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Nutrient function, health and related claims on packaged Australian food products - prevalence and compliance with regulations

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RESEARCH ONLINE

Nutrient function, health and related claims on packaged Australian food products - prevalence and compliance with regulations

Abstract

Australia and New Zealand are currently reviewing the regulations governing nutrition function, health and related claims on foods. Health claims currently are not permitted on food labels, with one exception. The aim of this study was to describe the use of such claims on packaged food for sale in Australia (excluding nutrient content claims) prior to any changes to the regulations, and measure compliance with existing regulations. A survey was conducted of the labelling of 7850 products (including multiple pack sizes of individual foods) in 47 different food categories on sale in New South Wales in 2003. A total of 2098 nutrition function, health or related claims and 12 therapeutic claims were recorded. Fourteen percent of products carried some sort of claim. If nutrient function and general health maintenance claims are excluded, 8.1% of products carried a health or related claim. Using the claims categorisation proposed by Food Standards Australia New Zealand for a new standard on claims, general-level claims were found on 9.8% of products and high-level and therapeutic claims (illegal at the time) on 1.2%. The food categories with the highest proportion of products carrying claims were sports drinks (92%), energy drinks (84%), sports bars (57%) and breakfast cereals (54%). 118 high-level and therapeutic claims did not conform to current food standards and there were many general-level claims for ingredient benefits that were unlikely to be able to be scientifically substantiated. The results of this survey suggest that more than 5% of claims were not complying with the current regulations and that the standards were not being fully enforced. To be effective, the new standard will need to be accompanied by clear guidelines for manufacturers on requirements for substantiating claims. Comprehensive education and enforcement frameworks also will be needed, to reduce the number of illegal or apparently unsubstantiated claims.

Keywords

health claims, consumers, food labelling, packaged foods, Food Standards Australia New Zealand, FSANZ

Disciplines

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Original Article

Nutrition function, health and related claims on packaged Australian food products – prevalence and compliance with regulations

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Australia and New Zealand are currently reviewing the regulations governing nutrition function, health and related claims on foods. Health claims currently are not permitted on food labels, with one exception. The aim of this study was to describe the use of such claims on packaged food for sale in Australia (excluding nutrient content claims) prior to any changes to the regulations, and measure compliance with existing regulations. A survey was conducted of the labelling of 7850 products (including multiple pack sizes of individual foods) in 47 different food categories on sale in New South Wales in 2003. A total of 2098 nutrition function, health or related claims and 12 therapeutic claims were recorded. Fourteen percent of products carried some sort of claim. If nutrient function and general health maintenance claims are excluded, 8.1% of products carried a health or related claim. Using the claims categorisation proposed by Food Standards Australia New Zealand for a new standard on claims, general-level claims were found on 9.8% of products and high-level and therapeutic claims (illegal at the time) on 1.2%. The food categories with the highest proportion of products carrying claims were sports drinks (92%), energy drinks (84%), sports bars (57%) and breakfast cereals (54%). 118 high-level and therapeutic claims did not conform to current food standards and there were many general-level claims for ingredient benefits that were unlikely to be able to be scientifically substantiated. The results of this survey suggest that more than 5% of claims were not complying with the current regulations and that the standards were not being fully enforced. To be effective, the new standard will need to be accompanied by clear guidelines for manufacturers on requirements for substantiating claims. Comprehensive education and enforcement frameworks also will be needed, to reduce the number of illegal or apparently unsubstantiated claims.

Key Words: health claims, consumers, food labelling, packaged foods, Food Standards Australia New Zealand, FSANZ.

Introduction

In Australia and New Zealand a standard is currently being developed for the Food Standards Code, which will incorporate nutrition function, health and related claims within the one framework. With one exception (folate and prevention of neural tube defects), health claims are currently not permitted on food labels or associated advertising in Australia or New Zealand. In December 2003, the Food Regulation Ministerial Council released a policy guideline to direct Food Standards Australia New Zealand (FSANZ) in the development of a new standard[1] and in May 2004 FSANZ released an Initial Assessment Report of a proposal (P293) for a new standard.[2]

The proposal outlines a claims classification framework, definitions and a substantiation framework. Claims are categorised as being either general-level or high-level. Health claims are defined as 'a claim other than a therapeutic claim, that describes or indicates the relationship between the consumption of a food, a category of food or one of its constituents and health'. A single substantiation framework was also proposed by FSANZ to establish systematic processes for ensuring claims about food are scientifically valid and not misleading. High-level claims will be evaluated by FSANZ on a claim-by-claim basis following a comprehensive and systematic evaluation of all available scientific literature relating to the subject matter of each claim. General-level claims will be substantiated by the manufacturer or supplier following the same procedure or by reference to authoritative sources.

