine	Sanitarium Health Food Comp, ASMI
Head aches	Sanitarium Health Food Comp, Wyeth Aust, ASMI, NZ Dairy Foods
Pain/mild pain	ASMI, Wyeth Aust
Fever	Wyeth Aust
Minor Stress	ASA, Assoc. of NZ Advertisers, Cadbury Schweppes, NZ Magazines, NPANZ
Concentration	Nutra NZ
Sports performance	Goodman Fielder, National Foods
Lethargy	Sanitarium Health Food Comp, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Schweppes, NZ Magazines, Heinz Aust/ Heinz Watties NZ
Muscle Fatigue	Sanitarium Health Food Comp, NHF Aust, NHF NZ
Muscle strain	Nutra NZ
Muscle cramps	Lazarus Scientific Research
Joint inflammation/Symptoms of rheumatism and osteoarthritis	ASMI
Osteoporosis	GW Foods, National Foods
Over weight	Dairy Aust, National Foods, Naturalac Nutrition (but not obesity), CSIRO – HS&N
Insomnia/sleeplessness	ASMI, Parmalat Aust, Wyeth Aust.
Hangover	ASMI, Nutra NZ
Urinary tract infections	Lazarus Scientific Research, ASMI
Vitamin and mineral deficiencies	GW Foods
Low immunity	ASA, Assoc. of NZ Advertisers, Cadbury Schweppes, NZ Magazines, Nutra NZ
Reflux	Wyeth Aust.

Several submitters stated what they considered that non-serious disease might encompass:

- Normal biological changes e.g. hot flushes during menopause (ASMI);
- Conditions with temporary but not persistent or chronic changes in physical conditions (e.g. loss of appetite) (DSM Nut. Prod);
- Self-limiting conditions treated by the individual without having to see a health professional e.g. uncomplicated constipation, headaches (Diabetes Aust, DAA);
- Minor conditions that are related to diet such as constipation, indigestion (GI Ltd); and

- Non-serious conditions should reflect those indications, which are approved for non-prescription over the counter medicines (Wyeth Aust, Lazarus Scientific Research, Tomox). TCCA agree but ask 'where does over weight fit?'

Two submitters were of the opinion that a list should be determined and assessed by teams of health professionals (CML, Food Tech. Assoc. of Aust.).

There was much discussion and comment surrounding the wide spectrum of severity of disease and the difference of disease severity according to individuals. Some non-serious diseases are treated by a health professional (eczema, gingivitis) and (Fonterra, NZFGC) and for some individuals may become serious or be indicative of serious disease (Auckland Reg. PHS, Monash Uni- N&D Unit, MoH, Tas DoH&HS, WA DoH).

Several submitters referred to the list of serious diseases given in the IAR as a reference point. Submitters commented that within the list there are some degrees of severity and some of the lesser server diseases could be non serious – most diseases are on a spectrum with the bottom end being manageable with out medical help (e.g. skin diseases which includes acne) (GW Foods, NSW Food Authority). NZFSA made the comment that from the table of serious diseases it is difficult to provide examples of non-serious diseases that would not fit in to a category relating to serious disease (skin diseases such as eczema).

The wide spectrum of disease promoted submitters to voice that concern exists where the non-serious disease implies a more serious condition, generally where the non-serious condition is symptomatic of a serious one (ASMI, Wyeth Aust, Horticulture Aust., Tas DoH&HS). Or where a non-serious disease is the cause of a more serious underlying condition. For example - constipation would normally be considered non serious but may have underlying serious causes, menopause may also be considered non serious, however in some instances symptoms result in women seeking medical advice and thus fit the definition of serious disease (Nutrition Aust, Tas DoH&HS).

Horticulture Aust. go on to list some claims with out reference to a serious disease or condition – detox, health eating, health living, perfectly balance, eat smart, super food, but comment that it could be argued that in isolations these claims should not be allowed as they are not specific.

ASMI considered that adequate guidance in labelling and advertising is required to ensure that persistent conditions should be followed up with a health care professional.

PHAA and ACA commented that serious and non-serious disease is problematic with out a precise definition. Approved biomarkers (based on burden of disease prevalence data and which meet all established criteria) should be listed in the standard and there should be a general prohibition on those biomarkers not included in the list. This was also the view of the Monash Uni- N&D Unit and WA DoH.

The AFGC thought that there are examples of non-serious manifestations of serious diseases and examples of non-serious diseases or conditions about which substantiated claims might be considered.

Mention was also made that provisions need to be made where a brand (e.g. healthy choice) has definite brand standards and nutrition criteria that are communicated to the consumer so that the claim is specific, provision need to be made (WA DoH).

Other legislation was also mentioned; AFGC though that a list should be consistent with guidelines for complimentary medicines, which are at the lower end of the spectrum for medicine regulation, exceptions that may be referred to include iron deficiency, arthritis and osteoporosis. Nutra-Life Health & Fitness NZ commented that the proposed definition would encompass some conditions, which fall within the current prohibited representations of the NZ Medicines Act.

NCEFF were of the opinion that rather than non-serious disease, reference to a state of health might better describe this category.

2.6 BIOMARKERS

Question 15

Do you prefer the term 'biomarker' to that of 'surrogate outcome'?

Out of 147 submitters 58% (86 in total) directly responded to this question. The distribution of these responses was follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	33	16	3	3	55
Government	7	1	-	-	8
Public health	10	4	-	-	14
Consumers	2	-	-	-	2
Other	5	2	-	-	7
Total	**57**	**23**	**3**	**3**	**86**

Overview

The majority of the 86 submitters preferred the term 'biomarker' to 'surrogate outcome'. Only three submitters did not prefer 'biomarker'. One submitter was of the opinion that both terms should be used. Several comments were made about the wording of the definition of biomarker, particularly concerning the use of the word 'predicts' and its appropriateness.

Discussion of submitter responses

The majority of the submitters who answered this question preferred the term biomarker to surrogate outcome (Aussie Bodies, ABC, AFGC, ASMI, Bakewell Foods, Cadbury Schweppes, CML, CHC, Dairy Aust, DSM Nut. Prod, Flour Millers Council of Aust, Food Tech. Assoc. of Vic., GW Foods, Horticulture Aust., Kellogg's Aust., Lazarus Scientific Research, MLA, National Foods, National Starch, Parmalat Aust, PB Foods, Sanitarium Health Food Comp, Solae Comp, ASA, NPANZ, Cadbury Schweppes, Fonterra, Frucor, Griffins Foods, Mainland Products, Naturalac Nutrition, NZ Dairy Foods, NZFGC, NZJBA, NZ King Salmon, Nutra-Life Health & Fitness NZ, Nutra NZ, NZ Magazines, Tegel Foods, Diabetes Aust, DAA, Dr C. Halais, GI Ltd, NHF Aust, NCEFF, TCCA, Tomox, NCWA, ACA, Crop & Food Research, Hort. & Food Research Instit. of NZ, Auckland Reg. - PHS, Canterbury DHB, NZDA, NHF NZ, ICA, CSIRO- HS&N, MoH, NZFSA, DAFF, NSW Food Authority, NSW DoH – N&PA Branch , SA DoH, WA DoH, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA, Heinz Aust/ Heinz Watties NZ, Nestle, Unilever Australasia).

Reasons given for preferring the term biomarker to surrogate outcome include:

- Biomarker has already been extensively used (Cadbury Schweppes, NCEFF, Nestle);

- While consumers do not generally understand the term biomarker, it is common terminology in scientific health research compared with surrogate outcomes. (National Foods); and

- Surrogate also means substitute and is not suitable (AFCG, Goodman Fielder).

One submitter that did not prefer the term biomarker to surrogate outcome was Uni of Adel. & Uni of SA - Nutrition Physiology Research Grp.

Wyeth Aust. considered that, as the terms are not interchangeable in every context that they both should be available for use.

Several comments were made in reference to the wording of the definition of biomarker. The AFCG and Unilever Australasia thought that word predicts should not be used in the definition of biomarker and that the term 'predictive of risk' better expresses the relationship between the biomarker and risk of disease etc. The recommend the definition read " a measurable biological parameter which is predictive of the risk of human disease, disorders, conditions or defects". Dr C. Halais

agrees and suggests that 'biomarkers is associated with the occurrence of human disease…' would be more appropriate. AFCG also commented that the proposed sentence " the biomarkers itself is not a measure of the disease, disorders, conditions or defect" is redundant.

Monash Uni- N&D Unit and Tas DoH&HS agreed that the term is not the issue it is more important that the definition is accurate. Monash Uni- N&D Unit and the WA DoH considered that the approved biomarkers are listed in the standard and that there be a prohibition on those terms not listed. The PHAA and ACA agreed with the inclusion of a definition of biomarker in the standard, along with a list of permitted claims in order to avoid confusion.

Question 16

What practical implications do you see from the proposed definition?

Out of 147 submitters 45% (65 in total) directly responded to this question. The distribution of these responses was follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	25	13	4	2	44
Government	5	1	-	-	6
Public health	5	2	-	-	7
Consumers	2	-	-	-	2
Other	6	1	-	-	7
Total	**43**	**17**	**4**	**1**	**65**

Overview

Several submitters commented on the appropriate of the word 'predicts' in the definition of biomarker and thought that the term 'predictive of the risk' better expresses the relationship between the biomarker and risk of human disease, disorder, condition or defect. There was also discussion pertaining to the ability of a biomarker to measure disease, as is the case with blood glucose and diabetes. Most submitters considered that FSANZ should provide a list of biomarkers either in the Standard or guideline document.

Discussion of submitter responses

Dairy Aust. had some concerns with the proposed definition for a biomarker. They are of the opinion that the term 'predicts' implies an absolute relationship with the risk of disease, disorder, condition or defect. Cadbury Schweppes comment that the word "predicts" may infer to some consumers that there may be positive health outcomes whereas this may not be the case. This is the differentiation between a high-level and a therapeutic health claim. Dairy Aust. suggests that the term 'predictive of the risk' better expresses the relationship between the biomarker and the risk of human disease, disorder, condition or defect (this is supported by Nestle, NSW DoH - N&PA Branch,

Goodman Fielder Parmalat Aust, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA).

Dairy Aust. also highlight that the proposed definition states 'the biomarker itself is not a measure of the disease, disorder or condition'. However, insulin resistance (a biomarker) can be a measure of diabetes, and bone mineral density (a biomarker) is part of the definition of osteoporosis – a measure of whether the disease is absent or present. Similarly, body mass index (a biomarker) is used in the classification of whether or not a person is obese. This suggests that the current definition is too wide (supported by Fonterra). Therefore, Dairy Aust. suggests the following definition be accepted: "a biomarker is a measurable biological parameter that/which is predictive of the risk of human disease, disorders, conditions or defects". GW Foods also support this definition.

The TGACC also comment that there may be difficulty differentiating those claims which are direct measures of a disease versus those that are of a predictive value only and that this is particular relevant in terms of the significance of a biomarker in multi-factorial disease. The ASMI made a similar comment.

The AFCG commented and Diabetes Aust. agrees that the exclusion of the sentence "the biomarkers itself is not a measure of the disease, disorders, conditions or defect" as they consider that blood glucose levels are an example of a biomarker, which is predictive as well as a measure of disease. DAA, Diabetes Aust., NZDA, Tas DoH&HS and GI Ltd commented on the difficulty of categorising blood glucose levels because of its ability to measure the disease.

NZFSA supports the compilation of an exclusive list of recognised biomarkers and the identification of a process for adding new biomarkers to this list. NCEFF and TCCA agree that a list of acceptable biomarkers would be useful. This list would help meet with substantiation requirements and should be provided for both general and high level claims. The PHAA and ACA consider that only having substantiated biomarkers permitted for use in claims will have the advantage of protecting health and safety and preventing misleading and deceptive claims. They also say that the evidence suggest that consumers do not discriminate between serious disease – risk reduction claims and biomarker claims (FSA, 2002) and it is imperative that biomarkers are giving the same level of substantiation (showing a causal link) as other high level claims.

Dairy Aust. PB Foods, Sanitarium Health Food Comp, CML and National Foods consider that an indicative list of biomarkers in a guideline document would be appropriate.

Monash Uni – N&D Unit, WA DoH, Horticulture Aust. and DAA and Dr R. Stanton thought that the list should be in a standard and reviewed regularly to minimise confusion. Lazarus Scientific Research agrees that there should a list in the standard but think that this list should be regularly reviewed and expanded. Wyeth Aust. considers that this list should be non-exhaustive. NHF Aust and NHF NZ believe that it is difficult to determine when a high level claim is implied by the words in a general level claim. They consider that a list of approved function claims, enhanced function

claims and risk reduction claims for non-serious diseases should be listed in the standard (i.e. that general level claims are pre-approved by FSANZ, as are the high level claims). They consider that this would remove the need for industry and enforcement agencies to determine what a biomarker or serious disease is. In addition, this would also reduce the potential for misleading and confusing claims.

Wyeth Aust. considers that there is ambiguity surrounding the difference between a biomarker and a normal physiological component. For example is cholesterol a biomarker, or a normal physiological component of the body? Does it depend on the context in which it is referred to in the claim?

Other contentious potential biomarkers include over weight/obesity and BMI and weight (Tas DoH&HS).

Several submitters thought that substantiation of the biomarker process should demonstrate that significant portions of the population or targeted sub groups understand a biomarker claim and find the claim relevant. Claims that reference a biomarker that is of no concern to the majority of the population have the potential to raise unnecessary fears in consumers which is not consistent with what is endorsed in the policy guideline (Tas DoH&HS, WA DoH, Horticulture Aust, PHAA, ACA). The NCEFF agree that consumer understanding will vary and that this needs to be considered. Several submitters discussed the importance of consumer education (Tomox, ASA, Assoc. of NZ Advertisers, NPANZ, Cadbury Schweppes, Nutra-Life H&F). The NSW Food Authority suggested that the term biomarkers should be explained to consumers as part of an overall education program on the health claims standard.

Other issues raised included:

- As science in this area is uncertain and changes rapidly with time, frequent reassessment of research is required (Food Tech. Assoc. of Vic.);

- Often "proof" as the basis for claims is based on a lack of acceptable evidence, only to be withdrawn/reversed on closer inspection but "damage" is done through media use of reports (Food Tech. Assoc. of Vic.);

- Also investigation of a single compound in isolation is not always the same as when subsequently it is added to a food/mixture of foods and other factors may be at work. The reverse can also be true where an isolated active has not the same potency when removed from its original source where the may be other unrecognised co-factors (Food Tech. Assoc. of Vic.);

- Canterbury DHB believes that this concept is beyond that of manufacturers and will be a source of confusion;

- It is important to note that biomarkers such as BMI and blood cholesterol have normal range. It is only when a biomarker goes outside the normal range, which needs to be interpreted by a qualified Health Professional, that it poses any concerns to individual health (WA DoH, Horticulture Aust.);

- CSIRO-HS&N questioned the need for the biomarker to be biological. He suggested that body weight or waist circumference are markers of adipose tissue mass and consideration that markers of disease or conditions may be more appropriate than biomarkers; and

- MasterFoods Aust. NZ considers that biomarkers of disease risk should be reviewed to define appropriate substantiation criteria and be classified under general level claims.

Question 17

What practical implications do you see from the proposed criteria for use of biomarkers in substantiation?

Out of 147 submitters 28.6% (42 in total) directly responded to this question. The distribution of these responses was follows:

Sector	Australia	New Zealand	Trans Tasman	International	Total
Industry	4	12	2	1	19
Government	5	2	-	-	7
Public health	8	3	-	-	11
Consumers	1	-	-	-	1
Other	4	-	-	-	4
Total	**22**	**17**	**2**	**1**	**42**

Overview

Several submitters acknowledged the importance of having a list of approved biomarkers in the criteria for substantiating a health claim. Many submitters commented that it is important to only use biomarkers where a causal link with disease has been established or at least an assessment of the weight of evidence by an independent panel of experts. Several submitters commented on possible consumer perceptions of biomarkers some believed that consumers would understand the concept, others were of the opinion that this would not be the case.

Discussion of submitter responses

Several submitters acknowledged the importance of having a list of approved biomarkers in the criteria for substantiating a health claim (SA DoH, National Starch, Solae Comp, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Schweppes).

Both the Auckland Reg. - PHS and the NZFSA stated that the proposed criterion provides a good level of guidance for FSANZ to determine acceptable biomarkers. The NSW Food Authority thought that the criteria appeared adequate.

