FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Supporting document 10

International Comparison of Regulatory Requirements for Nutrition Content and Health Claims

P293 – Nutrition, Health & Related Claims

The following tables present a summary of the regulatory requirements for nutrition content and health claims in the EU, Canada and the USA and the recommended regulatory requirements in New Zealand/Australia (Standard 1.2.7).

Table 1: Claims Classification

Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
Nutrition content claims	Nutrition claim	Nutrition (nutrient content) claim	Nutrient content claim
Health claims that do not refer to a serious disease or biomarker of serious disease (general level health claims)	Health claims that are not 'reduction of disease risk' claims (EC regulation No. 1924/2006, Article 13.1 general function; Article 13.5 emerging science and proprietary data; Article 14.1(b) children's claims)[1]	'Health claims' include: *Function claims:* describe the specific physiological effects of foods and food constituents associated with health or performance (can refer to nutrients or non-nutrients[2]) *General health claims[3]:* broad general claims that promote health through healthy eating or that provide dietary guidance. These claims do not refer to a specific or general health effect, disease, or health condition	Structure /function claim
Health claims that refer to serious disease or a biomarker of a serious disease (high level health claims)	Reduction of disease risk claim (Article 14.1(a))[1]	Disease reduction and therapeutic claims	Health claim

[1] The regulatory approach for all types of health claims is the same.
[2] Pre-market assessment of non-nutrient function claims is encouraged but is voluntary.
[3] These claims are subject to the Food and Drugs Act which prohibits false, misleading or deceptive product representation; however they have no specific additional requirements.

Please note: Reference to nutrient profiling in this international comparison refers to the application of specific criteria (for example, energy, salt, sugar, saturated fat, protein, dietary fibre levels and fruit/vegetable content, in the FSANZ system) for determining the eligibility of food products to make health claims. In the EU, this term is frequently used in the context of various types of nutrition labelling such as front-of-pack labelling. The World Health Organization is currently developing guidance on 'nutrient profiling' which may well cover both these types of applications.

Table 2: Nutrition Content Claims

	Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
Permission	Claims about specified food properties with specific conditions and qualifying criteria listed in Standard, e.g. vitamins, minerals, protein, dietary fibre, fat and components of fat. Claims using certain descriptors (eg. 'low', 'high', 'reduced', 'increased') permitted only for food properties listed in Standard. Certain claims (eg. 'source of') about food properties not listed in the Standard are permitted.	Conditions for some nutrition claims listed in EC regulation No. 1924/2006. Use of descriptors restricted. For example 'high' only permitted for fibre, protein, vitamins, minerals and fatty acids.	Only those claims listed in the regulations are permitted	Claims listed only in the regulations are permitted. New claims require pre-approval as such or under FDAMA. Such claims are based on an authoritative statement by a scientific body of the USA government or the National Academy of Sciences. Accurate quantitative statements may also be used, such as 'contains X grams of omega-3 fatty acids per serve'.
Substantiation	Food must on average contain the component that is the subject of the claim at levels that are referred to in the claim.	None	None	Data needed to demonstrate why use of the claim is of importance in human nutrition. Data needed to show the amount of nutrient that is present in the types of foods for which the claim is intended. Information needed on the effect of use of the claim on food consumption and of any corresponding changes in nutrient intake.

Table 2 continued

	Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
Nutrient profiling restrictions	Specific disqualifying criteria apply for some claims. Nutrient profiling does not apply.	Required for some nutrition claims based on the nature of the claim e.g. low sodium, high protein	None	Disclosure statement required where the food contains one or more of specified nutrients at levels that exceed set quantities. Four nutrients considered – fat, saturated fat, cholesterol, sodium – with minimum or maximum levels set per serve as appropriate.
Wording conditions	Some wording conditions relating to 'reduced', 'light' and 'increased' claims only.	Generally none specified.	Only prominence requirements	Claim may be no more than twice as prominent as name of the food Where disclosure statement required it must be adjacent to the claim and in minimum type size.