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Accepted

Few studies have been reported on the extent to which manufacturers use nutrition function, heath or related claims on the labelling of packaged food for sale in Australia. The aim of this study was to measure the prevalence of such claims being made on packaged food for sale in Australia, record the type of claims being made, the components and benefits used to make the claim, and examine how these comply with the current and proposed regulations for nutrition function, health and related claims in the Australia New Zealand Food Standards Code.

Materials and methods

Data Collection

In August and September 2003 a survey was conducted of the labels on packaged foods sold in Australian supermarkets in 47 categories of food (Table 2). The survey was conducted by five of the authors (AH, AR, JR, MS, BS) in Woolworths, Coles, Franklins, Independent Grocers of Australia (IGA) and Aldi supermarkets and a sample of health food and Asian food stores throughout the Wollongong and Nowra regions of New South Wales. Permission was sought from store managers before data collection, but because all the information was freely available in the public domain, approval of an Ethics Committee was not considered necessary in order to conduct the study.

Using a standard record form, the following information from the product labels was collected:

- Manufacturer
- Brand and product name
- Flavour and pack size variants
- Country of origin
- Exact wording of claim/s
- Implied claim/s (eg. heart/body symbols)
- Endorsements by health organisations

Multiple pack sizes for individual products were included in this survey to enable any differences in labelling on various pack sizes to be recorded. To account for duplication of claims across different pack sizes, data are presented where possible as a proportion of the total.

Claims were categorised into 17 categories as shown in Table 1. This classification uses more categories than those defined in P293, however it was thought that this would enable more detailed examination of the surveyed claims. Of the 17 categories, one category was therapeutic claims, six were high-level health claims, and seven were general-level claims. The remaining three categories included endorsement, implied and testimonial claims, and the allocation of such claims within the FSANZ proposed classification framework depends on the specific content.

Data Analysis

All data were entered into a Microsoft Access 2000 Database and analysed for:

- number and type of claims made on each product
- percentage of products carrying health claims in each food category
- the type of claims being made
- benefits and components referred to in the claim
- compliance of claims with current food regulations and reasons for non-compliance.

Claims were assessed against the criteria in Standard 1.1A.2 (Transitional Standard – Health Claims) of the Food Standards Code for compliance with current regulations.[3] Claims were also assessed against the definitions and criteria proposed in P293.[2]

Results

Prevalence of claims on product labels

A total of 7850 food products were surveyed. Table 2 summarizes the number of products in each of the 47 food categories surveyed, the percentage of products carrying any claims and, of the products carrying claims, the average number of claims per product.

Fourteen percent of all products surveyed carried some type of nutrition function, health or therapeutic claim. In 23 of the 47 food categories an average of more than one claim per product was recorded. Nutrient function claims – both general health maintenance (GHM) and specific health function (SHF) claims – are generally already permitted as nutrition messages at present in Australia.[4] If these two categories are excluded, the percentage of products carrying some type of health or related claim was 8.1%. Across all food categories the mean number of health claims per product was 0.4.

The products with the highest average number of claims per label were flour (7.0), breakfast cereals (4.9), frozen fish (4.0) and juice (cold) (3.5). Food categories in which a high proportion of the foods carried claims included: sports drinks (92.0%), energy drinks (84.2%), sports bars (57.4%) and breakfast cereals (53.7%). In the other 43 food categories the proportion of products carrying claims was below 50%. When GHM and SHF claims are excluded the top six categories with the highest percentage of products carrying claims did not change, although the order of the two top food categories was reversed, with 84.2% of energy drink products and 80% of sports drinks carrying claims. The products which carried no claims included soft drink, salsa/pesto, salad dressing, olives, meat (fresh & canned), ice-creams, frozen vegetables, frozen pastry, frozen dessert, custard, cream, coconut milk/cream, canned vegetables, and cake mixes.

Table 3 shows the number and percent of claims found in each claim category. Considering the total number of products examined in this survey, general-level claims were found on 9.8%, high-level claims on 1.1% and therapeutic claims on 0.1%. General level claims made up 76.1% of all claims identified while high-level claims comprised 5.2% and therapeutic claims comprised 0.6%. Of those claims not categorised as high- or general-level claims, implied claims were most frequently recorded (14% of the total) with endorsed claims making up 3.6% and testimonial claims 0.6% of the total. Of the general-level claims, SHF (28.5% of all claims) and GHM claims (21.8%) were the most common. Performance claims made up the next highest proportion of general level claims (16.4%). Of the high-level claims, slimming (22.5%), biomarker maintenance (20.8%) and biomarker improvement (20.8%) claims were most commonly observed.