Many submitters commented that it is important to only use biomarkers where a causal link with disease has been established (WA DoH, Tas DoH&HS) or at least an assessment of the weight of evidence by an independent panel of experts (National Starch, Solae Comp).

The Uni. of Adel. & Uni. of SA- Nutrition & Physiology Research Grp. stated that use of biomarkers would offer more validity than referring to a disease state alone.

Parmalat Aust. stated that there are no guidelines on assessing evidence for biomarkers. Solae Comp noted that the number of biomarkers recognised by the FDA in the U.S. is limited to three (LDL cholesterol, bone density and blood pressure). NSW DoH thought that there might be differences of opinion as to what constitutes a biomarker.

Several submitters commented on possible consumer perceptions of biomarkers. Both the WA DoH and TCCA believe that consumers should understand the meaning of biomarker claims and their relevance to public health. The Monash Uni - N&D Unit and Dr R. Stanton disputed this referring a FSA report giving evidence to suggest that consumers do not discriminate between serious disease – risk reduction claims and biomarker claims and that considering this it is imperative that biomarkers are given the same level of substantiation weighting as other high level claims. Dr Stanton considers that public understanding of biomarkers should be researched before a standard is put in place. Monash Uni – N&D Unit and Horticulture Aust. supported this view and suggested that it should be demonstrated that significant proportions of the population or targeted subgroups understand the biomarker claim and find the claim relevant. They were concerned that a claim referring a biomarker that is of no concern to the majority of the population has the potential to raise unnecessary fears in consumer and is not permitted under the agreed policy guidelines.

NZ MoH stated that the applicability of health claims to consumers will vary considerably given the relationship between health risk and benefit to consumers will differ based on physiological and environmental factors. Canterbury DHB suggested including practical examples of biomarkers relevant to classifying health claims. NCWA stated that a difficulty in using biomarkers relates to low or high intakes of nutrients.

CSIRO – HS&N, NHF NZ and several industry groups questioned the meaning of 'rigorously evaluated' and 'highly predictive' in relation to the use of biomarkers (Nestle, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust, CMA-NZ Branch, CMA- NSW Branch, CMA- Qld Branch, ICA, CMA-Vic Branch, CM of SA, Dairy Aust).

Nutra NZ believes that the costs associated with validating a biomarker would be financially out of reach of small companies and suggested providing a list of acceptable biomarkers to industry. However, Nestle commented that companies should be able to conduct biomarker research, retain the intellectual property and have subsequent health claims assessed by government.

Uni of Adel. & Uni of SA – Nutrition & Physiology Research Grp. commented that biomarkers were applicable to more than one condition will increase the usefulness as an index of health status. Mention was also made the some diseases more than one biomarker may be relevant, and some to more extent than others (Dr R. Stanton).

Dr Stanton mentioned that disqualifying statements will be important – for example, blood glucose is dependant on amount as well as the type of food consumed.

Both the Fonterra and the NZFGC commented that there were discrepancies between the definition of biomarker in substantiation and in the high level claims framework and this need to be clarified.

GW Foods, Goodman Fielder and National Foods are of the opinion that the word "highly" is subjective and should be removed from the statement highly predictive in relation to substantiation and that the statement should be modified to include that a biomarker should be predicative of a disease or health outcome.

CHAPTER 3: OTHER RELATED CLAIM DESCRIPTORS

3.1 CONTENT CLAIMS

Question 18

Should the descriptor for a 'content claim' refer to biologically active substances or other substances in addition to nutrients and energy?

Out of 147 submitters, 59.9% (88 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	20	4	3	56
Government	6	2	-	-	8
Public health	10	4	-	-	14
Consumers	2	-	1	-	3
Other	5	2	-	-	7

Total	**52**	**28**	**5**	**3**	**88**

Overview

Eighty per cent of submitters (70) agreed that the descriptor for a 'content claim' should refer to biologically active substances or other substances in addition to nutrients and energy. Only four submitters expressed their opposition to the inclusion of biologically active substances or other substances in addition to nutrients and energy.

Discussion of submitter responses

Seventy submitters agreed with the proposed content claim descriptor (Diabetes Aust, DAA, NZDA, GI Ltd, Tomox, Bakewell Foods, DSM Nut. Prod, F&B Importers Assoc., GW Foods, MLA, Parmalat Aust., Sanitarium Health Food Comp, CSIRO – HS&N, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Fonterra, Griffins Foods, Naturo Pharm Ltd, NZ Dairy Foods, Nutra NZ, NZ King Salmon, NZTBC, Unilever Australasia, William Wrigley Junior, ABC, AFGC, Masterfoods Aust. NZ, ASMI, CHC, Dairy Aust., Goodman Fielder, National Foods, PB Foods, NZFGC, NZJBA, Frucor, NZ Magazines, CML, National Starch, Solae Comp, NSW Health, DAFF, TGACC, Nutra-Life Health & Fitness NZ, Tegel Foods, MoH, NZFSA, Hort & Food Research Instit. of NZ, 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.), Masterfoods Aust. NZ, Heinz Aust./Heinz Watties NZ, Nestle, NHF Aust, NHF NZ, Nutrition Aust., Cadbury Schweppes, Horticulture Aust., Wyeth Aust., Crop & Food Research).

Many of these submitters added comments, clarifications or qualifying statements to their approval of a content claim descriptor that referred to biologically active substances or other substances in addition to nutrients and energy. These included reasons for the inclusion of biologically active substances, the deletion or retention of the words 'explicitly' and 'implicitly', clarification of the definition, issues relating to regulation (substantiation, standards or guidelines), a defined list of biologically active substances, reference levels and implied health benefits. These comments are outlined as follows:

Reasons for including biologically active substances

Five submitters acknowledged the growing evidence that ingredients such as phytochemicals (or phytosterols and stanols) were examples of biologically active substances that exerted beneficial biological effects (PB Foods, National Starch, Solae Comp, MoH, Crop & Food Research). As such, they needed to be covered in the same manner as nutrients (Solae Comp.). Crop & Food Research also highlighted the public awareness/interest of these substances.

Other reasons for including biologically active substances were that:

- There was a differentiation between nutrient and biologically active substance in standard 1.2.8 (Nestle);

- The proposed definition of health claim included reference to "food or one of its constituents" (SA DoH);

- They should not be treated differently to other substances because "at this level they are no different in many respects" (Crop & Food Research);

- Consumers were interested in these substances and the view of food had changed from a medium that simply delivered nutrients (Nutrition Aust);

- Consumers could easily access this information, along with the nutritional information (ASA, NPANZ, Assoc. of NZ Advertisers, Naturo Pharm, NZ Magazines, Cadbury Confectionery); and

- Defining nutrient content claims would give consumers confidence in their accuracy and use them to quickly locate foods with the characteristics they desired. [Consumers often saw nutrient content claims as marketing ploys (Anonymous, 1997; McNutt, 1997; Reid and Hendricks, 1993)]. Labelling regulations that clearly defined nutrient content terms could help reduce the risk of misleading nutrition claims (Stehlin, 1993; Silverglade, 1997 (SA DoH).

Use of the words 'explicitly' and 'implicitly'

Ten submitters recommended that the words 'implicitly' and 'explicitly' be removed from the definition (ABC, AFGC, MasterFoods Aust. NZ, ASMI, CHC, Dairy Aust., Goodman Fielder, National Foods, PB Foods, NZFGC).

However, CML suggested that the words 'explicitly' or 'implicitly' remain in the definition (and also be included in the definition of 'claim' on p 27 of IAR). NHF Aust. and NHF NZ recommended removal of brackets around 'explicitly or implicitly' from the content claims definition, in order to capture content claims that have an implication of nutrition content.

Clarification of the definition

Six submitters presented their definitions in full:

- "A general level claim, which describes or indicates the presence or absence of energy, or a nutrient or a biologically active substances in a food". (AFGC, Masterfoods Aust. NZ, Goodman Fielder, National Foods). In addition, National Foods clarified that the descriptor for a 'content claim' was a 'nutrition' content claim and that there should not be disqualifying criteria for a nutrition content claim.

- "A nutrition content claim is a general level nutrition, health and related claim which describes or indicates the presence or absence of energy or a nutrient or a biologically active substance, in a food" (Dairy Aust., Parmalat Aust).

Other comments relating to the wording of the definition were that:

- The term ‘nutrition content claim’ is used, as this is consistent with the current terminology included in Standard 1.2.8 of the Foods Standards Code (Unilever Australasia).

- The definition proposed by European Union be adopted – which includes 'other substances' which are defined as 'substances other than nutrients which have a nutritional or physiological effect'. Substances having a nutritional or physiological effect should be treated in the same way as nutrients, e.g. "low glycaemic load" was no different to "low in fat" (Crop & Food Research).

- The term 'content claim' was too broad. Suggested 'nutrient content' and 'nutrition content' as two distinct claims. For example, "This food contains whey protein concentrate" is a nutrient claim and "This food is high in protein" is a nutrition claim (Aussie Bodies).

In addition, it was noted that biologically active substance claims were covered by the proposed definition of ‘health claim’, which included reference to ‘food or one of its constituents’ (WA DoH).

Regulation: Substantiation, Guidelines and Standards

Twenty-five submitters expressed their viewpoint on regulation of biologically active substances. Twenty suggested or implied that the terms relating to content claims (in Section 5.5 in the IAR) be captured in the Standard in order to set criteria and conditions for content claims (Horticulture Aust, DSM Nut. Prod, 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.), Cadbury Schweppes, Nutrition Aust., NSW DoH, MoH, SA DoH, PHAA (supported by ACA), WA DoH and Monash Uni - N&D Unit).

Cadbury Schweppes asserted the use of the Standard (and not Guidelines or interpretive user guides) so that they became legally binding. In contrast, Crop & Food Research recommended clear regulatory parameters (rather than general provisions in food law and fair trading) as they believed that many would not be informed enough to know what may be misleading and deceptive. Heinz Aust./Heinz Watties NZ also supported the view that criteria for making claims are set out in a Guideline.

Horticulture Aust., NSW DoH, PHAA (supported by ACA), SA DoH, WA DoH and Monash Uni - N&D Unit stated that all claims related to biologically active substances should require the same degree of substantiation and regulation as nutrients. PHAA (supported by ACA), WA DoH, SA DoH and Monash Uni - N&D Unit also affirmed that these substances be captured within the Standard.

NSW DoH and SA DoH both stated that biologically active substances that could not be substantiated should not be permitted. NSW DoH also cautioned careful consideration in the substantiation process of them because there were no officially recognised health reference standards for biologically active substances as well as limited knowledge of the “efficacy of these substances outside their effect within whole food”.

DAFF noted that the appropriateness of their addition to foods would be regulated through other standards and policy guidelines (e.g. fortification with vitamins and minerals and other substances).

NZ MoH recommended that when making claims, the bioavailability of either nutrients or biologically active substances should be substantiated.

NCEFF noted that in the Australian market place there was already wide spread use of claims on foods for a number of biologically active substances or other nutritive qualities. These included wholegrain, antioxidants, lycopene, isoflavones, phytoestrogens, creatine, resistant starch, 'cultures' and glycaemic index. NCEFF expressed a concern that if regulation of such claims was left to general provisions within food law and fair trading, there was likely to be lack of consistency in the levels or conditions regarded by manufacturers as sufficient to justify such claims – as already found for claims not currently covered by food standards (refer reference 21 in submission).

Defining biologically active substances

Four submitters clearly advocated the need to specify a list of acceptable biologically active substances that could be claimed (NHF Aust., NHF NZ, WA DoH and Hort & Food Research Institute of NZ – which also recommended regular updates).

However, two other submitters did not recommend the identification of defined lists although they did agree that biologically active substances should be defined as a term (Tegel Foods, Heinz Aust./Heinz Watties NZ).

Seven submitters recommended that the development of an exclusive list of approved claims (in relation to biologically active substances) would minimise the possibility of misinterpretation (Horticulture Aust., PHAA (supported by ACA), Tas DoH&HS, SA DoH, WA DoH and Monash Uni - N&D Unit).

Tas DoH&HS also noted that additional substances should be considered on a case-by-case basis to avoid spurious content claims that are general level claims but that imply benefit without substantiation.

Reference levels

Twelve submitters expressed concerns around the issue of establishing a process for measuring biologically active substances and identifying levels that were effective before claims were permitted (NZFSA, Wyeth Aust., Crop & Food Research, Nutrition Aust., PHAA (supported by ACA), SA DoH, WA DoH, Naturalac Nutrition, Monash Uni - N&D Unit and NHF Aust. supported by NHF NZ). Points noted were:

- The need to develop a list of reference levels to ensure that content claims were not made when the amount of bioactive substance present was not clinically significant (Wyeth Aust., Nutrition Aust). For example,

phytochemicals and synergies between certain nutrients such as lycopene and beta-carotene (Wyeth Aust.);

- The mere presence of a biologically active substance should not be sufficient to allow a claim. However, like nutrients, they would need to be in a certain concentration as determined by a review of the evidence for their effectiveness (PHAA (supported by ACA), SA DoH, Monash Uni - N&D Unit and WA DoH);

- If a claim was made in relation to a biologically active substance then the quantity present in the food should be clearly stated. This requirement should also apply to whole ingredients, but may be covered by provisions such as percentage labelling and some specific situations such as Std 2.9.4(4) (Naturalac Nutrition);

- The claim that 'low' or 'high', informed consumers what they were, but did not indicate what effect they would have on health (Crop & Food Research);

- The difficulty of making claims about whether it was a 'source' or 'good source' because the information was not necessarily available (Nutrition Aust.); and

- The lack of generally agreed recommended 'intakes', which made it difficult to determine minimum levels (criteria) suitable for making content claims (NHF Aust. and NHF NZ).

Nutra-Life H&F believed that descriptors could be misleading if given without qualification or comparisons. For example, 'contains colostrum' should specify how much, why, what for, etc.

Nutrition Aust. identified bioavailability as a related issue, which also applied to added nutrients. Auckland Reg. PHS suggested that nutrients, for which a content claim was made, should be in bioavailable form. Dr R. Stanton considered that biologically active substances needed evidence of bioavailability and functionality for the quantity being added.

PHAA (supported by ACA) and SA DoH also referred to Ashwell (2001) in considering aspects of bioavailability. The point quoted was that "nutrient content claims … should be based not only on evidence for presence of the component in the food but also on scientific evidence using markers of exposure that indicate biological accessibility of the active component, such as its delivery to the intestine or its absorption through the intestinal wall and into the relevant cells, as appropriate". Monash Uni - N&D Unit also quoted Ashwell (2001) re biological accessibility of the active component.

Implied health benefits

Six submitters commented on related health benefits:

- Hort & Food Research Institute of NZ noted that many foods contain a complex array of components that are bioactive and therefore have the potential to influence health;

- Nutrition Aust. mentioned that content claims for biologically active components could be seen as an implied health claim; and

- Dr R. Stanton suggested that since the presence of a biologically active substance might be seen by consumers as implying a health benefit, it was a strong reason for having pre-approved claims – which could include biologically active substances for which adequate evidence of efficacy exists. Dr Stanton noted that following the experience in other countries, many food companies were likely to want to add biologically active substances to foods once the new regulatory framework for nutrition, health and related claims was in force.

However, the other three submitters clearly stated that health benefits should not be implied by including biologically active substances in a food (ASMI, CHC, TGACC).

- ASMI and TGACC noted this in terms of selective formulation and declaration of other biologically active ingredients in the absence of information about the context of the substance with regard to total diet; and

- CHC stated that implied health benefits should not be made from selective formulating on non-validated or substantiated biologically active ingredients that add no benefit to the consumer's health. They added that all content claims should be fully substantiated and monitored.

Other comments

Further comments were made by two submitters who agreed to the inclusion of biologically active substances in the descriptor for a content claim:

- Wyeth Aust. noted that as functional foods became more widely available, claims of this nature would likely increase; and

- Crop & Food Research noted that for nutrients there was a reliance on people's knowledge about the nutrient. However, a statement like "this food has a low glycaemic load which may help to maintain healthy blood glucose levels and a healthy weight" is not different to a statement such as "this product is high in calcium, which is important for building strong bones". Both are general level claims and both should meet the same requirements.