Table 3: General Level Health Claims

	Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
Permission	The food-health relationship underpinning a general level health claim must be either pre-approved by FSANZ or self-substantiated. Pre-approved food-health relationships are listed in the Standard along with wording conditions and qualifying criteria as appropriate. At gazettal, the Standard will include >200 pre-approved food-health relationships that can be used to support general level health claims.	Claims permitted only if gazetted and included in the EC Register of 'Nutrition and Health Claims made on a food'. The Register contains 241 authorised claims (last updated May 2012).	Two types of function claims not considered drug claims: (1) 'Nutrient function' claims are expressly permitted in regulations. (2) 'Non-nutrient function' claims are not expressly prohibited if they are truthful and not misleading. 'General level' claims also permitted (do not refer to a specific health effect, disease or health condition, but includes dietary guidance).	If claim mentions a disease or health-related condition, it is classified as a health claim, not a structure/function claim Can be made without pre-approval but should not be false or misleading. Guidance for industry available.
Substantiation	For pre-approval, FSANZ will assess the food-health relationships based on the totality and weight of evidence. External scientific advice on FSANZ's assessment will also be obtained. For self-substantiation, food businesses must establish the food-health relationship according to the requirements set out in Standard 1.2.7. The degree of certainty required for FSANZ pre-approval and industry self-substantiation of food-health relationships underpinning general level health claims is the same.	European Food Safety Authority (EFSA) provides an opinion based on generally accepted scientific evidence of beneficial physiological effect in humans. EFSA opinion referred to EC for approval in conjunction with Member States. For Article 13(5) claims authorisation is required on a case-by-case basis. For confidentiality reasons summaries of these applications are not published.	Pre-approved list established for 'nutrient function' claims for known nutrients and well established functions. List can be updated for substantiated claims. Industry encouraged to seek guidance on acceptability of new non-nutrient function claims and to hold the evidence for these claims if they are not pre-approved.	Any claim made must be truthful and not misleading. The manufacturer is responsible for their accuracy and truthfulness.

Table 3 continued

	Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
Qualifying compositional criteria	Qualifying criteria specified in Standard 1.2.7 for general level health claims derived from pre-approved food-health relationships, as appropriate. For general level health claims based on self-substantiation, qualifying compositional criteria are not specified.	Conditions of use specified for each claim e.g. information to the consumer of the amount to be consumed to obtain the beneficial effect.	Apply. Claims around protein must meet the requirements for 'source of protein'; claims for vitamins and minerals must have a minimum of 5% RDI for that vitamin or mineral. Qualifying criteria not specified for claims relating to other nutrients.	N/a
Nutrient profiling restrictions	Foods carrying general level health claims must pass the nutrient profiling scoring criterion.	Originally planned to be in place by 2009 but this was not achieved. As of October 2012 nutrient profiling is still being considered.	None	N/a
Wording conditions	For general level health claims derived from pre-approved food-health relationships, specific wording conditions for population group and dietary context statements are included in Standard 1.2.7, as appropriate. Actual wording of a claim is not prescribed. For general level health claims based on self-substantiation, there is a general requirement that the population group and dietary context statement be included in the claim, as determined by industry.	FSANZ understands that it is a model claim. The following information also must be provided: • importance of a balanced diet and healthy lifestyle; • quantity of the food and pattern of consumption required to obtain the claimed beneficial effect; • details of persons who should avoid the substance concerned; and • details of the health risks caused by excessive consumption.	All words, signs, numbers and symbols must be of equal prominence. Information required to accompany the claim must be in type of equal prominence to the claim, and must be adjacent to the claim.	N/a