Table 1. Health and related claims classification

Claim classification †	Claim Type	Description	Examples
General- level claims	Food/Nutrient Function Claim – General health maintenance (GHM)	Role in maintaining or supporting good health of a system or organ	Support the body's ability to resist infection For a healthy heart
	Nutrient Function Claim – Specific health function (SHF)	Role in maintenance of normal function, growth, development	Calcium is good for strong bones and teeth Iron is needed to transport oxygen in blood
	Diet Claims – general	Based on dietary guidelines but do not refer to a serious disease or condition	A healthy balanced diet with plenty of fibre can help manage constipation
	Performance Claim	Benefits for performance or wellbeing	Gives you energy Improves endurance Controls appetite
	Enhancement Claim	Modifying a body function or structure without mentioning disease	Improve bone strength Increase urinary flow Improve concentration
	Symptom Relief	Reduce signs and symptoms but do not mention disease	Relief from hot flushes of menopause Reduce joint pain Soothe upset stomachs
	Risk Reduction – non-serious	How a diet, food or component can reduce risk of non-serious disease or condition	Can help reduce risk of stomach upsets Help protect you from the common cold
High level claims	Biomarker management or control	How a diet, food or component can help maintain a biomarker in a normal range	Low GI diet can help manage your blood glucose Help maintain healthy cholesterol levels
	Biomarker improvement	Can help reduce or improve an abnormal biomarker	Help reduce your cholesterol levels Assist in lowering raised blood pressure
	Diet Claim - serious	Based on dietary guidelines; refers to serious disease or condition	A diet rich in wholegrains, fruit and vegetables may reduce your risk of heart disease
	Risk reduction – serious	Assist in reducing the risk of a serious disease or condition	Consumption of 3 serves of oats per day may reduce your risk of heart disease
	Disease Management	How a food or component can help control or manage a serious disease or condition	Help you manage your diabetes
	Slimming	How a food or component can help people to lose weight (not just a low joule nutrient content claim)	"Slimming" tea Helps you lose excess fat
Therapeutic claims *	Therapeutic claim	Is a claim that refers to the prevention, treatment, alleviation, or cure of a disease, ailment, defect or injury	This food is high in iron for the treatment and prevention of anaemia.
	Endorsement	Endorsement or linkage with a disease-related organisation (excluding Heart Foundation Tick)	GI symbol (Diabetes Australia) Coeliac society International Diabetes Institute
	Implied claim	Any other possible implied claims eg, use of the word "health" or "healthy" in name or pictures of medical equipment or personnel	*"Weight Watchers"* brand
	Testimonial	Message or recommendation from an individual associated with health or performance	Dr X recommends Famous sports person uses as part of training regime

* In Australia and New Zealand, the Therapeutic Goods Association (TGA) regulates therapeutic claims, while health claims on foods are regulated by FSANZ. Therapeutic claims are therefore separate categories of claims and are not considered health claims.
† According to the claim classification framework included in the Initial Assessment Report to Proposal P293 Nutrition, Health and Related Claims

Table 2. Prevalence of claims

Category	Number of products	Percent of products with claims	Total number of claims	Avg number of claims per product
Sports drinks	25	92.0	59	2.6
Energy drinks	19	84.2	47	2.9
Sports bars	54	57.4	68	2.2
Breakfast cereals	307	53.7	813	4.9
Drink bases	45	46.7	36	1.7
Teas	316	40.8	214	1.7
Yoghurt	353	29.7	286	2.7
Muesli bars	152	29.6	37	0.8
Meat substitutes	61	26.2	10	0.6
Eggs	35	25.7	19	2.1
Milk	147	25.2	65	1.8
Frozen meals	131	23.7	58	1.9
Fruit bars	38	15.8	12	2.0
Fat spreads	122	13.9	21	1.2
Bread	215	13.5	62	2.1
Juice	188	13.3	59	2.4
Sugar	48	12.5	6	1.0
Edible oils	167	11.4	25	1.3
Juice (cold)	120	8.3	35	3.5
Spreads	262	5.0	33	2.5
Biscuits and crackers	564	4.8	55	2.0
Frozen fish	94	4.3	16	4.0
Chips	207	3.9	8	1.0
Flour	53	3.8	14	7.0
Rice	58	3.4	5	2.5
Pasta	486	2.9	26	1.9
Cordials	113	2.7	3	1.0
Noodles	195	2.6	9	1.8
Canned seafood	348	1.4	5	1.0
Cheese	297	1.0	3	1.0
Cooking sauces	354	0.3	1	1.0
Ice Creams	281	0	0	0
Cake mixes	47	0	0	0
Canned fruit	290	0	0	0
Canned vegetables	354	0	0	0
Coconut milk/cream	47	0	0	0
Cream	38	0	0	0
Custard	18	0	0	0
Frozen dessert	91	0	0	0
Frozen pastry	22	0	0	0
Frozen vegetables	98	0	0	0
Meat (fresh & canned)	237	0	0	0
Olives	47	0	0	0
Salad dressing	104	0	0	0
Salsa/pesto	20	0	0	0
Soft drink	310	0	0	0
Soups	272	0	0	0
Total	7850	14.0	2110	0.4