Crop & Food Research also discussed the issue of clearly defined and validated Virtual Food Components (VFCs) that:

- Should be allowed as they represented effects (rather than substances) expressed in terms of the amount of reference substance required to produce an equal effect;

- Provided information to overcome the problem that there were important food activities related to health that could not be expressed by nutrient content date, and which were misrepresented by current nutrient thresholds for nutrient claims;

- Did not make a health claim but communicated information in a format compatible with food content information so that nutrient information could concurrently express not only what a food was, but also what it did and how well it did it. Therefore, VFCs would have an important future role in modern nutrition management systems;

- Should appear on food labels with the same level of regulation as content claims; and

- Requested consideration is given to the potential public health benefit of VFCs when developing the new Standard.

Crop & Food Research attached additional notes to their submission regarding information on VFCs and associated research. Cadbury Schweppes stated that Appendix 6 did not adequately describe the criteria and conditions for biologically active substances and further work was required in this area.

Ten submitters did not clearly state whether they agreed or disagreed with a content claim that referred to biologically active substances or other substances in addition to nutrients and energy (Dr R. Stanton, PHAA (supported by ACA), Tas DoH&HS, NSW DoH, SA DoH, WA DoH, Monash Uni-N&D Unit, Naturalac Nutrition, NCEFF).

However, many of their comments supported those raised by submitters who clearly stated that they agreed with the proposed content claim descriptor. Therefore, comments by the above nine submitters were included in the previous section.

Four submitters disagreed that a 'content claim' should refer to biologically active substances or other substances in addition to nutrients and energy (TCCA, Food Tech. Assoc. of Vic., Public Health South and Mainland Products)

More specifically, TCCA clarified that content claims should only describe the presence or absence of nutrients. Mainland Products believed that food law should limit this definition to nutrients and energy.

TCCA and Public Health South both expressed concern about the issue of misleading claims, noting that:

- The understanding of what biologically active substances are and their effects was low among consumers. Allowing claims in relation to biologically active substances or other substances in addition to nutrients and energy would be confusing and misleading (Public Health South);

- Content claims such as ‘fat free marshmallows’ are sufficiently misleading in that they imply that by the absence of one micronutrient (e.g. fat) that the product is healthy and subsequently can be eaten in large quantities without associated adverse health effects. A further expansion of claims that could be made under the category of ‘content claim’ would further increase the capacity of food marketers to make misleading claims (TCCA); and

- An alternative approach would be to make full disclosure mandatory. Food products making a content claim (e.g. reduced salt) should also be required to report – equally prominently – the measures of energy and fat content. Consumers would then be more meaningfully informed about the product content (TCCA).

TCCA also expressed concern about content claims relating to the presence of phytochemicals (e.g. lycopene) where there was a very real risk of an implied health claim.

Food Tech. Assoc. of Vic. commented that “this question as with many others in the proposal is not easily understood and hence difficult to interpret and answer”. They noted that all nutrients and most substances found in food or added intentionally to food are biologically active at some level and questioned what TGA’s reaction would be to this question.

Three other submitters made comment in response to this question as follows:

- No claims should be allowed, due to risk of misinterpretation of claims by consumers. Standards governing nutrient and energy declarations should be sufficient to allow labels to convey accurate and unambiguous messages to consumers regarding content (Dr C. Halais);

- They supported the use of a 'content claim' descriptor (Uni of Adel. & Uni of SA – Nutrition Physiology Research Grp.); and

- Where content claims referred to products being ‘free-from’ allergens, and if such claims were to be considered health and nutrition claims, they referenced a serious disease (allergy/anaphylaxis) so would not be a general level claim under this descriptor. Gluten free claims referenced celiac disease, which is a serious disease of the gastrointestinal tract (Allergy NZ & Anaphylaxis Aust.).

Other comments regarding the issue but not in direct response

AFGC and Masterfoods Aust. NZ recommended the use of the term nutrition content claim be the descriptor for a content claim, as these would be inclusive of nutrient, energy and biologically active substances, as defined in Standards 1.2.8 for nutrition claim. They also noted:

- The terms ‘explicitly or ‘implicitly’ in all descriptors unnecessarily complicated interpretation of the claim descriptor, creating difficulty for industry and enforcement agencies. The interpretation of an implied claim was

likely to fall under Section 52(1) of the TPA where the relevant test is whether the consumer was mislead or deceived;

- The presence of the words 'explicitly' or 'implicitly' would not assist in the courts interpretation of the regulation, where the relevant test is whether the consumer was mislead or deceived (AFGC and Masterfoods Aust. NZ).

Kellogg's Aust. noted that content claims should not only be restricted to nutrients but also permissible for ingredients and biologically active substances.

Lazarus Scientific Research stated that 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).

Unilever Australasia supported the use of the term 'nutrition content claim' as this was consistent with the current terminology included in the Foods Standards Code Standard 1.2.8 and would include nutrients, energy and biologically active substances.

GW Foods considered that the words 'explicitly' and 'implicitly' should not be included in the definition.

GW Foods supported the term 'nutrition content claim' and agreed that a nutrition content claim is a type of general level claim.

3.2 HEALTH CLAIMS

Question 19

Do you agree that in accordance with the FSANZ claims Classification Framework all claims other than content claims are health claims?

Out of 147 submitters, 55.1% (81 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	18	5	2	52
Government	6	2	-	-	8
Public health	10	3	-	-	13
Consumers	2	-	-	-	2

Other	5	1	-	-	6
Total	**50**	**24**	**5**	**2**	**81**

Overview

Almost sixty per cent of submitters (48) agreed that in accordance with the FSANZ claims Classification Framework all claims other than content claims were health claims. Thirteen submitters either opposed the concept of having a separate definition of a health claim or disagreed that all claims other than a content claim were health claims.

Discussion of submitter responses

Forty-eight submitters agreed with the statement that all claims other than content claims were health claims (Diabetes Aust., DAA, NZDA, Dr C. Halais, Dr R. Stanton, GI Ltd, Nutrition Aust., Tomox, Aussie Bodies, Bakewell Foods, Cadbury Schweppes, Horticulture Aust., National Starch, Solae Comp., DAFF, CSIRO-HS&N, Uni of Adel. & Uni. of SA – Nutrition Physiology Research Grp., Auckland Reg. PHS, NZ Dairy Foods, Nutra-Life Health & Fitness NZ, NZFSA, Crop & Food Research, ASA, Cadbury Confectionery, NZTBC, NPANZ, Assoc. of NZ Advertisers, WA DoH, NSW DoH - N&PA Branch, Griffins Foods, NZ Magazines, MoH, NCWA, TCCA, NHF Aust, NHF NZ, PHAA (supported by ACA), CML, Dairy Aust., DSM Nut. Prod., Sanitarium Health Food Comp., Wyeth Aust., SA DoH, Monash Uni -N&D Unit, NZ V&P Fed/NZFG Fed, Tegel Foods and Heinz Aust./Heinz Watties NZ).

Provisos to agreeing that all claims other than content claims are health claims included:

- The assumption that they related to health (NZ Magazines, ASA. Cadbury confectionery, NZTBC, NPANZ, Assoc. of NZ Advertisers);

- The consideration that some content claims are implied health claims (Dr R. Stanton and TCCA). Examples cited of implied health claims included '99% fat free', yoghurt promoting its content of a biologically active substance, and other content claims relating to the presence of biologically active substances e.g. phytochemicals like lycopene. Dr R. Stanton clarified that the addition of biologically active compounds should not be permitted unless there was a clear proven benefit – at the levels added;

- The declaration of health claims on packaging only (not dietary advice) – with allowance made for education strategies, which provided adequate information for consumers to make informed choices. It was noted that " well-executed dietary advice should not be construed as a health claim" (Refer Q3/NZ V&P Fed/NZFG Fed.); and

- Although Tas DoH&HS did not agree that all claims other than content claims are health claims they stated that the health claims definition implied application to nutrition education materials not produced by food manufacturers e.g. National Health Foundation, Cancer Councils etc. It needed

clarification as this had significant implications regarding substantiation of claims. The question was raised that if nutrition education material was excluded, how did this fit with information sheets produced by manufacturers or supported by manufactures?

Reasons for agreeing that all claims other than content claims are health claims were that:

- Health was not just treating or reducing disease risk, but also involved maintenance of normal body responses (Sanitarium Health Food Comp.);

- This was consistent with the Policy Guideline. It would mean that all claims were considered in the context of the total diet, with the exception of content claims (DAFF);

- This classification was consistent with the Codex Draft Guidelines for Use of Nutrition and Health Claims (2004) (Dairy Aust., DSM Nut. Prod.).

However, Dairy Aust. added that it was inconsistent with the Policy which suggested the classification should be as general level claims and high level claims divided on their proposed risk to public health and safety (general level claims: low risk and high level claims: high risk).

Deleting words from the descriptor

It was recommended that the words 'explicitly or implicitly' be deleted from the definition (NZJBA, Frucor). This was supported by six other submitters who did not agree with the statement that all claims other than content claims were health claims, but suggested that if a health claim term needed to be defined then the wording 'explicitly or implicitly' be omitted from the definition (F&B Importers Assoc., AFGC, Masterfoods Aust. NZ, Parmalat Aust., CHC and TGAC).

Additional points concerning clarification of a health claim descriptor included:

- Reservations about the 'other general level claims' category (NZ MoH);

- The suggestion that if all other claim types were defined there might not be a requirement for a health claim definition (SA DoH, Monash Uni -N&D Unit);

- A recommendation that the words 'within the context of the total diet' be added to the definition (CML). It was also noted by CHC and TGACC that the descriptor did not reference the context of a total diet; and

- The suggestion that health claims may also be interpreted as therapeutic claims, "which rendered the qualifier 'other than a therapeutic claim' obsolete" (Wyeth Aust.).

Biologically active substances

- The specific reference to biologically active substances to be included in the health claim definition and not simply refer to "food or one of its constituents" (WA DoH, NSW DoH, PHAA (supported by ACA), Monash Uni -N&D Unit).

Function claims

- The need to include specific reference to function claims in the health claim definition and not simply refer to "food or one of its constituents". Traditionally Health claims have not included function claims (SA DoH, Monash Uni -N&D Unit).

Usage of 'health'

- The concern that the definition of 'health claim' could be interpreted to mean that the word 'health' or similar e.g. 'healthy' in product names or company logo, is to be restricted. It was recommended that neither restriction nor any covering by the claims standard be placed on the use of 'health' (or variations) in trade names or trademarks. A request was made to clarify this point. The comment was also made that trade names and trademarks are covered by existing Fair Trading law, and require substantiation (Sanitarium Health Food Comp.).

  Sanitarium Health Food Comp noted the incorporation of 'health' e.g. Soy Healthy sausages in their existing products and that their logo incorporated the words 'The Health Food Company' dating back to the late 1800s. If restrictions were imposed on the use of 'health' it was requested that they did not have a retrospective effect.

Content claims

- The recommendation that the health claim definition explicitly excludes content claims, as this is unclear (Tegel Foods, Heinz Aust./Heinz Watties NZ).

Other comments noted:

- A recommendation that general level claims is pre-approved (NHF Aust, NHF NZ);

- The requirement for some consumer education as there might be confusion about the differences between health and content claims (NCWA). In particular, the urgent need to research the interpretation of content claims by consumers (TCCA);

- The lack of clarity as to why there needed to be differentiation in the framework when there are three classifications from a regulatory perspective – general, high and therapeutic (Griffins Foods); and.

- The view that terminology was not as important as giving explicit direction to industry and enforcement agencies on appropriate claims (NHF Aust, NHF NZ).

Prohibiting general level claims on infant foods

Heinz Aust./Heinz Watties NZ mentioned that general level claims are not regarded as health claims under Standard 1.1A.2 Transitional Standard – Health Claims, health claims defined as per Clause 3a-e. Health Claims as defined by this standard are not permitted on foods including those standardised in Standards 2.9.1, 2.9.2 and 2.9.4. They also commented that:

- Heinz Watties and major competitor Golden Circle currently make general level claims on some infant foods and infant food advertising (examples attached to submission);

- Consideration was sought on the impact of prohibiting general level claims on infant foods labels and advertising – if proposed definition of health claims continues to include general level claims. (It was noted that The Policy Guideline suggesting exclusion of certain categories of foods was probably based on the Transitional Standard);

- Iron was important in infant food e.g. infant cereal fortified with iron. General level claims about iron fortified infant cereal also provided education and ensured carers were informed when choosing foods that might be useful in providing iron;

- In categories such as infant formula – where advertising direct to consumers is prohibited – labels contain sufficient information to enable informed choice. It was suggested that general level claims might also communicate the reason for the presence of certain ingredients in various infant formulas.

Four submitters specifically rejected the statement that all claims other than content claims are health claims (Food Tech Assoc. of Vic., National Foods, Nutra NZ and Unilever Australasia). Comments relating to this were that:

- The subdivision of general level claims was inconsistent with Ministerial guidance for a two-level system of high level claims and general level claims. It was noted that all claims must be substantiated and the management of general level claims should be commensurate with risk, i.e. all general level claims should be managed as low risk (National Foods, AFGC, Masterfoods Aust. NZ, Parmalat Aust);

- Nutrient function claims under the current system were not health claims, as they did not relate to a health outcome. This was viewed as inconsistent with COAG principles regarding minimum necessary regulation (National Foods). Three submitters clarified that function claims were about actions in the body of the nutrient or nutritional component and did not relate to a health outcome, yet had been arbitrarily assigned as a 'health claim' (AFGC, Masterfoods Aust. NZ and Parmalat Aust); and

- There was no demonstrated regulatory requirement to distinguish between content claims and other general level claims (NZJBA, Frucor, AFGC, Masterfoods Aust. NZ, Parmalat Aust). In addition, the intent of a regulatory regime for health claims was that there be general level claims and high level claims, the management of which would be dependent on risk (NZJBA, Frucor). This view was similarly endorsed by Goodman Fielder who considered the diagram separating claims into content, general level and high level was inconsistent with Ministerial guidance –, which suggests there should be high level claims and general level claims. Goodman Fielder also agreed that the management of general level claims should be commensurate with risk, i.e. all general level claims should be managed as low risk.

A health claim was also described as "a relationship between a food and health in the context of the appropriate diet" (ABC). AFGC, Masterfoods Aust. NZ, Parmalat Aust. and Nestle shared this viewpoint and they clarified that it was not a relationship between diet and health, as suggested by FSANZ.

Another nine submitters specifically opposed the proposal of a separate definition of a 'health claim' (ABC, NZJBA, Frucor, AFGC, Masterfoods Aust. NZ, Parmalat Aust., F&B Importers Assoc., Goodman Fielder and Mainland Products).

Reasons for this opposition were that: there was no need for the additional definition (F&B Importers Assoc.), the term would become redundant under the new framework (Mainland Products) and health claims were already defined under nutrition, health and related claims (National Foods, ABC, NZJBA, Frucor, AFGC, Masterfoods Aust. NZ and Parmalat Aust).

Twenty other submitters made comments which related mostly to the more subtle distinctions between the claims classification framework terms relating to content, other general level claims, high level claims and health claims, (NCEFF, CHC, MLA, PB Foods, Tas DoH&HS, NSW Food Authority, TGACC, Fonterra, 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] and Nestle).

Thirteen submitters stated that not all of the claims would be health claims in accordance with the proposed definition of 'health claims'. Points noted were that:

- The proposed definition of health claims was ambiguous as the term 'health' was left open to interpretation (Fonterra);

- Content claims and some function claims were not necessarily health claims, as they did not always denote a health outcome. For example, mint freshens

your breath or glucose assists with brain function/concentration (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). MLA also supported the view that function claims did not relate to a health outcome, so they should not have the same regulatory requirement as a health claim;

- A nutrient function claim was a claim about the action of the nutrient within the body. It did not necessarily indicate a health outcome and would therefore not necessarily be a 'health claim' (Nestle); and

- Claims such as 'good for you' or 'nutritious' should not be considered claims that fall under this framework, but are general marketing terms to be regulated according to fair trading law. Beyond this, there is little benefit in distinguishing health claims from other claims such as content claims (Fonterra).

Other comments about the health claims descriptor were that:

- The definition was not fully explanatory, as the word 'health' was not further defined (PB Foods).

- The definition already made it clear that the claim based on 'consumption of a food' differentiated it from medicinal use. Therefore, the specific differentiation from a therapeutic claim might not be accurate when the health outcomes were the same. (TGACC).

NCEFF discussed issues concerning industry and consumer perceptions in which:

- The claims classification appeared logical from a scientific point of view and appropriate for regulation. However, consumers were unlikely to be conscious of subtle distinctions between content, function and risk reduction claims;

- Studies indicated that a hierarchy of claims based on a scientific structure did not correspond to consumer response. Increasing the strength of claims did not automatically increase the level of benefit perceived by the consumer/ submission reference 7, 22-24; and

- The trend in the USA for manufacturers was to use content and function claims rather than risk reduction claims because they were easier to substantiate and more appealing to consumers

Another comment about the framework was that the framework did not make allowances for comparative quality claims (CHC).