Table 4: High Level Health Claims

	Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
Permissions	The food-health relationship underpinning a high level health claim must be pre-approved by FSANZ. Pre-approved food-health relationships are listed in the Standard along with wording conditions and qualifying criteria as appropriate. At gazettal, the Standard will include 13 pre-approved food-health relationships that can be used to support high level health claims.	As for general level health claims above.	Claims listed only in the regulations are permitted	Claims listed in the regulations are permitted and new claims require pre-approval. Alternatively, FDA can exercise its enforcement discretion and authorise health claims made under the FDA Modernization Act (FDAMA) or qualified health claims and published them on the FDA website.
Substantiation	For pre-approval, FSANZ will assess the food-health relationships based on the totality and weight of evidence. External scientific advice on FSANZ's assessment will also be obtained. The degree of certainty required will be the same as for general level health claims.	Applications for Article (14) claims are transmitted to EFSA by competent authorities in Member States. Thereafter, EFSA provides an opinion based on generally accepted scientific evidence of beneficial physiological effect in humans. EFSA opinion referred to EC in conjunction with Member States for approval.	Substantiation evidence must be presented to the regulator, and must incorporate – a high level of scientific rigor and depth, with consideration given to the totality of evidence, study quality, causality, relevance and generalisability, and a systematic approach. Disease risk reduction claims – preapproved by Health Canada if supported by 'significant scientific agreement'. No system of 'qualified' health claims of FDAMA health claims.	Three options for pre-approval or authorisation by FDA: 1. Manufacturer submits evidence that must meet a high standard of 'significant scientific agreement' for approval. 2. Manufacturer submits scientific evidence, but is sufficient for authorisation as a 'qualified health claim' according a level of evidence (B – D): (PTO)

Table 4 continued

<table>
<tr><th></th><th>Australia/New Zealand (Standard 1.2.7)</th><th>EU</th><th>Canada</th><th>USA</th></tr>
<tr><td>Substantiation continued</td><td></td><td></td><td></td><td>
Standardized Qualifying Language for Qualified Health Claims.
<table>
<tr><th>Scientific Ranking*</th><th>FDA Category</th><th>Appropriate Qualifying Language**</th></tr>
<tr><td>Second Level</td><td>B</td><td>... "although there is scientific evidence supporting the claim, the evidence is not conclusive."</td></tr>
<tr><td>Third Level</td><td>C</td><td>"Some scientific evidence suggests ... however, FDA has determined that this evidence is limited and not conclusive."</td></tr>
<tr><td>Fourth Level</td><td>D</td><td>"Very limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim."</td></tr>
<tr><td colspan="3">*From Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data.
**The language reflects wording used in qualified health claims as to which the agency has previously exercised enforcement discretion for certain dietary supplements. During this interim period, the precise language as to which the agency considers exercising enforcement discretion may vary</td></tr>
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	Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
				depending on the specific circumstances of each case

Table 4 continued

	Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
Substantiation continued				3. Manufacturer submits evidence based on authoritative statements by a scientific body of the USA government or the National Academy of Sciences (FDAMA claims) for FDA authorisation.
Qualifying compositional criteria	Qualifying criteria specified in Standard.	As for general level health claims above.	Specific criteria apply to individual claims (both qualifying and disqualifying as appropriate)	Specific qualifying criteria apply to individual claims. General qualifying criteria also apply: - a food product must contain, without fortification, ≥10% Daily Value of one of: vitamin A , calcium, vitamin C, protein, iron, or fibre
Nutrient profiling restrictions	Foods carrying high level health claims must pass the nutrient profiling scoring criterion.	As for general level health claims above.	None	General disqualifying criteria also apply: - a food cannot exceed specified levels of total fat, saturated fat, cholesterol, or sodium. Specific disqualifying criteria may also apply to individual claims.
Wording conditions	Specific wording conditions for population group and dietary context statements are included in Standard as appropriate. Actual wording of a claim is not prescribed.	As for general level health claims above. For claims relating to reduction of disease risk, the presentation of the claim shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a	Exact wording prescribed, with alternative options provided. Specific nutritional information required for some claims.	Exact wording for claim in regulation (i.e. that meets significant scientific agreement) not prescribed, but required elements of the claim are specified and model claims are suggested. Exact wording for qualified health claims which includes reference to the strength of evidence as indicated above. Exact wording for FDAMA health claims

	Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
		beneficial effect.		but no reference made to the strength of evidence (as it is a high standard of evidence already).

Table 4 continued

	Australia/New Zealand (Standard 1.2.7)	EU	Canada	USA
Wording conditions continued				Claim must be expressed using 'may' to express the relationship between substance and disease. Context of the claim is expressed in terms of a 'total daily diet'. All information relating to claim must be positioned in one place without intervening material.