Table 3. Types of claims used on packaged food labels

Claim Type	Number of claims	% total claims	% products (N = 7850)
Specific health function	602	28.5	2.80
General health maintenance	460	21.8	2.20
Performance	347	16.4	2.90
Implied	296	14.1	2.85
Enhancement	113	5.4	0.98
Endorsed	75	3.6	0.96
Risk Reduction - non-serious	33	1.6	0.39
Diet - general	30	1.4	0.31
Slimming *	27	1.3	0.24
Biomarker improvement *	25	1.2	0.28
Biomarker management *	25	1.2	0.31
Symptom Relief	22	1.0	0.17
Risk reduction – serious *	19	0.9	0.15
Testimonial	12	0.6	0.13
Therapeutic	12	0.6	0.11
Diet – serious *	8	0.4	0.09
Disease Management *	4	0.2	0.03
Total	2110	100%	15.7 **

* High-level health claim according to proposed FSANZ health claims classification. **This is higher than the total of 14% in Table 1 because more than one claim appeared on some products.

Health organisations which formed the basis of endorsement claims recorded in this survey included the International Diabetes Institute, Coeliac Society, Australian Institute of Sport, Sports Dietitians Association, Cancer Society, Heart Research Institute and Diabetes United Kingdom.

Table 4 summarizes the type of health claims found in each food category. Sixty-two percent of claims were found in three food groups – breakfast cereals (38.5%), yoghurt (13.6%) and teas (10%). The largest proportion of specific health function (48%), performance (44%), enhancement (46%), implied (36%), risk-reduction non-serious (79%), risk-reduction serious (74%) and testimonial claims (58%) were all found on breakfast cereals. The highest proportion of general health maintenance claims was found on yoghurt (27%) and breakfast cereals (27%). Yoghurt also carried a high proportion of specific health maintenance claims (20%).

Table 4. Claim types used in each food category

Category	General health maintenance	Specific health function	Diet - general	Performance	Enhancement	Symptom Relief	Risk Reduction - non-serious	Biomarker management	Biomarker improvement	Diet - serious	Risk reduction - serious	Disease Management	Slimming	Endorsement	Testimonial	Implied	Therapeutic	Total
Breakfast Cereals	124	290	6	153	52		26	9	10	2	14			11	7	106	3	813
Yoghurt	124	118	7	15	13	5		2					2					286
Teas	51	28		43	14	14	2					4	4	25		29		214
Sports bars	12	9		12	10			3			2		3	3		14		68
Milk	11	25		2	1	1	2	1	1	2	1			3	1	13	1	65
Bread	19	13		5										1	3	21		62
Juice	27	14		3	7			1			2			1		2	2	59
Sports drinks		18		26			2									13		59
Frozen meals	19	13	15	3												8		58
Biscuits and crackers	16	1		18				8						1		11		55
Energy drinks				23	12											12		47
Muesli bars	3												16	17		1		37
Drink bases		17		12										3		1	3	36
Juice (cold)	9	17	2		2											4	1	35
Spreads	12	7		3	2	1	1							2	1	2	2	33
Pasta	4			13												9		26
Edible oils	8							1	3	2						11		25
Fat spreads	8	1							11							1		21
Eggs	4	7		1										1		6		19
Frozen Fish	4	12																16
Flour	4	10																14
Fruit bars				4										4		4		12
Meat substitutes																9		9
Noodles				3												6		9
Chips																8		8
Canned Seafood																6		6
Sugar										2			2	2				6
Rice				5														5
Cheese	1	2																3
Cordials				3														3
Cooking sauces														1				1
Total	460	602	30	347	113	21	33	25	25	8	19	4	27	75	12	297	12	2110

Disease management claims were found exclusively on teas, which also had the highest proportion of symptom relief claims (67%). Teas carried a large number of the endorsement claims (33%) followed closely by muesli bars (23%), which also carried the majority of the slimming claims (59%). Biomarker improvement claims were predominantly found on breakfast cereals (40%) and fat spreads (44%) while biomarker management claims were found predominantly on breakfast cereals (36%) and biscuits and crackers (32%). Diet-general claims were predominantly found on frozen meals (50%) and referred mostly to the relationship of the food and overall health (73%).