Some submitters recommended care be taken in wording health claims

It was recommended that care be taken in wording the clause that 'claims other than content claims', such as organic, be excluded from this definition. Other examples included free range and no added hormones (Tegel Foods) and suitable for

vegetarians, natural, wholesome, nourishing, pure, comfort foods and fresh (Heinz Aust./Heinz Watties).

Nutra NZ stated that claims based on sensory properties (e.g. mouth feel, creaminess, flavour) were not health claims and therefore should not be excluded or overlooked as product claims.

NSW Food Authority suggested that 'claim' might refer to the physical characteristics of a product which lie outside the scope of this standard, e.g. colour or flavour of a product (e.g. light olive oil) and other 'quality' descriptors, which may be misconstrued as implied health claims. This needed to be taken into account in the definition.

A recommended definition by Fonterra and PB Foods was that health claims be related to 'general level' or 'high level claims' that "describe or indicate a relationship between the consumption of a food, a category of food or one of its constituents and the human body". Fonterra also highlighted the link to the human body, which encompassed the consideration that a benefit should be specific before it came under the proposed framework.

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

ACA stated that pictures and graphics must also be included in the definition of a health claim as they could convey a health benefit as well as any written claim. This was consistent with other areas of the Food Standards Code that stated that a label must not carry pictures or graphics that implied the presence of ingredients when that ingredient was not in the product.

NSF stated that the definition of health claims needed to be examined to allow for the discussion of the relationship between nutrition and health to be outlined in programmes providing educational opportunities. For example, University lectures, or in Evidence Based Clinical Guidelines and their accompanying consumer material that might be prepared by organisations such as health related government and non-government bodies.

Campbell Arnott's Asia Pacific stated that health claims other than content claims be made in relation to biologically active substances.

ACDPA stated that the definition of 'health claim' should be tightened. It is critical that this definition does not lead to health education, (e.g. a university lecture on the link between diet and chronic disease) or materials published in evidence-based clinical guidelines and accompanying consumer material by organisations such as the Australian Government and ACDPA member organisations being regarded as health claims, as appears possible under the current definitions.

Responses from Naturo Pharm to question 71 also refer to the equity between foods and therapeutic products/claims.

3.3 FUNCTION CLAIMS

Question 20

Should claims other than content claims (that is, health claims) be made in relation to biologically active substances?

Out of 147 submitters, 57.8% (85 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	2	54
Government	5	2	-	-	7
Public health	10	5	-	-	15
Consumers	2	-	-	-	2
Other	5	2	-	-	7
Total	**51**	**27**	**5**	**2**	**85**

Overview

Eighty-eight per cent of submitters (75) agreed that claims other than content claims (i.e. health claims) should be made in relation to biologically active substances. Most added provisos with regard to substantiation or gave clarifying statements to their responses. Another three submitters that implied agreement and two clearly did not.

Discussion of submitter responses

Twenty-two agreed without further comment that claims other than content claims (i.e. health claims) should be made in relation to biologically active substances (Diabetes Aust., GI Ltd, Aussie Bodies, MLA, National Starch, Parmalat Aust., CSIRO-HS&N, Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp., Auckland Reg. PHS, NZ Dairy Foods, NZFSA, Nutra NZ, Mainland Products, WA DoH, Solae Comp, Bakewell Foods, Hort & Food Research Instit. of NZ, Tomox, NCEFF, GW Foods, ABC and NZFGC).

However, the majority of submitters agreed that claims other than content claims (i.e. health claims) should be made in relation to biologically active substances, subject to adequate substantiation (Naturalac Nutrition, F&B Importers Assoc., PB Foods, NHF Aust., NHF NZ, CML, Unilever Australasia, NSW DoH – N&PA Branch, Griffins Foods, Fonterra, Crop & Food Research, MoH, 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.), NSW Food Authority, Nutra-Life Health & Fitness NZ, Cadbury Schweppes, Horticulture Aust., Nutrition Aust., Monash Uni. – N&D Unit,. National Foods, PHAA (supported by ACA), AFGC, Masterfoods Aust. NZ, Dairy Aust. Goodman Fielder, SA DoH, CHC, DAA, NZDA, ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZTBC, DSM Nut.Prod, Wyeth Aust. Food Tech. Assoc of Vic., NZJBA, Frucor, Nestle, Sanitarium Health Food Comp, and Heinz Aust./Heinz Watties NZ).

Wyeth Aust. stated that in addition to substantiation, these health claims needed to be true and not misleading or deceptive. Other submitters raised further points with regard to substantiation of a health claim in relation to biologically active substances. These included the relevance to general and high level claims, examples of biologically active substances, reference levels and an approved list of claims.

Substantiation relevant to general level and high level claims

TCCA stated that health claims relating to biologically active substances should not be allowed in any category other than a high level health claim. They believe that an expansion of content claims, such that content relates to biological mechanisms, will be universally interpreted as a health claim (TCCA).

It was noted that function claims are an important aspect to include (Nutra NZ) and Industry would want to make function, enhanced function and high level claims in relation to biologically active substances (Monash Uni. – N&D Unit, PHAA (supported by ACA), WA DoH and SA DoH). The latter two added that the classification of claims would depend on the type of claim made.

Another submitter supported the view that function claims should be regulated in the same way as high level claims (Northland Health Dietitians).

Substantiation related to listing ingredients

Seven submitters agreed that health claims could be made – at the discretion of the manufacturer or advertiser – in relation to biologically active substances if the substances were listed as ingredients (ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZTBC and NZ Magazines).

Examples of biologically active substances were cited by other submitters as follows:

- Antioxidants (National Foods, 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.);

- Isoflavones (National Foods, AFGC, Masterfoods Aust. NZ, Dairy Aust.);

- Omega 3 (National Foods, Dairy Aust.).
- Lycopene (AFGC, Masterfoods Aust. NZ, Dairy Aust, Heinz Aust./Heinz Watties NZ);

- Non-culinary herbs (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.);

- Probiotics (National Foods, Fonterra); and

- Stanols (NZ MoH).

National Foods stated that they had invested significant capital to launch Yoplait Optimal probiotic drink (with anti-oxidants) – one of their food products manufactured with biologically active substances.

MoH noted that health claims made in relation to biologically active substances should be made if the content of the substance was able to be easily defined

Heinz Aust./Heinz Watties NZ noted that they currently make general level claims regarding lycopene.

Reasons why health claims should be made in relation to biologically active substances.

The reasons ranged from the fact that they should simply be part of it (Bakewell Foods) to statements that biologically active substances may potentially (and positively) influence health (Hort & Food Research Instit. of NZ and Solae Comp.) and as such, should be regulated within the health claims framework (Solae Comp.).

It was also noted that biologically active substances were defined in Standard 1.2.8 as a substance 'other than a nutrient' with which health effects are associated. Therefore, it was appropriate to be able to claim those substantiated health effects for these substances (Nestle).

Other reasons were that:

- These claims provide the consumer with access to current scientific knowledge (NCEFF);

- Health claims for biologically active substances should not be treated any differently from other health claims. They need equal proof of efficacy and there is no theoretical reason why they should not be included in a list of pre-approved health claims in the Standard However, in practice, few biologically active substances would be included because adequate proof of efficacy and bioavailability may not be available (Dr R. Stanton);

- The danger of allowing content claims without health related claims is that the content of biologically active substances could be declared without the requirement to hold evidence that such fortification is of any real dietary benefit (ASMI, TGACC). It was also noted that if health related claims were made in relation to biologically active substances it would assist in holding sponsors accountable for the formulation rationale and dietary evidence (ASMI); and

- It made the practice of declaring ingredients without stating the purpose difficult to justify if other products were making such claims. An argument could then be mounted that consumer understanding of the presence of a particular ingredient translates to an implied health benefit (ASMI).

A number of submitters expressed their views concerning the regulation process. This included the notion that biologically active substances posed a challenge for the

substantiation process, that they might fit as novel foods and that there were consequences to imposed restrictions.

Four submitters stated that the science relating to the effects of biologically active substances had not been well developed (PHAA (supported by ACA), Nutrition Aust., WA DoH and SA DoH). It was suggested that these substances might fit within Standard 1.5.1 Novel Foods. As such, pre-market approval would be required and, potentially, criteria and conditions governing their use (PHAA (supported by ACA), Nutrition Aust, Monash Uni. – N&D Unit and SA DoH).

There were suggestions that these claims be regulated under the Fair Trading Act/Trade Practices Act (Mainland Products) and other standards and policy guidelines e.g. fortification with vitamins and minerals and other substances (DAFF).

There were comments that all claims about biologically active substances should require the same degree of substantiation and regulation as nutrients and energy (Horticulture Aust., Wyeth Aust.). NSW Food Authority and Heinz Aust./Heinz Watties NZ also stated that claims should meet all specified criteria in the policy guidelines.

It was also pointed out that substantial scientific evidence should not only be related to a potential benefit but that there was no evidence of potential harm (Crop & Food Research).

The issue of consequences of a regulation – which restricted claims about biologically active substances – was raised by National Foods who stated that:

- It would severely damage their capability to deliver innovative food choices and restrict investment in the research and development of commercial food products; and

- Prohibition on nutrition claims (for biologically active substances) would have a significant economic impact on National Foods (refer to submission for details of implications).

Some submitters made comment about reference standards, reference levels or an approved list of health claims, (in relation to biologically active substances).

These included the following points:

- Health reference standards are needed to set criteria for content claims (Horticulture Aust.);

- Health reference standards are needed for biologically active substances in order to set criteria for use (WA DoH, SA DoH);

- There must be evidence that the level present or that is likely to be consumed, will in fact influence health outcome (Nutra-Life Health & Fitness NZ);

- Unless the food is for a 'special purpose' there is unlikely to be any specifications regarding dosage, frequency etc. (Nutra-Life Health & Fitness NZ); and

- Consumers should be informed of the existence and concentration of a particular substance in a food and indicate the possible effect on health that may occur (Hort & Food Research Institute of NZ).

Six submitters also recommended that a list of approved substantiated claims, in relation to biologically active substances, be included in the Standard and all others to be prohibited. (Horticulture Aust., NSW DoH – N&PA Branch, Monash Uni. – N&D Unit, PHAA (supported by ACA), SA DoH and Dr. R. Stanton).

Specific provisos to permitting health claims being made in relation to biologically active substances

CHC stated that these claims should be made in the context of the daily diet, the manufacturer holding the evidence to support the claim and consumers not being misled onto believing that a biologically active substance can deliver unrealistic or unsubstantiated health benefits.

DAA and NZDA considered these health claims be made as long as there was proven efficacy of the substance, the quantity in the food would have a physiological effect when eaten under normal circumstances e.g. one serve per day, and that the substance was biologically available.

NCWA agreed that these claims be made only if they resembled the examples provided (FSANZ notes that these examples do not relate to biologically active substances).

Other general comments

Nutrition Aust. stated that it would depend on the type of claim being made as to whether health claims should be made in relation to biologically active substances.

It was noted by Goodman Fielder that health claims made in relation to biologically active substances was another opportunity for manufacturers to market the product benefits or health messages to consumers – which would assist them in their purchasing decisions.

SA DoH recommended that unless <u>any</u> type of claim in relation to biologically active substances can be fully substantiated, it should not be permitted. They quoted Ashwell (2001): "nutrient content claims…should be based not only on evidence for presence of the component in the food but also on scientific evidence using markers of exposure that indicate biological accessibility of the active component, such as its delivery to the intestine or its absorption through the intestinal wall and into the relevant cells, as appropriate".

Food Tech. Assoc of Vic. requested that examples be provided and questioned what was excluded as well as what was the relationship between the terms 'biological' and 'pharmacological'? They also stated that <u>all</u> claims would have to be substantiated.

Tomox suggested that some explanation for roles is needed.

Seven submitters stated "It could be a different story when the product is promoted by a supermarket further down the line, for instance, who may want to enhance the product's purpose by making a claim. This could be at odds with the category the product is considered to be in". They believed that this issue should be covered in an Advertising Code of Practice, which would give the ability to ensure that claims made were in accordance with the manufacturer's wishes (ASA, NPANZ, Assoc. of NZ Advertisers, Cadbury Confectionery, Naturo Pharm, NZTBC, NZ Magazines).

Two submitters clearly disagreed with the statement that health claims be made in relation to biologically active substances (Dr. C. Halais, Canterbury DHB).

Other comments regarding the issue but not in direct response to Question 20

Tas DoH&HS noted the following points concerning health claims made in relation to biologically active substances and the substantiation process:

- Function, enhanced function or high level claims would only be permitted if these claims were adequately substantiated;

- In addition to evidence of the level of the biologically active substance in the food, there should be evidence of the bio-availability of these substances and also the level required for them to have a bioactive effect – to ensure claims regarding biologically active substances are not misleading or deceptive;

- The concern that the fortification of food with vitamins and minerals and other biologically active substances (standards not yet completed) would enable health claims to be made on foods of limited nutritional value; and

- That a list of approved, substantiated claims in relation to biologically active substances could be included in the Standard and all other claims prohibited.

SA DoH recommended the Canadian approach be adopted which allows only content claims for biologically active substances and prohibits health claims being made.

Kellogg's Aust. supported that nutrition health and related claims could be made for biologically active substances where there was scientific evidence to support the claims.

Question 21

Do you agree with the descriptors for a function claim and an enhanced function claim?

Out of 147 submitters, 55.1 % (81 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	4	2	51
Government	6	2	-	-	8
Public health	10	3	-	-	13
Consumers	2	-	-	-	2
Other	5	2	-	-	7
Total	**51**	**24**	**4**	**2**	**81**

Overview

Nearly 30 per cent of submitters (22) agreed with the descriptors for a function claim and an enhanced function claim. In addition, 43 submitters agreed subject to provisos, which mostly related to the addition, deletion or replacement of words in the brackets of the descriptors. Another five submitters, who agreed with the proposed definitions, also questioned the practical value in differentiating between the two descriptors. Eight submitters stated that they did not agree with the descriptors for a function and an enhanced function claim. It should be noted that the majority of submitters who agreed with the definitions focused mostly on the descriptors themselves, while those who disagreed, focussed on wider issues and opposed the need for function and enhanced function sub-categories.

Discussion of submitter responses

Twenty-two submitters agreed with the descriptors for a function claim and an enhanced function claim (NCWA, DAA, NZDA, Tomox, Aussie Bodies, National Starch, Solae Comp, Wyeth Aust., Uni. of Adel. & Uni of SA – Nutrition Physiology Research Grp., Auckland Reg. PHS, ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery, Naturalac Nutrition, NZ Dairy Foods, Hort & Food Research Instit. of NZ and CML who noted that although the descriptors were satisfactory, the word 'normal' may need to be defined).

Forty-three submitters agreed with the proposed descriptors for a function claim and an enhanced function claim, subject to specific provisos (Nutrition Aust., NSW DoH, Tas DoH&HS, Sanitarium Health Food Comp, MLA, NZFGC, NZJBA, Frucor, CHC, ASMI, TGACC, F& B Importers Assoc., PHAA (supported by ACA), NCEFF, NZFSA, SA DoH, WA DoH, Monash Uni. – N&D Unit, Parmalat Aust., Dairy Aust., GW Foods, Goodman Fielder, National Foods, Nutra NZ, Crop & Food Research, Nestle, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA, CMA-Vic Branch and CM of SA, AFGC, Masterfoods Aust. NZ, ABC, Unilever Australasia, NHF Aust., NHF NZ).

Most provisos related to clarification of the exact wording of the descriptors (deletion, retaining and/or replacement of words in the brackets) as follows:

<u>Both descriptors</u>

- Inclusion of all words in brackets (Nutrition Aust., NSW DoH, Tas DoH&HS, Sanitarium Health Food Comp.);

- Inclusion of 'explicitly or implicitly' and 'normal' (PHAA (supported by ASA), SA DoH, WA DoH, Monash Uni. – N&D Unit);

- Deletion of 'explicitly or implicitly' only MLA stated that the inclusion was unclear. (Note that although Fonterra did not agree with the need for the sub-category levels of the descriptors, they described the descriptors as "reasonable", adding that 'explicitly or implicitly' were not useful and should be removed);

- Deletion of the word 'implicit' but retaining 'explicit'. It was stated that it was probably not feasible to expect this framework to fairly manage implicit claims, adding that dietary guidelines could be seen as making implicit health claims (NCEFF);

- The deletion of 'explicitly or implicitly' and 'normal', but retaining 'or a biologically active substance' (NZFGC, NZJBA, Frucor);

- Deletion of words 'explicitly or implicitly' but retaining 'normal' and 'or biologically active substance'(CHC, ASMI, TGACC, NZFSA). A reason for deleting 'explicitly or implicitly' was noted – the reference to "implication" which is very difficult to regulate. It was also noted that different claims imply different ideas, to different people (NZFSA); and

- Replacement of 'normal' with 'usual', in addition to the deletion of 'explicitly or implicitly' and the retaining of 'or biologically active substances'. It was suggested that the current trade practices and fair trading legislation suitably covered both situations (Nestle, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA, CMA-Vic Branch and CM of SA).

Function claim descriptors

- Deletion of words 'explicitly or implicitly' but retaining 'or a biologically active substance'. There was no comment made whether to delete or retain 'normal' (F& B Importers Assoc., ABC); and

- Deletion of words 'explicitly or implicitly' and 'normal', but retaining 'or a biologically active substance'. It was recommended that the definition should read: "*A function claim is a general level claim which describes the biological role of a food or energy or nutrient or a biologically active substance in growth, development, maintenance and other like functions of the body*" (AFGC, Masterfoods Aust. NZ, Parmalat Aust., Unilever Australasia. Dairy Aust., GW Foods, Goodman Fielder, National Foods).

Enhanced function claim descriptors

- Deletion of words 'explicitly or implicitly' and 'normal', but retaining 'or a biologically active substance' (Goodman Fielder);

- Deletion of words 'explicitly or implicitly', but retaining 'normal' and 'or a biologically active substance'. It was recommended that the definition should read:

  "An enhanced function claim is a general level claim which describes the biological role of a food or energy or a nutrient or a biologically active substance beyond normal growth, development, maintenance and other like functions of the body" (Dairy Aust., Parmalat Aust.); and

- Replacement of 'normal' with 'usual', in addition to the deletion of explicitly or implicitly' and the retaining of 'or biologically active substances'. It was suggested that:

  "*An enhanced function claim is a general level claim which describes the biological role of a food or energy or a nutrient or a biologically active substance beyond usual growth, development, maintenance and other like functions in the body"* (ABC, AFGC, Masterfoods Aust. NZ, Unilever Australasia, GW Foods, National Foods).

Other recommendations were that:

- The words 'e.g. improvements in physiological processes and functions' be added to the definition of enhanced function claims (NHF Aust., NHF NZ).

- These descriptors should not prevent the use of function claims which are not health claims or nutrition related, e.g. claims related to sensory or technical innovation (Nutra NZ).

- There should be clarification of "what classes as a function". It was noted that there was a need for an approved list (Crop & Food Research).

Five submitters, who agreed with the proposed definitions of a function claim and enhanced function claim, also questioned the practical value in differentiating between the two descriptors when they were virtually the same (Griffins Foods, Diabetes Aust., Cadbury Schweppes, G I Symbol Prog, and Food Tech. Assoc. of Vic., who suggested that only the 'function claim' was required).

Underlying concerns about differentiating the descriptors were that:

- Both of them are covered under general level claims (Griffins Foods);

- Both are to be dealt with in the same manner in a Standard or Guideline (Diabetes Aust., Griffins Foods, G I Ltd.); and

- There is a very fine line of differentiation, which may need to be better defined (Cadbury Schweppes).

Note that these reasons were among those given by some of the submitters who took a stronger stance and opposed the proposed descriptors.

Other recommendations by submitters who agreed with the descriptors were that:

- The definitions belong in a guideline (Dairy Aust.);

- There should not be disqualifying criteria for a function claim/enhanced function claim (National Foods).

Three submitters did not clearly state their position as to whether they agreed with the proposed descriptors or not, but made comment or recommendations as follows:

Dr. R. Stanton suggested that for consumers, enhanced function claims are likely to be perceived as health claims. This could mean that manufacturers will go for enhanced function (general level) claims, which have occurred in the US. (Refer Nestle M, Food Politics, University of California Press, chapters 11& 12, especially page 276).

NZ MoH stated that the definitions are really general. They added that the example given under the descriptor on pg 37 (of the IAR for P293) could be made regarding most nutrients and skin, and that claims need to be specific and substantiated.

TCCA raised issues concerning tighter regulation and recommended that:

- Function and enhanced function claims require more regulation than what is currently proposed under P293. These types of claims are open to misinterpretation and so should be more tightly regulated like health claims;

- FSANZ develop a list of appropriate and permissible function and enhanced function claims to accompany this definition, e.g. Canadian list in Attachment 5 of the IAR; and

- The wording of all general and high-level claims conveys the correct meaning to consumers and is not misleading. In order to address this, they suggested that FSANZ prescribe the exact wording of claims based on agreement amongst health professionals and the testing of claim interpretation with consumers.

Eight submitters did not agree with the descriptors for a function and an enhanced function claim (Dr. C. Halais, Bakewell Foods, NSW Food Authority, PB Foods, DAFF, CSIRO-HS&N, Fonterra, Mainland Products).

The reasons for their disapproval included the following points:

- The descriptors were not necessary in the context of the framework (Mainland Products, DAFF). Therefore, there was no need to define them or even include

them in the Guideline or Standard, in line with Q5 (this relates to the proposed FSANZ working definition of a general level claim, which includes function and enhanced function claims) (DAFF);

- There was concern about identifying "(normal) growth, development, maintenance, and other like functions of the body"(PB Foods). This phrase was also described as being too vague and may readily be misinterpreted (Dr. C. Halais). Fonterra noted that the meaning of 'normal' might differ according to the target group and general population, e.g. athletes;

- There should only be content claims and health claims - general and high level (CSIRO-HS&N). Fonterra clarified that there did not seem a lot of point in defining claims at the (function/ enhanced function) sub-category level since they were included in the definition of general level claims. However, they considered the reasons for having these definitions might be related to categorisation and terminology factors;

- There should only be one category/no separate definition of 'function' and 'enhanced function' claims (Bakewell Foods, NSW Food Authority, PB Foods, CSIRO-HS&N, Fonterra). It was noted that the Policy Guideline do not require them (Bakewell Foods, PB Foods, Fonterra), that non-separation would align with international trends (NSW Food Authority) and that there is an artificial border between function and enhanced function claims (CSIRO-HS&N). It was also suggested that the sub-categories add complexity (Fonterra).

It was also noted that these descriptors:

- Should only be used in a guideline (Fonterra, PB Foods) to explain different claims (PB Foods);

- Have caused much stakeholder discussion and debate, have yielded little information, and that they distract and confuse (Mainland Products).

Other comments

These comments included concern about classification issues relating to structure/function claims and the opportunities presented by Validated Food Components (VFCs) as follows:

Structure/function claim classification issues

According to Parker (2003), "structure/function claims describe how a product affects the structure or function of the body, but do not mention or imply a relationship to a disease. An example of a structure/function claim would be 'calcium builds strong bones" (Horticulture Aust., SA DoH).

It was suggested that under the proposed classification framework, function and enhanced function claims would be classified as general level claims and would therefore not require pre-approval by FSANZ and would only require the

manufacturer to substantiate (PHAA (supported by ACA), SA DoH, Monash Uni. – N&D Unit).

Submitters added that there was evidence for requiring further scrutiny of the classification of these types of claims. Heller (2001) described the situation in the US as "perhaps the biggest loophole in the US regulatory scheme". It was also stated that some companies have decided to bypass the health claim approval process by the FDA in favour of using structure/function claims (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni. – N&D Unit, Horticulture Aust.).

Heller (2001) also makes the point that despite the differences in requirements for the different types of claims (in relation to substantiation, pre-approval and in degree of regulation afforded) consumers will not necessarily interpret the claims any differently (PHAA (supported by ACA), SA DoH, WA DoH, Monash Uni. – N&D Unit).

Validated Food Components (VFCs) opportunities

Crop & Food Research stated that:

- VFCs provide an objective measure of food function that cannot be provided by usual food composition data, and could be used as a quantitative basis for a function claim if validated criterion thresholds were identified. (Refer submission for example to be read in conjunction with the extra information on VFCs);

- Function claims in association with VFCs would be helpful in educating consumers about VFCs. General criterion levels could be set with reference to biomarkers or health outcomes affected by the food function that the VFC represents;

- The benefit of VFC is that it gives the value upon which a claim is based, so allows a higher degree of discrimination between products than a simple claim allows.

Other comments provided but not in direct response to the question

SA DoH recommended that the Standard should include a list of 'approved' claims regarding growth, development, maintenance and other like functions of the body, which can be made. However, if it is not included in the Standard, it should be prohibited. When this list is developed, a causal link will need to be demonstrated between the food, food ingredient or component and the claimed benefit.

NZ Beef and Lamb considered that function claims should not be considered health claims, as they do not relate to heath outcomes.

3.4 RISK REDUCTION CLAIMS (NON-SERIOUS DISEASE)

Question 22

Should the descriptor for a risk reduction claim include the word 'significantly'?

Out of 147 submitters, 58.5% (86 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	6	2	-	-	8
Public health	10	4	-	-	14
Consumers	2	-	-	-	2
Other	5	2	-	-	7
Total	**52**	**26**	**5**	**3**	**86**

Overview

More than 60 per cent of submitters (53) opposed the inclusion of the word 'significantly' in the descriptor for a risk reduction claim. Twenty-six submitters agreed that the descriptor for a risk reduction claim should include the word 'significantly'.

Discussion of submitter responses

Fifty-three submitters did not agree with the inclusion of the word 'significantly' in the descriptor for a risk reduction claim (Solae Comp, NHF Aust., NHF NZ, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA, CMA-Vic Branch, CM of SA, NCEFF, ABC, AFGC, Masterfoods Aust., Unilever Australasia, Dairy Aust., DSM Nut. Prod, F&B Importers Assoc., Food Tech. Assoc. of Vic., GW Foods, Goodman Fielder, National Foods, National Starch, Parmalat Aust., NSW DoH - N&PA Branch, Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp., ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, Cadbury Confectionery, NZ Magazines, Fonterra, Griffins Foods, Mainland Products, Naturalac Nutrition, Canterbury DHB, NZFGC, Nutra-Life Health & Fitness NZ, Nutra NZ, MoH, NZFSA, Hort & Food Research Instit. of NZ, Heinz Aust./Heinz Watties NZ, Nestle, William Wrigley Junior, NZJBA, Frucor, Dr C. Halais). Many of these submitters explained their reasons, while some added comment or made recommendations.

In addition, one submitter disagreed with the inclusion of 'significantly', unless a risk reduction claim was corroborated by statistical analysis and indicated the level of significance (Dr C. Halais).

Reasons for opposing the inclusion of 'significantly' related to its lack of clarity and difficulty to measure. It was also considered superfluous – as the substantiation process and fair trading laws already covered any requirement for statistical significance.

Reasons for opposing the inclusion of the word 'significantly' were that:

Lack of clarity

- The meaning is unclear (F&B Importers Assoc., Mainland Products, Parmalat Aust.). It raised the following questions: What would constitute a significant reduction in risk? (F&B Importers Assoc.). Who would determine the degree of significance, and what are the costs of finding this out? (Mainland Products);

- 'Significantly' is undefined (Heinz Aust./Heinz Watties NZ). It requires a definition (Food Tech. Assoc. of Vic.). It was also noted that 'significantly' should be excluded if it cannot be "precisely defined", but if it can be defined, then 'substantially' should be included (Griffins Foods);

- It can have more than one meaning /open to interpretation (AFGC, Masterfoods Aust., Goodman Fielder, Dairy Aust. Canterbury DHB, National Foods, Nutra-Life Health & Fitness NZ). Some interpretations were described as statistically significant, physiologically significant, or perceptually significant (AFGC, Masterfoods Aust.). Others differentiated between statistical significance or perceived significance (Goodman Fielder), or statistical and general meanings (Canterbury DHB). There was also a non-specific reference made to 'dual' meanings (National Foods);

- It has a very specific & important meaning statistically in medical research (NZ MoH);

- It is a statistical term and is open to confusion (Hort & Food Research Instit. of NZ);

- It's inclusion means that an additional term has to be defined and to avoid misinterpretation (Fonterra); and

- It means little to the lay public (Uni. of Adel. & Uni of SA – Nutrition Physiology Research Grp.).

It was also implied that without the word 'significantly' the wording of the descriptor is simple and easily understood (ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, Cadbury Confectionery, NZ Magazines).

Difficult to measure

- It would be difficult to quantify what 'significance' means in relation to a non-serious disease or condition (National Starch, Solae Comp.). Both submitters agreed it would be difficult to demonstrate 'significant' reduction of risk if there is no uniform agreement for an appropriate measure of improvement. For example, 'significant' improvement in constipation;

- Those making such claims will need to have some independent evidence supporting the contention of the 'reduced risk' claim (Solae Comp);

- It is likely to prove prohibitive in terms of substantiation (Mainland Products). The concern expressed in this statement was supported by NZFSA who believed that 'significantly' cannot be measured. Heinz Aust./Heinz Watties NZ stated that it was unquantifiable; and

- This issue demands an understanding of sociolinguistics (Refer Q25 which relates to the inclusion of 'significantly' in the descriptor for a risk reduction claim in relation to a serious disease or condition). For the scientific community, the term 'significantly' carries with it statistical connotations, but the claims framework targets consumers, so it is probably unnecessary. (NCEFF).

Considered unnecessary

- Independent evidence would be required to support such claims (National Starch);

- There must be sufficient statistical evidence to support many of the risk reduction claims, which would be difficult for industry. However, it was clarified that if there was sufficient evidence to demonstrate the efficacy of a particular substance, risk reduction claims for non-serious diseases should be permitted (DSM Nut. Prod.);

- It will be covered under the substantiation process (National Foods, Dairy Aust., NSW DoH - N&PA Branch, NHF Aust., NHF NZ). The latter two submitters added that the substantiation framework would take into account the statistical significance of the relationship. Therefore, the word 'significantly' did not need to be listed in the descriptor;

- Covered by fair trading laws, enabling prosecution of any claim that might be misleading or deceptive (Nestle, Heinz Aust./Heinz Watties NZ). If there is insufficient effect then a claim is likely to be considered misleading. The legislation not only prohibits deceptive or misleading conduct but also conduct that is likely to mislead or deceive (Nestle);

- Substantiation criteria mean that reduction of risk must be demonstrable (Fonterra). Substantiation requirements should prevent false or misleading claims (William Wrigley Junior);

- It should be considered a given (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);

- This probably sets the bar too high (Naturalac Nutrition);

- It is superfluous (Heinz Aust./Heinz Watties NZ). It was similarly described as an irrelevant question because it is not necessary to define a non-serious disease/condition (Mainland Products);

- It would add uncertainty (NZFGC). It would exclude a large number of risk reduction claims (Nutra NZ); and

- There is already an issue with the difference between prevention (in the definition of therapeutic claim) and terms such as used in the prevention of, risk reduction, may prevent, etc (Fonterra).

Recommendations from submitters who opposed the inclusion of 'significantly', related mostly to the specific wording of the descriptor or to issues concerning the substantiation process. Most of these recommendations have been integrated with those of submitters who approved the inclusion of 'significantly'.

However, other recommendations were that:

- A base point comparator was needed if 'significantly' was included (Nutra-Life H&F);

- The substantiation process should ensure that all claimed benefits would be both clinically and statistically significant (Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp.);

- The claim should not be made if there is no significant benefit (NZ MoH); and

- The information used to substantiate a claim should be used to quantify the extent of the likely health benefit (Hort & Food Research Instit. of NZ).

Although NZJBA and Frucor opposed the inclusion of 'significantly' in the descriptor for a risk reduction claim, they stated that if used, it would need to be defined.

Other submitters who opposed the inclusion of 'significantly' commented that:

- The word 'may' used in the given example ("This food is high in fibre which may reduce constipation") negates any concept of significance. It was suggested that constipation relief on too 'significant' a scale could also be unpleasant and acutely embarrassing. (Refer to submission for further discussion on substantiation in which the pharmaceutical and food industries are compared)(Mainland Products);

- There are no disqualifying criteria for a nutrition content claim (National Foods); and

- With reference to the example of a risk reduction claim (p41 of IAR P293) it was noted that it contained 45 words, which would require a very large food pack size or label (National Foods).