Foods on which therapeutic claims were found included breakfast cereals, drink bases, juice, spreads, juice (cold) and breads. Ten of the twelve therapeutic claims recorded in this survey referred to: the essential fatty acids omega-3 and omega-6 and heart disease (n=2), vitamin A and infection (3), vitamin E and heart (3), silica and heart disease (1), and calcium and brittle bones (1). Two of the claims referred to the general therapeutic health benefit of a honey, with the following wording: 'is a therapeutic honey for dietary use' and 'offers the benefits of high levels of therapeutic activity'.

Health benefits claimed

Tables 5 and 6 summarise the most common health benefits reported with each type of health claim. Seventy-seven different health benefit descriptions were established based on the claims recorded in this survey. More detailed tables showing all of the health benefit and component relationships for each claim type are available from the authors and can be viewed at the website of the National Centre of Excellence in Functional Foods.[5]

The greatest number and variety of claimed health benefits were found in the GHM and SHF categories with 35 and 33 different types of health benefits recorded in each, respectively. For GHM claims the most common health benefits were: overall health (25%), digestion (18%), heart (12%) and immune (8%). For SHF claims the most common benefits were: metabolism (24%), growth (12%), oxygen transport (7.6%) and bones and oral health (7%). Over half of the performance claims referred to energy as the claimed health benefit while the claimed benefits in enhancement claims included digestion (28%), bowel (14%), mental function (11.5%) and mood (10.6%). In the general-level claims, seven of the top ten most frequently recorded pairings were found in specific health function claims and included: metabolism and vitamins B1, B2 and B3; oxygen transport and iron; bones and calcium, bones and oral health and calcium; and growth and folate. The top two benefit/component pairings made in performance claims related to energy and whole food and energy and carbohydrate.

Amongst the high-level claims, 92% of the biomarker improvement claims related to blood cholesterol while 80% of biomarker management claims referred to blood glucose levels. In the risk reduction-serious claims, cardiovascular disease (58%) was most frequently cited, with 26% of claims referring to cancer.

Table 5. Most commonly recorded health benefit and component relationships in general-level claims

Claim-type	Benefit	Component	%
Specific health function $N = 602$	Metabolism	Vitamin B2	7.6
	Oxygen transport	Iron	7.5
	Bones & Dental	Calcium	6.9
	Metabolism	Vitamin B1	6.9
	Metabolism	Vitamin B3	6.9
	Growth	Folate	6.8
	Bones	Calcium	5.9
	other combinations ($N = 111$, each < 3.5%)		
General Health Maintenance $N = 460$	Digestion	Cultures	8.4
	Overall health	Cultures	7.4
	Digestion	Fibre	6.8
	Heart	Omega 3 fats	4.7
	Overall health	Whole food	4.7
	Overall Health	Antioxidants	4.5
	other combinations ($N = 101$, each < 3.5%)		
Performance $N = 347$	Energy	Whole Food	26.6
	Energy	Carbohydrate	18.3
	Satiety	Fibre	5.6
	Mental function	Whole food	5.3
	Mood	Whole food	5.0
	Energy	Iron	4.4
	Overall Health	Whole food	4.4
	other combinations ($N = 35$, each < 3.5%)		
Enhancement $N = 113$	Digestion	Fibre	16.5
	Bowel	Fibre	14.7
	Digestion	Cultures	11.9
	Mental	Whole food	11.0
	Mood	Whole food	9.2
	Recovery from exercise	whole food	4.6
	Muscles	whole food	3.7
	other combinations ($N = 27$, each < 3.5%)		
Risk-reduction-non-serious $N = 33$	Fatigue	Iron	68.8
	Cold & Flu	Whole food	6.3
	Fatigue	Whole Food	6.3
	other combinations ($N = 7$, each < 3.5%)		
Diet – general $N = 30$	Overall Health	Whole Food	36.7
	Heart	Glycaemic Index	23.3
	Overall health	Fibre	10.0
	Digestion	Fibre	6.7
	other combinations ($N = 7$, each < 3.5%)		
Symptom relief $N = 22$	Digestion	Whole food	27.3
	Menopause	Isoflavones	9.1
	Vomiting	Whole food	9.1
	other combinations ($N = 12$, each = 4.5%)		

Table 6. Commonly recorded health benefit and component relationships recorded in high-level claims