Supported the inclusion of 'significantly'

Twenty-six submitters agreed that the descriptor for a risk reduction claim should include the word 'significantly' (Diabetes Aust., GI Ltd, Tomox, Bakewell Foods, CSIRO-HS&N, Auckland Reg. PHS, NCWA, TCCA, DAA, NZDA, Nutrition Aust.,

ANIC, CML, CHC, Wyeth Aust., NSW Food Authority, DAFF, WA DoH, Monash Uni. – N&D Unit, TGACC, PHAA (supported by ACA), ASMI, Sanitarium Health Food Comp, Tas DoH&HS, SA DoH). Many of these submitters explained their reasons, added comment and/or made recommendations.

Reasons for support

Most reasons for the inclusion of 'significant' related to strengthening the claim and that claim pre-requisites/conditions would ensure that the risk reduction claims were true and non-misleading. They were expressed as follows:

- To add value (CML);
- To be meaningful to the consumer (ASMI);
- To limit frivolous claims (NSW Food Authority);
- To indicate the strength of the evidence for a health claim. (ANIC);
- It is important to prevent claims that don't have a clinically relevant effect, as this could be misleading (Sanitarium Health Food Comp.);
- Claim pre-requisites, conditions and criteria are in place to ensure that claims are true and not misleading (DAFF);
- Unless the relationship between the consumption of the food, energy, nutrient or biologically active substance can be demonstrated as 'significant' it calls into question the validity of the substantiation process. If only a small reduction in risk is obtained then it just becomes a marketing exercise (Nutrition Aust.); and
- It is important that the claim is well substantiated as to efficacy. There would be an expectation that any relationship between the consumption of the food, energy, nutrient or biologically active substance would be demonstrated as 'significant'. Otherwise, this would call into question the validity of the substantiation process (SA DoH, Tas DoH&HS, PHAA (supported by ACA), Monash Uni. – N&D Unit).

Additional comments about the word 'significant'

Many submitters provided additional comments about the meaning and application of the word 'significant'. These included reference to statistical and clinical significance and the validity of the substantiation process.

- Several submitters questioned the meaning of the word. One asked whether there was any general agreement on what 'significant' means (NCWA). The other queried as to whether there should be a definition of 'significantly' or whether the dictionary definition was sufficient (NSW Food Authority);

- It must indicate a high level claim that requires full substantiation (CHC);

- Such claims should only be made when a 'convincing level of evidence' is available. Lower assessments on the totality of the evidence (such as 'possible' or 'probable') are not acceptable levels for the approval of health claims, as they will mislead consumers and will very likely require review within a short period of time (TCCA);

- Health claims should only be allowed where the evidence is strong. The proposed FSANZ substantiation framework would ensure the level of evidence is able to support use of the word 'significantly' or a health claim would not be allowed (ANIC);

- Statistical significance of the scientific evidence is important for supporting claims, given that a non-statistical finding may represent a chance association Consideration should also be given to clinical significance (Wyeth Aust.);

- The substantiation process should determine if the relationship between the nutrient or food and the degree of risk of developing a disease is clinically significant, a level which is likely to be different for each food/nutrient and disease/biomarker (Sanitarium Health Food Comp.);

- There was concern over what is 'scientifically significant' (e.g. $p < 0.001$) and what consumers consider 'significant' (e.g. 50% reduced fat). Implementation of all claims including risk reduction claims need to be made clear to consumers about what is meant by not only health claims, but what is meant by terms such as 'significant' to ensure that health claims are not misleading (Tas DoH&HS);

- Although Crop & Food Research did not give a clear answer to the question they stated that it would depend on what was classed as 'significantly'. They added that the degree of risk reduction could depend on other factors and that a factor might be significant alone, but not when taken in light of other dietary/lifestyle factors. They also stated that a risk reduction may be significant for a particular group of the population (e.g. those over 45, females) and asked how this would be dealt with.

Recommendations

The following recommendations incorporate some that were also made by submitters who opposed, or did not state a clear position, with regard to the inclusion of 'significantly' in the risk reduction claim descriptor. These additional responses were related to the actual wording of the definition and the need for a pre-approved list of substantiated risk reduction claims. In summary, the recommendations were that:

- A definition of 'significantly' should be defined for consumers. For example, scientific significance may not translate into physiological significance (DAA, NZDA);

- Although Aussie Bodies did not directly respond to the question they stated that if 'significantly' was included, there would need to be a clear definition of what is regarded as 'significant'. They added that the definition of 'significant' needs to accord with the level of health outcome expected from a food, not a drug (as not talking about therapeutic agents). If so, the word significant has merit, to limit marginal or spurious claims;

- The Standard needs to identify a measure for 'significantly' otherwise the term may be applied loosely (Cadbury Schweppes). 'Significantly' should be quantified e.g. a 10 or 20% reduction in risk for each food/nutrient (CML);

- Deletion of words 'explicitly or implicitly' and 'significantly' (NZFSA).

- Deletion of words 'explicitly or implicitly' but retaining 'or a biologically active substance' (CHC, TGACC);

- Deletion of words 'explicitly or implicitly' and 'significantly', but inclusion of 'biologically active substance' (Nestle, Dairy Aust., Goodman Fielder). These amendments were supported by AFGC and Masterfoods Aust. who recommended that the definition should read:

  "*A general level claim which describes the biological role of a food or energy or a nutrient or a biologically active substance in reducing the risk of developing a non-serious disease or condition"*.

- Similar wording was proposed by GW Foods who recommended the following definition:

  "A risk reduction claim in relation to a non-serious disease or condition is a general level claim which describes the biological role of a food, energy, nutrient or a biologically active substance in reducing the risk of developing a non-serious disease or condition".

- Unilever Australasia stated that they supported the proposed AFGC definition. However, it was noted by FSANZ that the word 'developing' was omitted from Unilever Australasia's proposed definition;

- All claims should be pre-approved by FSANZ. This will simplify the process for food companies and for monitoring. It will also mean that any claim that is not significant will not arise (Dr R. Stanton);

- The development of an approved list of substantiated risk reduction (non serious disease) claims (Dr R. Stanton, WA Do, Monash Uni. – N&D Unit, PHAA (supported by ACA), SA DoH). Associated reasons were related to simplicity for food companies and for monitoring (Dr R. Stanton), or, to avoid confusion and to provide clarity to all stakeholders (WA DoH, SA DoH, PHAA (supported by ACA);

- Horticulture Aust., who did not express a clear position with regard to the question, also recommended an approved list of substantiated risk reduction (non-serious disease) claims – to avoid confusion and provide clarity to stakeholders; and

- Although NSW DoH - N&PA Branch opposed the inclusion of 'significantly' (because it is covered by the substantiation process), they also stated that their preferred approach was for FSANZ to provide an approved list of substantiated risk reduction claims that can be used rather then leaving it open to interpretation;

Seven submitters did not clearly answer the question (Dr R. Stanton, Aussie Bodies, Cadbury Schweppes, NZ Dairy Foods, PB Foods, Horticulture Aust., Crop & Food Research). Responses (relating to the definition of 'significantly', the measurement of it and developing a pre-approved list of risk reduction claims) have already been added to similar statements made by other submitters. The remaining responses were as follows:

- If the risk reduction is not significant it should not be permitted (Dr R. Stanton);

- Unsure as to whether the descriptor for a risk reduction claim should include the word 'significantly'. Opinion was equally divided among their team of four food professionals (NZ Dairy Foods); and

- The Policy Guideline does not require the definition. It makes the Standard too complex (PB Foods).

Other comments provided but not in direct response to the question

NZFGC recommended the deletion of 'explicitly or implicitly' and the inclusion of 'biologically active substances' in the description of a risk reduction claim in relation to a non-serious disease or condition.

Question 23

Are there likely to be claims, which reference a non-serious disease or condition, which would not be expressed as 'risk reduction claims'? If so, is there a need to identify another sub-category of claim in the Claims Classification Framework?

Out of 147 submitters, 47.6% (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	16	4	2	48
Government	5	2	-	-	7
Public health	7	2	-	-	9

Consumers	1	-	-	-	1
Other	4	1	-	-	5
Total	**43**	**21**	**4**	**2**	**70**

Overview

Forty-six per cent of submitters (32) agreed or implied agreement that it was likely that there would be claims that reference a non-serious disease or condition which would not be expressed as 'risk reduction claims'. Sixteen submitters identified other sub-categories of claims in the Claims Classification Framework. Thirteen submitters did not express a clear position or were uncertain as to the need for more sub-categories. Twenty-three submitters did not agree that it was likely that there would be claims which reference a non-serious disease or condition, which would not be expressed as 'risk reduction claims'.

Discussion of submitter responses

Thirty-two submitters agreed that it was likely that there would be claims which reference a non-serious disease or condition which would not be expressed as 'risk reduction claims' (Nutra-Life Health & Fitness NZ, CHC, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA, CMA-Vic Branch, CM of SA, GW Foods, Nutra NZ, Dr. R. Stanton, NCEFF, ASMI, PHAA (supported by ACA), Tas DoH&HS, NSW DoH - N&PA Branch, SA DoH, WA DoH, CSIRO-HS&N, Monash Uni. – N&D Unit, TGACC, MoH, NZFSA, Hort & Food Research Instit. of NZ, Sanitarium Health Food Comp., Diabetes Aust., GI Ltd).

Although Diabetes Aust. and GI Ltd agreed that these claims were likely, they both added that they could not see the practical value in differentiating between the two, if they were to be dealt with in the same manner in the Standard or Guideline.

Horticulture Aust. did not explicitly agree that there would be claims (that referenced a non-serious disease or condition), which would not be expressed as 'risk reduction claims'.

Sixteen submitters identified other sub-categories of claims that would be required in the Claims Classification Framework. Examples of these claims (non-serious diseases or conditions) not described as 'risk reduction' included:

- Risk increase claims for use in nutrition education (PHAA (supported by ACA), NSW DoH - N&PA Branch, SA DoH, Monash Uni. – N&D Unit, MoH, Tas DoH&HS) or health maintenance claims, if the health claims Standard refers to general nutrition education material e.g. produced by a non-government organisation (NGO). (MoH noted that too much of a food could be harmful. Tas DoH&HS sought clarification as to where general nutrition education messages sat within the framework);

- Over-consumption of a food which may pose a problem for someone with a specific health problem e.g. sugars and diabetes (Nutra-Life Health & Fitness NZ);

- Maintenance claims (NZFSA). To 'help manage' non-serious conditions, or words of similar meaning. (Not all statements about health need to be disease related) (NCEFF);

- Many enhanced function claims – which are likely to refer to a non-serious disease or condition (Dr R. Stanton). It was also noted that claims that refer to 'management' of conditions e.g. management of lactose/gluten intolerance are not risk reduction claims, but enhanced/function claims (Sanitarium Health Food Comp.);

- Weight management claims (CSIRO-HS&N);

- A general level claim, which describes a wellness, well-being or performance improvement outcome (Hort & Food Research Instit. of NZ);

- A non-serious disease which is vague e.g. memory, energy levels, hot flushes, or 'keeps you healthy' (Dr. R. Stanton);

- The statement that "This product is suitable for people with gluten intolerance such as celiac disease" (GW Foods); and

- Many examples from claims and indications in Listed Medicines: www.tgasime.health.gov.au/SIME/DCT/webdct.nsf/STDIND1?OpenView (TGACC).

Although Dairy Aust. (supported by Parmalat Aust.) rejected the need for subcategorising claims for risk-reduction claims (for non-serious diseases/conditions) they identified "aids in recovery from" as an example of such a claim. They also noted that it was possible to have a claim on a food product where the target is the 'person' with the non-serious disease, e.g. "suitable for people with gluten intolerance".

Twenty-three submitters did not agree that it was likely that there would be claims which reference a non-serious disease or condition which would not be expressed as 'risk reduction claims' (Food Tech. Assoc. of Vic., Solae Comp., Auckland Reg. PHS, TCCA, NHF Aust., NHF NZ, ABC, AFGC, Masterfoods Aust. NZ, Bakewell Foods, Dairy Aust., F&B Importers Assoc., National Foods, National Starch, Parmalat Aust., PB Foods, Griffins Foods, NZFGC, NZJBA, Frucor, Nestle, Unilever Australasia, Wyeth Aust.).

Reasons mostly related to the fact that more sub-categories were considered unnecessary or redundant as follows:

- There was no need to identify another sub-category (NHF Aust., NHF NZ, National Starch, NZJBA, Nestle). In particular, it would only add unnecessary complexity (Bakewell Foods, F&B Importers Assoc, NZFGC, Unilever Australasia, PB Foods). Bakewell Foods preferred to simplify, rather than complicate the process. Unilever Australasia also related 'unnecessary complexity' to a system that had not yet been road tested;

- These terms are redundant and there is no need to define them or even include them in the Guideline or Standard (in line with Q5, which asks whether the working definition of a 'general level claim' captures all the possible types of claims, which would not reference a biomarker or a serious disease or condition (DAFF);

- Ministerial guidelines conclude that the proposed regulation is in proportion to risk (AFGC, Masterfoods, National Foods). National Foods suggested this would be achieved by "implementing a risk management approach that will protect public health and safety through scientific substantiation of high risk claims, generic health claims for ease of use where evidence is clear and minimal regulation where there are no risks to public health". In addition, they stated that categorising claims as high level and general level, provided regulation proportional to risk (National Foods);

- The two categories of claims (general level and high level) were considered sufficient (Griffins Foods);

- This list is inclusive rather than exclusive (Dairy Aust., Parmalat Aust.); and

- The Policy Guideline does not require the definition (PB Foods).

General comments

TCCA stated that the so called ' non serious' diseases or conditions would no doubt be considered serious by those suffering from them. Food products claiming benefits relating to such conditions would be likely to be interpreted as health claims by those consumers who have such conditions. They added that these types of claims require the same degree of regulation as high level health claims.

Three submitters did not express a clear position concerning the question (Fonterra, Goodman Fielder, Dr. C. Halais). However they made comment as follows:

- There was no need to identify another sub-category of claim, as the list was inclusive rather than exclusive. Other types of claims included claims made in the context of the total diet to treat, alleviate or cure the effects or symptoms of a non-serious disease or non-serious condition. It was also considered possible to have claims for product where people with the non-serious disease or condition are the target market rather than as part of the claim, e.g. "suitable for people with gluten intolerance" (Fonterra);

- Claim sub-categories would only increase complexity. However, examples of claim types or descriptors would be helpful to industry if added to the guideline document (Goodman Fielder): and

- Not applicable, if no (health) claims are allowed (Dr. C. Halais).

Another 10 submitters were uncertain as to the need for more sub-categories.

Most of these submitters suggested that if there were more claims then they would probably be therapeutic claims (ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery). Mainland Products was 'unsure' as to the need for any other sub-category.

Other submitters indicated that:

- It might be necessary to include some subcategories (in the interest of ensuring that these definitions are well understood) but preferred to keep the number and type of claims to a workable level. (Cadbury Schweppes); and

- They were unable to comment until a list of non-serious conditions was developed (CML).

Recommendations, which included 'road testing' potential claims and developing a list of pre-approved claims, were that:

- Reference be made to currently accepted Coded Indications for complementary medicines on the TGA website (ASMI, CHC);

- FSANZ should issue guidelines for use of words such as 'booster' (energy booster), 'energiser', 'detox' ingredients, 'stress reliever' but preferably prohibit vague terms that are ill defined or defy definition (Dr R. Stanton);

- Consideration should be given to claims that reference the word 'detox' (PHAA (supported by ACA), Monash Uni. – N&D Unit, Horticulture Aust., WA DoH, SA DoH). The latter three submitters noted that although it is unlikely there is any evidence to substantiate this claim, it is a very popular choice in other countries;

- Consideration should be given to claims that reference the word 'health' (PHAA (supported by ACA), Monash Uni. – N&D Unit, NSW DoH - N&PA Branch, WA DoH, SA DoH, Horticulture Aust). It was pointed out that there are a number of 'healthy eating' brands, which claim to be good or better choices for a healthy diet; whilst not making any explicit claims (NSW DoH - N&PA Branch, SA DoH);

- Standard criteria should be 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 (NSW DoH - N&PA Branch, WA DoH, SA DoH, Horticulture Aust);

- The provision of claim descriptors in a guideline would assist in industry compliance with the Standard (AFGC, Masterfoods, Dairy Aust., Parmalat Aust.). It would particularly assist industry and enforcement agencies in recognising likely general level claims and high level claims (AFGC, Masterfoods Aust. NZ, Parmalat Aust.);

- The development of a list of pre-approved claims to simplify the process and remove the likely string of spurious claims which are unlikely to be policed on the basis that they do not refer to a serious disease. Consumers are entitled to know that government authorities take all claims that are made seriously (Dr R. Stanton);

- There should be early involvement of industry in road testing potential claims through the health claims system to provide examples for consideration (AFGC, Masterfoods Aust., NZ, Dairy Aust., Parmalat Aust.). As the situation progressed, any perceived need for sub-categories could be addressed in a guideline document (Unilever Australasia);

- The experience in the market place would determine whether claims that may reference a non-serious disease (or non-serious manifestation of a serious disease) could be expressed without reference to risk reduction (AFGC, Masterfoods Aust. NZ, Parmalat Aust);

- FSANZ adequately 'road tests' potential claims through the system to ensure appropriate delineation between claim sub-categories (CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA, CMA-Vic Branch, CM of SA) and

- The food industry should trial the process and 'road test' definitions, claims, pre-requisites, conditions and criteria to ensure the system is robust (National Foods).