Claim-type	Benefit	Component	%
Slimming *N* = 27	Weight	Whole food	78.6
		Glycaemic index	7.1
		Amino acids	3.6
		Citric acid	3.6
		Energy	3.6
		Phaseolamin	3.6
		Total	100%
Biomarker improvement *N* = 25	Cholesterol	Sterols/stanols	44.0
	Cholesterol	Fibre	16.0
	Cholesterol	Polyphenols	12.0
	Blood glucose	Glycaemic index	4.0
	Blood triglycerides	Omega 3 fats	4.0
	Cholesterol	Beta Carotene	4.0
	Cholesterol	Omega 3 fats	4.0
	Cholesterol	Omega-6 fats	4.0
	Cholesterol	Phytic Acid	4.0
	Cholesterol	Psyllium	4.0
		Total	100%
Biomarker management *N* = 25	Blood glucose	Glycaemic index	31.0
	Blood glucose	Resistant starch	27.6
	Cholesterol	Whole food	17.2
	Blood glucose	Carbohydrate	10.3
	Blood glucose	Fibre	10.3
	Cholesterol	Polyphenols	3.4
		Total	100%
Risk reduction – serious *N* = 19	Cancer	Diet	22.2
	Cardiovscular disease	Diet	22.2
	Cardiovscular disease	Fibre	11.1
	Cardiovscular disease	Soy Protein	11.1
	Birth defects	Folate	5.6
	Cancer	Wholegrain	5.6
	Cardiovscular disease	Beta Carotene	5.6
	Cardiovscular disease	Omega 3 fats	5.6
	Cardiovscular disease	Wholegrain	5.6
	Spina bifida	Folate	5.6
		Total	100%
Diet – serious *N* = 5	Diabetes	Whole food	25.0
	Cholesterol	Whole food	25.0
	Cancer	Diet	12.5
	Cardiovascular disease	Diet	12.5
	Birth defects	Folate	25
		Total	100%
Disease management *N* = 4	Dyspepsia	Whole food	50.0
	Asthma	Whole food	25.0
	Hematemesis	Whole food	25.0
		Total	100%

Sixty-seven different types of nutrients or food components were the subject of health claims in this survey. The largest category was claims for the whole food (30.1% of all claims), followed by fibre (7.7%), calcium (5.4%), cultures (5.4%), iron (4.9%) and glycaemic index (3.5%). Benefits most commonly claimed for whole foods were: overall health (31% of whole food claims), energy (20%), mood (6.7%), mental function (5.9%), weight (5.2%), digestion (4.6%) and performance (4.1%). The most frequently cited components with SHF claims were calcium (15%), folate (9%), iron (9%), vitamin B2 (9%), vitamin B1 (9%) and vitamin B3 (8%). In the high-level claims such as biomarker improvement claims, sterols and stanols were most frequently recorded as the active components (44%). For biomarker management claims glycaemic index (36%) and resistant starch (32%) pre-dominated. Biologically active substances, other than recognized nutrients or energy, which were the subject of claims included: alfalfa, bioflavonoids, catechins, chamomile, choline, citric acid, cranberry, creatine, echinacea, ginko, isoflavones, lemon, peppermint, phaseolamin, phytic acid, phytoestrogens, polyphenols, prebiotics, probiotics, psyllium, resistant starch, rutin, silica, soy protein, St John's Wort and sterols and stanols.

Claims for some components - such as those for cultures, glycaemic index, and the whole food – were included in more than one claim category. The differences in the wording of claims across the different categories were often subtle but provide some insight into how such variation can lead to different classification of health claims. Examples to demonstrate these differences are presented in Table 7.

Compliance with regulations

All 12 therapeutic claims and all but one of the high-level claims recorded in this survey did not appear to comply with the current provisions of the Food Standards Code. When assessed against Standard 1.1A.2, only one of two risk-reduction-serious claims about folate and reduced risk of neural tube defects reflected the wording of the pilot claim required by the Food Standards Code and was therefore a legal claim. None of the high-level claims could be assessed against the criteria contained in P293 without applying the proposed process for substantiating health claims, which was beyond the scope of this study. Under the current standard 1.1A.2 (3b) manufacturers are not permitted to use the word 'health' as part of or in conjunction with the name of the food.[3] In this survey 52 products (0.7%) included 'health' or 'healthy' in their name.

Discussion

Claims from all different pack sizes for each product were included in this survey to enable any differences in labelling on various pack sizes to be captured. While this resulted in duplicate claims being recorded, it also provided insight into the number of claims actually presented to the consumer when grocery shopping. Due to time and resource limitations some food categories were not included in the survey, including confectionery, nuts and seeds.

Table 7. Examples of wording of claims in different claim categories relating to the same component

Component	Claim wording	Type of claim
Culture	Contains A,B &C cultures which can assist in digestion and maintaining good health	General health maintenance
	Contains live A&B cultures which everybody needs for balanced digestive enzymes	Specific health function
	Bifidus BL, eaten regularly it strengthens your digestive system	Enhancement
Whole food	Has been a healthful delight for centuries, it promotes a state of calm serenity…fosters an ambiance of response and relaxation	General health maintenance
	For sustained energy and performance	Performance
	Improves and increases concentration and reaction speed	Enhancement
	Dancing body with the word 'REVIVE' next to it	Implied
Low GI	For better long term health	General health maintenance
	Provides sustained energy release	Specific health function
	Can benefit appetite control	Performance
	Particularly suitable for people regulating their blood sugar levels	Biomarker management
	Can benefit blood glucose levels	Biomarker improvement
	Can help with weight loss by keeping you fuller for longer	Slimming

Furthermore, of the food categories surveyed it was not possible to obtain a complete census of foods. Although the outlets surveyed were mostly in the Illawarra region of NSW, this is unlikely to have significantly biased the results. The outlets surveyed included a range of socio-economic areas and all the leading national brand products were included in the survey. Some State-specific and local brands found outside of NSW would not have been included. Unpackaged foods such as fresh fruits, vegetables and hot breads, were also not included in the survey sample. Accordingly, the quantitative data in this study should be treated with some caution and cannot be taken to represent all the foods currently available in Australia. This survey did however attempt to include all the leading products in an extensive range of food categories and provides useful information on the use of nutrition function, health and related claims on packaged food in the Australian market place in 2003.

Prevalence and type of claims

In the current survey 14% of products carried a nutrition function, health or related claim. This is significantly less than the 35% of products found to be carrying nutrient content claims in 2001.[6] Few surveys have been conducted, either in Australia or elsewhere, which examine claim use on packaged food labels. In one study, conducted in 2000/2001 by the USA Food and Drug Administration (FDA), Le Gault *et al*., reported that of 1281 packaged food items surveyed, 4.4% carried a health claim and an estimated 6.2% carried a structure-function claim.[7] Thus, the total proportion of products carrying a health or related claim in the FDA study was approximately 10.6%. In the current survey, because of the inclusion of multiple pack sizes, it is likely that 14% may be a slight overestimation of the true proportion of products carrying health and related claims on the Australian market. Nonetheless the data suggest that while there are similar levels of use of nutrient function claims in Australia as in the US (around 6% of products), the high-level health and related claims may be present to a greater extent on foods in Australia than in the US. The experience in the US was that after the introduction of the legislation that regulated health claims there was a significant decrease in the use of health claims on pack and in advertising.[8, 9] It may be that the current prevalence of high-level claims in Australia will also decline after the introduction of a new standard.

In the US FDA study, only one third of the 57 food categories surveyed carried health claims compared with two thirds of the 47 food categories included in the current study.[7] This proportion of food categories remains unchanged if specific health function and general health maintenance claims are removed from the data set. The food categories with the highest proportion of products carrying health claims in the current survey were: energy drinks, sports drinks, sports bars and breakfast cereals.

The results of this study can also be compared to those from a 1996 study that examined food advertisements in Sydney.[10] Of 1428 magazine advertisements for food that were examined, 7.4% were classified as containing high-level health claims, while a further 3.3% were general well-being or nutrition function messages. This total of 10.7% is similar to the finding of 14% of products with health or related claims reported here. The apparently higher level found in the current survey may reflect an increase in the use of claims over the past seven years, or it may be that claims on packs are not always used in print advertising.

The finding of a large number of claims on breakfast cereals reflects the findings of another study undertaken in the USA in 19 food categories from 1992-1999.[11] The

authors reported a significant increase in the presence of health claims on food labels from 1995-1999 with the greatest increase occurring in the cereal category, in which 41% of products carried a health claim.

There was also a high prevalence of claims on teas (41%). It may be that some of these products were actually classified as dietary supplements rather than foods, since a number of teas have successfully applied to be Listable Goods with the Therapeutic Goods Authority. Such products would be able to make claims about their health effects in ways that are not currently permitted for foods.

General – level claims

Most of the claims recorded in this survey were general-level claims (76%). This is to be expected, given the current regulatory environment that prohibits most high-level claims. This use of general-level claims is likely to remain more common after the legalisation of health claims in the Food Standards Code, if high-level health claims are to require FSANZ pre-approval while general-level claims will not.

A significant proportion of the claims recorded in this survey related to nutrients promoted in the dietary guidelines including dietary fibre, protein, carbohydrate, folate and wholegrain.[12] It is feasible that many benefits associated with these nutrients could be substantiated by reference to the dietary guidelines and associated scientific literature. However, a number of claims were for health benefit and component relationships which reference bioactive substances that are less well known (eg, "catechins…help eliminate toxins"; "contain rutin a bioflavonoid which protects and preserves the elasticity of vein"; "phytic acid a phytonutrient believed to lower cholesterol"). It is uncertain whether these claims could be scientifically substantiated. The high number of components for which claims are being made also raises the question of whether consumers are able to interpret and use such information in a way that promotes health. When there are 67 different ingredients or nutrients promoted with claims on food packs, how are consumers able to decide the ones most relevant to their own needs and relate these claims to general nutrition education messages about a balanced diet?