A general comment was that claims regarding allergens and additives should not be included in the Nutrition Health and Related Claims Standard (WA DoH, SA DoH, Horticulture Aust).

Other comments provided but not in direct response to the question

Beef & Marketing Bureau considered that the definition for 'non-serious disease' should be clarified in relation to conditions such as overweight/obesity, mineral and vitamin deficiencies.

3.5 BIOMARKER CLAIMS

Question 24

Should the descriptor for a biomarker maintenance claim and biomarker enhancement claim include the phrase 'recognised biomarker'?

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	27	17	5	2	51
Government	6	2	-	-	8
Public health	10	4	-	-	14

Consumers	2	-	-	-	2
Other	5	2	-	-	7
Total	**50**	**25**	**5**	**2**	**82**

Overview

More than half of submitters that responded (42) disagreed that the descriptors for a biomarker maintenance claim and a biomarker enhancement claim should include the phrase 'recognised biomarker'. Three submitters considered it irrelevant as to whether these claims included 'recognised' or not. Seventeen submitters agreed to the inclusion of 'recognised biomarker in the descriptors. Another 12 submitters agreed, subject to specific conditions.

Discussion of submitter responses

Forty-two submitters disagreed that the descriptors for a biomarker maintenance claim and a biomarker enhancement claim should include the phrase 'recognised biomarker' (DAA, NZDA, Dr. C. Halais, NCEFF, AFGC, Masterfoods Aust. NZ, CML, Dairy Aust., F&B Importers Assoc., G W Foods, National Foods, Parmalat Aust., PB Foods, Sanitarium Health Food Comp, Goodman Fielder, CSIRO-HS&N, Canterbury DHB, ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery, Fonterra, Griffins, NZFGC, NZJBA, Frucor, Hort & Food Research Instit. of NZ, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA., CMA-Vic Branch, CM of SA, Nestle, Unilever Australasia)

Their reasons for excluding 'recognised biomarker' were mostly related to the fact that it was unnecessary to include this term in the definition because the biomarker was already defined or the processes of approval and substantiation would determine the suitability of a biomarker. The reasons were noted as follows:

<u>Unnecessary as already defined</u>

The term 'biomarker' is already adequately defined (on p34 of the Initial Assessment Report Proposal 293) (DAA, NZDA, CML, AFGC, Masterfoods Aust. NZ, Sanitarium Health Food Comp, Griffins Foods, NZFGC).

<u>Implication of an approval process</u>

The term 'recognised biomarker' implies that an approval process for biomarkers is required (NCEFF, AFGC, Masterfoods Aust. NZ, Goodman Fielder, Nestle, CMA, 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 by Nestle that the inclusion of a 'recognised biomarker' has not been discussed in the document and that it seems it would be difficult to have a 'new biomarker' accepted.

Unnecessary as subject to approval and substantiation

- The review of the appropriateness of biomarkers for such claims will be part of the pre-approval consideration of all the evidence provided to support any such claim (NCEFF);

- The approval process will allow flexibility for the emergence of new biomarkers (CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA, CMA-Vic Branch, CM of SA);

- The approval process and substantiation will determine the suitability of the biomarker within the proposed claim. It is likely that a new biomarker claim would undergo extensive trials and testing of the substantiation prior to manufacturers applying for approval of a high-level claim (Nestle);

- An appropriate substantiation process will determine whether a biomarker is predictive of disease or not (AFGC, Masterfoods Aust. NZ, Goodman Fielder, NZFGC, Dairy Aust., National Foods). Therefore, it was unnecessary to add further qualification with the word 'recognised' (Goodman Fielder);

- Biomarker claims could not be substantiated if the biomarker was not 'recognised' (Griffins Foods).

'Recognised' by whom?

Six submitters raised the issue of who was the 'recognised' authority (Dr. C. Halais, F&B Importers Assoc., National Foods, Parmalat Aust., Fonterra, Dairy Aust.). In addition it was quoted that:

- The proposed definition is sufficient. (F&B Importers Assoc);
- Either something is a biomarker or it is not (Fonterra); and
- It is meaningless unless the name of the authority recognising the biomarker is also stated (Dr. C. Halais).

NCEFF stated that there is no single authoritative body that is established to 'recognise' biomarkers at present and it is unlikely that such a process will be developed in the future. (However, they mentioned that significant work has been done as part of the PASSCLAIM project to develop criteria for the appropriate biomarkers that could be used to assist substantiation of the health effects of nutrients and foods).

Other reasons were that:

- 'Recognised' is a subjective word (CML);

- 'Recognised' would have to be defined (Hort & Food Research Instit. of NZ);

- The term is too complicated to explain to the public (Canterbury DHB);

- There is no official means by which biomarkers are recognised within the health claims regulatory framework (Unilever Australasia);

- If the biomarker is recognised for the purpose by FSANZ then it is not necessary to mention the term. In addition, it will reduce clutter on the label or advertisement (ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery); and

- The Policy Guideline does not require definitions of biomarker maintenance claims and biomarker enhancement claims (PB Foods).

Other points noted were that:

- The status of 'recognised' biomarkers will continually evolve with emerging science. 'Recognised status' required updating and was difficult to implement and enforce (National Foods); and

- Information regarding relationship between biomarkers and disease outcomes is developing quickly (Hort & Food Research Instit. of NZ).

Four submitters disagreed that the descriptors for a biomarker maintenance claim and a biomarker enhancement claim should include the phrase 'recognised biomarker', unless specific terms were satisfied as follows:

- There is an adequate explanation of the biomarker provided in the claim if it is not well recognised (CHC);

- The effect of the biomarker was defined (Nutra-Life Health & Fitness NZ);

- There is a schedule identifying recognised biomarkers (NZ MoH); and

- A list of recognised biomarkers can be identified and listed in the guidelines (DSM Nut. Prod.) (They disagreed based on the fact that since no reference is made to any diseases, it is impossible to define whether a biomarker qualifies as 'recognised' or not).

It is worth noting that another eight submitters agreed, subject to provisos, that the descriptors for a biomarker maintenance claim and a biomarker enhancement claim should include the phrase 'recognised biomarker'. The provisos were similar to those mentioned by the four submitters above who disagreed, unless conditions were met. They stated that the Standard include a list of approved biomarkers. However, if these were not available, there should be provision of a definition/clarification as to what is meant by a 'recognised biomarker' (Horticulture Aust., Tas DoH&HS, NSW DoH - N&PA Branch, SA DoH, WA DoH, Monash Uni. – N&D Unit, PHAA (supported by ACA)).

Three submitters considered it irrelevant as to whether a biomarker was 'recognised' or not − if, all approved claims were listed in the standard (NHF Aust., NHF NZ) or,

since biomarkers were included in high level claims, they would have to be pre-approved (Heinz Aust./Heinz Watties NZ). It was also noted that the substantiation process should be robust enough that it prevents misleading claims involving unrecognised biomarkers (NHF Aust., NHF NZ).

Seventeen submitters agreed that the descriptors for a biomarker maintenance claim and a biomarker enhancement claim should include the phrase 'recognised biomarker' (NCWA, TCCA, Diabetes Aust., Dr. R. Stanton, G I Symbol Prog, Tomox, Aussie Bodies, Bakewell Foods, National Starch, Solae Comp, Wyeth Aust., Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp., Auckland Reg. PHS, NZ Dairy Foods, Nutra NZ, NZFSA, Crop & Food Research).

Reasons for including the words 'recognised biomarker' related to scientific evidence, which would limit the chances of any misleading claims from being made (National Starch, Solae Comp.).

Other points were that:

- "Accepted science" would be used where there is some consensus regarding the suitability of a biomarker in terms of being a meaningful reflection of a disease or condition (Solae Comp.);

- "New science" would reveal new biomarkers over time and this would need to be submitted for inclusion into the relevant Standard once the science supporting the biomarker had reached the point where an opinion as to its usefulness could be reached (Solae Comp.);

- There are numerous biomarkers under investigation, which are likely to come into common usage (Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp.).

Eight submitters did not express a clear position **(**Nutrition Aust., ASMI, Cadbury Schweppes, NSW Food Authority, Food Tec. Assoc. of Vic., DAFF, TGACC, Mainland Products).

Comments noted were that:

- The criteria for a biomarker seem to cover this issue adequately. However, if 'recognised' is used, it will have to be defined unless there is a list of recognised biomarkers included in the Standard (Nutrition Aust.);

- It is unclear as to whom/what authority biomarkers are 'recognised' by as valid measures or predictive parameters (ASMI, NSW Food Authority, Food Tec. Assoc. of Vic., TGACC). In addition, Food Tec. Assoc. of Vic. questioned 'where' the biomarkers are 'recognised';

- There are a great number of possible biomarkers, and it is largely subjective to include the term 'recognised biomarker'(DAFF);

- The inclusion of 'recognised' in the descriptor was questioned, given that biomarkers would need to be pre-approved and recognised in the first instance (Cadbury Schweppes);

- Since all biomarker claims will be high level claims, the usefulness of sub-categorising them further is very questionable (Mainland Products); and

- Agree in principle that as a surrogate marker it needs to be meaningful and relevant. If the biomarker is tied to a disease state, caution is required if variation to this marker can occur without significantly changing the overall risk profile for this disease (ASMI).

Recommendations

The following recommendations are sourced from submitters who agreed, disagreed or did not state a clear position with regard to the question. It was recommended that:

- A list of recognised biomarkers should be developed (Dr. R. Stanton, Hort & Food Research Instit. of NZ). The list would be updated at defined regular intervals or using a petition process (Hort & Food Research Instit. of NZ);

- More specifically, that FSANZ should provide this list in the Standard (Solae Comp, Wyeth Aust., NZFSA, Crop & Food Research). It would be used for substantiated claims and require regular review (Wyeth Aust.);

- A list of 'recognised' biomarkers should be included in the guideline (NSW Food Authority, DAFF);

- A process should be established to identify new claims as they are discovered or developed (NZFSA, Crop & Food Research);

- Biomarker maintenance claims should be considered general level claims (NZFSA);

- Any product claim which makes reference to biological functions (biomarker maintenance and enhancement claims) relating to the human body are likely to be interpreted as a high level health claim and should be treated as such (TCCA);

- There should be the deletion of 'explicitly or implicitly' but inclusion of 'biologically active substance' in the descriptors (AFGC, Masterfoods Aust. NZ, Nestle, Dairy Aust). Note that Dairy Aust. referred to Q16 for their recommended definition of a 'biomarker';

- There should be the deletion of 'biomarker maintenance' and 'biomarker enhancement' and describe them all as high level claims (CSIRO-HS&N); and

- The definition of a biomarker is "*a measurable biological parameter which is predictive of the risk of human disease, disorders, conditions or defects"* (National Foods).

Other comments provided but not in direct response to the question

SA DoH believed that there should be a list in the Standard of 'approved' biomarkers, which can be used in claims. If the biomarker is not on the list it should be prohibited from being used. This would reduce ambiguity and misinterpretation and reduce consumer confusion. It would also provide ease and equity for small businesses that do not have the vast resources of large businesses.

They were concerned that biomarker claims will each have a normal range which will only become an issue when they are outside that range. Most consumers would not be aware of the level of their 'biomarkers'. Therefore, it is essential that claims regarding biomarkers should not lead to consumer alarm.

The 'biomarker' definition has varied from that provided in the Ministerial Council guideline.

GW Foods do not support the inclusion of the words 'explicitly' and 'implicitly' in the definitions for biomarker maintenance and biomarker enhancement but do support the inclusion of 'biologically active substance' in both definitions.

3.6 Risk reduction claims (serious disease)

Question 25

Should the descriptor for a risk reduction claim in relation to a serious disease or condition include the word 'significantly'?

Out of 147 submitters, 55.1% (81 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	16	5	2	51

Government	6	2	-	-	8
Public health	10	3	-	-	13
Consumers	2	-	-	-	2
Other	5	2	-	-	7
Total	**51**	**23**	**5**	**2**	**81**

Overview

Fifty-one per cent of submitters (41) opposed the inclusion of the word 'significantly' in the descriptor for a risk reduction claim in relation to a serious disease or condition. Twenty-six submitters agreed that the descriptor for a risk reduction claim (serious disease) should include the word 'significantly'. Ten agreed, subject to provisos and one regarded the inclusion of 'significantly' as irrelevant.

Discussion of submitter responses

Forty-one submitters did not agree with the inclusion of the word 'significantly' in the descriptor for a risk reduction claim in relation to a serious disease or condition (NCEFF, NHF Aust., NHF NZ, ABC, AFGC, Masterfoods Aust. NZ, Cadbury Schweppes, Dairy Aust., F&B Importers Assoc., Food Tech. Assoc. of Vic., GW Foods, Goodman Fielder, National Foods, Parmalat Aust., PB Foods, Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp., Fonterra, Griffins, NZFGC, Mainland Products, NZJBA, Frucor, Nutra-Life Health & Fitness NZ, Nutra NZ, MoH, NZFSA, Hort & Food Research Instit. of NZ, CMA, Mandurah Aust., Palatinit GmbH, Kingfood Aust., CMA-NZ Branch, CMA-NSW Branch, CMA-Qld Branch, ICA, CMA-Vic Branch, CM of SA, Nestle, Unilever Australasia, ASMI, CHC).

In addition, one submitter disagreed with the inclusion of 'significantly', unless a risk reduction claim was corroborated by statistical analysis and indicated the level of significance (Dr. C. Halais).

Reasons for opposing the inclusion of 'significantly' related to its lack of clarity and difficulty to measure. It was also considered superfluous – as the substantiation process already covered any requirement for statistical significance.

Reasons for opposing the inclusion of the word 'significantly' were expressed as follows:

<u>Lack of clarity</u>

- It is ambiguous (F&B Importers Assoc., Parmalat Aust.);
- It is subjective (Nutra-Life Health & Fitness NZ, AFGC, Masterfoods Aust.NZ);
- It can have more than one meaning/open to interpretation (AFGC, Masterfoods Aust. NZ, National Foods, Goodman Fielder). It was noted that there was 'statistical' significance or 'perceived' significance (Goodman

Fielder). One submitter clarified that 'significantly' is a statistical term, which is open to confusion (Hort & Food Research Instit. of NZ). Another made reference to 'dual' meanings (National Foods);

- It requires further definition (Food Tech. Assoc. of Vic.). It cannot be clearly defined (Griffins). It means an additional term to be defined and (mis)interpreted (Fonterra); and

- It means little to the lay public (Uni.of Adel. & Uni. of SA – Nutrition Physiology Research Grp.

Difficult to measure

- It cannot be measured (NZFSA); and

- This issue demands an understanding of sociolinguistics (Refer Q25 which relates to the inclusion of 'significantly' in the descriptor for a risk reduction claim in relation to a serious disease or condition). For the scientific community, the term 'significantly' carries with it statistical connotations, but the claims framework targets consumers, so it is probably unnecessary (NCEFF).

Considered unnecessary

It will be covered under the substantiation process (National Foods, PB Foods, Uni. of Adel. & Uni. of SA – Nutrition Physiology Research Grp., NHF Aust., NHF NZ, Unilever Australasia). Related comments were that:

- Since the substantiation framework would take into account the statistical significance of the relationship, the word 'significantly' did not need to be included in the descriptor (NHF Aust., NHF NZ);

- The substantiation process (in which these claims will go through as high level claims) will provide FSANZ the opportunity to determine the significance of the risk reduction claim (AFGC, Dairy Aust., Goodman Fielder);

- The substantiation criteria mean that reduction of risk must be demonstrable (Fonterra);

- This is a function of the approval process and the assessment of the substantiation provided by the company seeking the approval of the claim (Nestle). If risk factor exposure were not significantly reduced by use of the food product, it would not be allowed to make a health claim (NZ MoH).