The diversity of component/benefit pairings in the general-level claims raises the question of how many of the claims could be substantiated using the proposed FSANZ process of evaluation of the scientific literature or by reference to authoritative sources.[2] In Japan, for the category of 'foods with nutrient function claims' there is a list of standardized health claims equivalent to general health maintenance, specific health function and enhancement claims as proposed in P293. The claims relate to Vitamin A, D, E, B1, B2, B6, B12, C, folate, calcium and iron.[13] The Joint Health Claims Initiative of the United Kingdom has also compiled a list of approved structure-function claims for a broad range of vitamins and minerals.[14] The general-level nutrient function claims found in this survey were reviewed for consistency with approved Japanese and UK claims. Only 12 of the 65 recorded components (18.5%) and only 33 of the 255 benefit/component pairings (12.9%) were consistent with these approved claims, although this does not mean that the others are incapable of substantiation.

Health claims referencing the whole food product were the most frequently recorded claims in this survey. Sweden, Japan and Canada are countries that have established food-specific health claim policies. Without evidence from high quality clinical trials testing the health benefit to be claimed about a specific food product, whole food claims may be difficult to substantiate in the regulatory framework currently being proposed by FSANZ. Ongoing monitoring of these claims, and the frequency with which they are present on product labels following the introduction of the new health claim regulations, is therefore warranted.

High-level claims

Thirty-four different health benefit/food component pairings formed the basis of the high-level claims recorded. In the United States, United Kingdom, Sweden and Canada numerous high-level health claims have been approved for use on food products. Of the health benefit/food component pairings recorded in the risk reduction-serious, diet-serious and biomarker improvement claims in this survey, 80%, 60% and 40% respectively are similar to approved claims in other countries.[15]

Australia and New Zealand will have a possible six pre-approved high-level claims included in the health claims standard when it is finalised in 2006. Only 14% of the claims noted in this survey relate to those potential claims. Only one claim was made which was worded in accordance with the pilot health claim currently permitted in the Code on folate and neural tube defects.[3] It seems from the findings of this survey that the peak of manufacturer' use of this claim, reported in 1998 two years after it had been implemented, has significantly declined.[16]

Compliance with the Food Standards Code and implications for regulation

There may be many reasons why there are health and related claims on Australian food labels that do not comply with current regulations. It may be that some food manufacturers or importers are unaware of the controls on claims within the food standards regulations. Some may have difficulty interpreting the Food Standard Code and distinguishing between permitted nutrient function statements and illegal health claims. Some may choose to ignore the current prohibitions on health claims. Enforcement of the Food Standards Code in Australia is the responsibility of each State's food and health authorities. Due to the priority given to other aspects of their work - such as food safety inspections - food standards enforcement is often reactive to complaints rather than being proactively monitored. The number of non-compliant high-level health and therapeutic claims recorded in this survey (119) suggest that many illegal claims are being missed by the enforcement agencies or that inadequate resources are devoted to monitoring and compliance. With the proposed new standard for health claims it will be important that guidance for the food industry is clear, monitoring is regular, and agency enforcement effective

to minimise the number of illegal and unsubstantiated claims made on food labels.

The range of health claims recorded in the present survey was very broad and well beyond the scope of health claims authorised for use in other countries. The number of relatively new bioactive substances cited in health claims in this survey indicates that emerging areas of scientific research are readily being applied to food product development and that health claims are an important medium by which manufacturers drive consumer interest in these benefits. Furthermore, the recorded claims ranged across two thirds of 47 food categories surveyed. With the area of functional foods developing both nationally and globally, manufacturers are likely to be increasingly active in promoting health-type messages to consumers and producing foods with claimed nutritional and health benefits.[17] The degree to which these claims and products are consistent with nutrition messages from public health agencies, thereby reinforcing sound decision-making by consumers, or provide a plethora of messages which may confuse or block decision-making, is yet to be determined. In this climate, and with the legalisation of health claims due by 2006 in Australia and New Zealand, it is important that a management framework for the regulation of health claims is established that is built on the application of sound scientific evaluation, clear and unambiguous communication and comprehensive enforcement.

The results of this study will provide useful baseline data for both manufacturers and regulators to assist evaluation of the impact of proposed changes in health claim regulations in Australia and New Zealand.

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