- It should be considered a given (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);

- It would exclude a large number of risk reduction claims (Nutra NZ); and

- There is already an issue with the difference between prevention (in the definition of therapeutic claim) and terms such as used in the prevention of, risk reduction, may prevent, etc. (Fonterra).

Twenty-six submitters agreed that the descriptor for a risk reduction claim (serious) should include the word 'significantly' (TCCA, Diabetes Aust., DAA, NZDA, Dr. R. Stanton, GI Ltd, Nutrition Aust, PHAA (supported by ACA), Tomox, ANIC, Bakewell Foods, CML, DSM Nut. Prod., National Starch, Sanitarium Health Food Comp., Wyeth Aust., NSW Food Authority, SA DoH, DAFF, WA DoH, Tas DoH&HS, CSIRO-HS&N, Monash Uni. – N&D Unit, TGACC, Auckland Reg. PHS).

Most reasons for the inclusion of 'significantly' related to strengthening the claim and that claim pre-requisites/conditions would ensure that the risk reduction claims were true and non-misleading.

They were expressed as follows:

- To add value (CML);

- To indicate the strength of the evidence for a health claim (ANIC);

- To limit frivolous claims (NSW Food Authority);

- To prevent claims that don't have a clinically relevant effect, as this could be misleading (Sanitarium Health Food Comp.);

- To reflect that it is an important definer of effect in science (WA DoH, Monash Uni. – N&D Unit, PHAA (supported by ACA), SA DoH);

- To reflect the importance of high level claims, which require a significant effect in terms of health outcome. (Biological significance is fundamental to the science underlying the impact of a food, nutrient or active compound on a disease. Therefore, science must show that changes observed are biologically meaningful) (National Starch);

- Claim pre-requisites, conditions and criteria are in place to ensure that claims are true and not misleading. (As an additional certainty, these claims will all require pre-market approval and if the term is inappropriate, it will be drawn out by FSANZ during the assessment) (DAFF);

- Unless the relationship between the consumption of the food, energy, nutrient or biologically active substance can be demonstrated as 'significant' it calls into question the validity of the substantiation process. If only a small reduction in risk is obtained then it just becomes a marketing exercise. It was also pointed out that the use of significance reflected the power of association and that the issues raised were considered more relevant to the serious type of risk reduction claim as compared to the non-serious type raised in Q22 (Nutrition Aust.); and

- It is important that the claim is well substantiated as to efficacy. There would be an expectation that any relationship between the consumption of the food, energy, nutrient or biologically active substance would be demonstrated as 'significant'. Otherwise, this would call into question the validity of the substantiation process (Tas DoH&HS, PHAA (supported by ACA), SA DoH).

Ten submitters agreed, subject to provisos, that the descriptor for a risk reduction claim (serious) should include the word 'significantly' (Solae Comp, NCWA, NSW DoH - N&PA Branch, ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery). The provisos for including 'significantly' were that:

- It means 'statistically significant' because biological significance is fundamental to the science underlying the impact of a food/nutrient/active compound on a disease. In order to claim a benefit, the science needs to consistently show that the changes observed are biologically meaningful – that there is some biological significance in terms of its impact (Solae Comp.);

- It is adequately defined (NSW DoH - N&PA Branch, NCWA). It is also explained to allow accurate judgement based on the level of evidence (NSW DoH - N&PA Branch);

- It is a fact. This would need to be decided by the evaluation process. Otherwise it could be misleading (ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery).

Two submitters did not clearly answer the question (Crop & Food Research and Aussie Bodies) and another submitter described the inclusion of 'significantly' in the definition as "irrelevant" because the risk reduction claims have to be pre-approved as part of the high level claim criteria (Heinz Aust./Heinz Watties NZ).

Recommendations, from submitters who opposed the inclusion of 'significantly', related mostly to the substantiation process and specific wording of the descriptor as follows:

- A base point comparator was needed if 'significantly' was included (Nutra-Life H&F);

- The substantiation process should ensure that all claimed benefits would be both clinically and statistically significant (Uni.of Adel. & Uni. of SA – Nutrition Physiology Research Grp, who referenced their response to question 22);

- The information used to substantiate a claim should be used to quantify the extent of the likely health benefit (Hort & Food Research Instit. of NZ);

- The deletion of 'explicitly or implicitly' but inclusion of 'biologically active substance' in the claim descriptor (AFGC, Dairy Aust., Goodman Fielder, NZFGC, Nestle). These recommendations were also expressed as a definition:

  "…is a high level claim which describes the biological role of a food, energy, nutrient or a biologically active substance in reducing the risk of developing a serious disease or condition"(GW Foods).

- The deletion of 'explicitly or implicitly' in the claim descriptor (ASMI, CHC, TGACC). Note that TGACC's response has been integrated here, even though they agreed with the inclusion of 'significantly' in the claim descriptor.

Recommendations, from submitters who agreed with the inclusion of 'significantly', stated the need to clearly define 'significantly', to convey the correct meaning and not be misleading, to pre-approve general diet claims and to ensure that claims should not simply focus on specific words but take into account the overall effect of food products. They were expressed as follows:

- To define for the consumer what is meant by 'significantly' (DAA);

- To define 'significant' quantitatively. Examples were "at least 10% reduction" (CSIRO-HS&N), and "a 10 or 20% reduction in risk for each food/nutrient" (CML);

- Although Aussie Bodies did not directly respond to the question, they recommended that if 'significantly' was included, it should be clearly defined in accord with the level of health outcome expected from a food, not a drug (therapeutic agent). Only then would the word 'significant' have merit, to limit marginal or spurious claims;

- The degree of risk reduction, which is deemed 'significant', should be articulated for each serious disease or condition in the food standard (NZDA);

- The wording of all claims should convey the correct meaning to consumers and is not misleading. (FSANZ should prescribe the exact wording of claims based on agreement among health professionals and the testing of claim interpretation with consumers) (TCCA);

- General diet claims likely to be used by organisations such as the Cancer Council or Heart Foundation should be pre-approved. If the effect is not significant it should not be permitted. However for consumer confidence it may be wise to include the word 'significantly' (Dr. R. Stanton); and

- Rather than focus on the use of a specific word, which has particular meaning when used in a scientific context, consideration should be given to preventing claims being made where the totality of the food product might have adverse health impacts. For example, foods "high in fibre" might also be high in energy density or high sodium and actually increase the risk of the nominated disease or other diseases (TCCA). NZDA supported this view by

recommending that claims should not be used on foods or food products where other aspects of the food might negate the effect of the 'protective' nutrient or biologically active substance e.g. high fibre in a high energy dense food (NZDA).

Additional comments were made about the various interpretations of 'significantly' by submitters, who (with one exception) agreed that it should be included in the descriptor for a risk reduction claim (serious). These comments were as follows:

- Several submitters questioned the general meaning/understanding of 'significantly'. One asked if there should be a definition or whether the dictionary definition was sufficient (NSW Food Authority). Another doubted whether consumers would interpret differently: "X will significantly reduce the risk of Y" versus "X will reduce the risk of Y." (TCCA);

- Health claims should only be allowed where the evidence is strong. The proposed FSANZ substantiation framework will ensure the level of evidence is able to support use of the word 'significantly' or a health claim would not be allowed (ANIC);

- If risk reduction is not sufficiently great to provide clinical benefit, the claim is misleading, as it would suggest an outcome that may not be occurring (Wyeth Aust.);

- The substantiation process should determine if the relationship between the nutrient or food and the degree of risk of developing a disease is clinically significant, a level which is likely to be different for each food/nutrient and disease/biomarker (Sanitarium Health Food Comp.);

- There was concern over what is 'scientifically significant' (e.g. $p < 0.001$) and what consumers consider 'significant' (e.g. 50% reduced fat). Implementation of all claims including risk reduction claims need to be made clear to consumers about what is meant by not only health claims, but what is meant by terms such as 'significant,' to ensure that health claims are not misleading (Tas DoH&HS); and

- Although Crop & Food Research did not give a clear answer to the question they stated that it would depend on what was classed as 'significantly'. They added that the degree of risk reduction could depend on other factors and that a factor might be significant alone, but not when taken in light of other dietary/lifestyle factors. They also stated that a risk reduction may be significant for a particular group of the population (e.g. those over 45, females) and asked how this would be dealt with.

It was noted that the Policy Guideline did not require this definition (PB Foods).

Question 26

Are there likely to be claims that reference a serious disease or condition, which will not be expressed as 'risk reduction 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	24	12	4	2	42
Government	3	2	-	-	5
Public health	8	2	-	-	10
Consumers	2	-	-	-	2
Other	3	2	-	-	5
Total	**40**	**18**	**4**	**2**	**64**

Overview

Almost 30 per cent of submitters (18) did not agree that it was likely that there would be claims which reference a serious disease or condition, which would not be expressed as 'risk reduction claims'. Another 18 submitters were unable to either determine or provide examples of such likely claims. Twenty-two submitters agreed or implied agreement that it was likely that there would be claims that reference a serious disease or condition, which would not be expressed as 'risk reduction claims'. Most of these submitters identified examples.

Discussion of submitter responses

Eighteen submitters did not agree that it was likely that there would be claims (referencing a serious disease or condition) which would not be expressed as 'risk reduction claims (NCWA, Aussie Bodies, National Starch, Solae Comp, Wyeth Aust., CSIRO-HS&N, Auckland Reg. PHS, ASA, NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery, NZJBA, Frucor, TCCA, National Foods).
Related comments were that:

- Other claims were most likely to be health claims or therapeutic claims (ASA supported by NPANZ, Assoc. of NZ Advertisers, NZTBC, Naturo Pharm, NZ Magazines, Cadbury Confectionery);

- Under a system of voluntary health claims, most industry-initiated claims were likely to be expressed as risk reduction claims. However, it was also noted that there would be claims made by those aggressively marketing their products to enhance their capacity to increase sales. It was questionable as whether such claims would be valid (TCCA); and

- If the claims regulatory system was well defined, there would be no need to regulate for exceptions (National Foods).

Another 18 submitters stated that they were unable to determine or provide examples of likely claims (referencing a serious disease or condition), which would not be

expressed as risk reduction claims (NCEFF, Cadbury Schweppes, MoH, Unilever Australasia, Nestle, Dairy Aust., Parmalat 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). Additional points were that:

- There was a need to thoroughly test the claims classification framework in the development of Std 1.2.7 before implementation (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);

- The most likely way for these types of claims to be discovered was through early involvement of industry in road testing the proposed health claims system (Dairy Aust., Parmalat Aust., National Foods). National Foods (who thought it unlikely that a nutrition or health claim would promote the risk of a serious disease or condition) clarified that this involved testing definitions, claims, pre-requisites, conditions and criteria, to ensure a robust system for the claims;

- The Policy Guideline provided an example – 'People with 'G' disease should eat a varied diet low in 'A' and 'B' and high in 'S', 'X' & 'Y' (Nestle); and

- It was not possible to comment until a list of serious diseases was developed (CML).

Twenty-two submitters agreed or implied agreement, that it was likely that there would be claims that reference a serious disease or condition, which would not be expressed as 'risk reduction claims' (Dr. R. Stanton, NHF Aust., NHF NZ, PHAA (supported by ACA), ASMI, Bakewell Foods, CHC, GW Foods, Goodman Fielder, Horticulture Aust., Sanitarium Health Food Comp, TGACC, Fonterra, Nutra NZ, NZFSA, Tas DoH&HS, SA DoH, WA DoH, Monash Uni. – N&D Unit, Diabetes Aust., GI Ltd).

Most of these submitters identified examples of other claims (referencing a serious disease or condition), which would not be described as 'risk reduction claims'. They included risk increase claims, comparative claims, claims that don't explicitly include the term 'risk', claims that relate to weight loss, slimming, image and obesity, maintenance claims, improvement claims, management claims and endorsements from non-government organisations (NGOs) as follows:

- Risk increase claims for use in nutrition education (PHAA (supported by ACA), Tas DoH&HS, SA DoH, WA DoH, Monash Uni. – N&D Unit). An example of a risk increase claim was "eating a low carbohydrate diet may increase the risk of bowel cancer" (Dr. R. Stanton);

- Comparative claims between products or groups of products that discuss risk reduction and/or increased risk of a serious disease or condition. For example, a consumer group may take out advertisements containing warning statements for individual foods that increase risk of serious disease. However, submitters questioned whether this example was a health claim or dietary advice (SA

DoH, WA DoH, Monash Uni. – N&D Unit, PHAA (supported by ACA), Horticulture Aust.);

- Maintenance claims, improvement claims, e.g. “improves immune function” (NZFSA). Other examples were: "helps recovery..." (Nutra NZ), and “This food is an excellent source of fibre which is an important factor for bowel cancer” (Goodman Fielder);

- Claims that refer to the management of a serious disease or condition e.g. coeliac disease, diabetes or claims that refer to cause-related marketing campaigns or endorsements (Sanitarium Health Food Comp.);

- Claims that do not explicitly include the term ‘risk’ e.g. “reducing LDL-cholesterol is important for heart disease” and “improving bone density is important for osteoporosis” (NHF Aust., NHF NZ). Other examples were substantiated claims such as “reduces cholesterol an important factor for (management of) heart disease” (AFGC, Masterfoods Aust. NZ, Parmalat Aust., GW Foods). It was noted by FSANZ that Parmalat Aust. supported both Dairy Aust. (who were unable to provide an example) and AFGC (who did suggest an example);

- Claims relating to weight loss, slimming and image (CHC) or obesity, weight loss and slimming (ASMI). It was also noted that such claims are proposed as prohibited under the European Union Proposed Guidelines on Nutrition and Health claims made in food. The proposed guidelines also prohibit reference to psychological and behavioural functions that are often associated with serious conditions e.g. ADHD (ASMI);

- Endorsements from non-government organisations (NGOs) that are associated with diseases and their prevention (Diabetes Aust., GI Ltd, TGACC); and

- Claims made in the context of the total diet to treat, alleviate or cure the effects or symptoms of a non-serious disease or non-serious condition. It is possible to have claims for product where people with the non-serious disease or condition are the target market rather than as part of the claim, e.g. "suitable for people with gluten intolerance" (Fonterra). It was noted by FSANZ that the response cross-referenced Q23, which related to non-serious diseases and conditions. However, the submission did not specify any relevance of these comments to a serious disease or condition.

Six submitters did not directly answer the question but made comment (AFGC, Masterfoods Aust. NZ, Dr. C. Halais, PB Foods**,** Hort & Food Research Instit. of NZ, Crop & Food Research). The following points were noted:

- Not applicable, if no claims are allowed (Dr. C. Halais);

- Not relevant, covered by general level definition (PB Foods);

- The concept of 'risk reduction' is difficult for many to appreciate and is often confused with 'prevention'. Alternative wording was suggested to improve

public understanding e.g. “reduces the chances of contracting...” (Hort & Food Research Instit. of NZ);

- Biomarkers and disease states are used for VFCs validation. VFCs have been developed to provide a measure of the relative efficacy of foods as effectors of a biomarker or intermediate state that has been linked to disease, but without necessarily making a claim (Crop & Food Research); and

- Validation trials are currently being conducted (i.e. support substantiation). It was suggested that VFCs would be useful tools for consumers in the future. Submitter asks that FSANZ consider the potential public health benefit of VFCs when developing the standard (Crop & Food Research).

FSANZ acknowledges the information regarding VFCs and associated research that has been attached to the submission. It is also noted that comment, by AFGC and Masterfoods Aust. NZ, concerning the ‘reduces cholesterol’ example is recorded in the examples above.

Other comments provided but not in direct response to the question

It was recommended that:

- Claims regarding diet related serious disease should be permitted (SA DoH);

- There should be a list in the Standard of 'approved' serious diseases about which claims are made and the use of serious disease claims outside this list to be prohibited (SA DoH);

- In relation to cancer, claims should be allowed but only to specific cancers, reflecting the complexity of the disease (Beef & Lamb Marketing Bureau).

SA DoH also suggested that differentiating between what is a serious disease and what is a non-serious disease is a critical issue. In addition, they supported the use of a number of strategies and policies as providing the foundation for decision making regarding diet related diseases/problems of greatest public health significance and priority setting in relation to approval of claims.