ATTACHMENT 12

FINAL ASSESSMENT REPORT FOR PROPOSAL P293 – NUTRITION, HEALTH & RELATED CLAIMS

International Benchmarking

Contents

1. INTERNATIONAL BENCHMARKING – A COMPARISON OF THE MAJOR REGULATORY FEATURES OF FOUR INTERNATIONAL REGULATORY SYSTEMS.

This chapter compares the proposed regulations for Australia and New Zealand, as developed by Food Standards Australia New Zealand (FSANZ) with the regulatory systems for nutrition and health claims of three international jurisdictions, specifically with regard to the key agencies responsible in each jurisdiction. These are: Health Canada (HC) for Canada, the Food and Drug Administration (FDA) for the United States (US) and the European Commission for the European Union (EU). It is recognised that other regulatory agencies within each jurisdiction will also have provisions that impact on the ultimate regulatory management of most food products, for example, fair trading laws.

These three jurisdictions are major international players in the regulation of nutrition and health claims. The US has a long history in regulating claims, starting with development of standards for evaluation of health claims in 1987. Prior to a change in the law in 1990 health claims had been prohibited. In Canada, a Policy Paper on Nutraceuticals/Functional Foods and Health Claims on Foods was published in 1998 and several health claims were put into Regulations in 2002. Canada is currently conducting further consultations on managing the different types of health claims on foods, touching on many of the topics discussed in this document. Regulations for nutrition and health claims in the European Union (EU) came into force after their publication in the Official Journal of the European Commission in January this year. There is ongoing work taking place in relation to implementation of these new regulations, including finalisation of the nutrient profiling system.

All of these jurisdictions are members of the Codex Alimentarius Commission (referred to here as Codex). Hence their regulations may draw, to varying degrees, on the Codex *Guidelines for Nutrition and Health Claims*, and *General Guidelines on Claims*. This adds an element of commonality to the approach taken towards nutrition and health claims. However, there are also notable differences in the regulatory structure used by each of the jurisdictions. Differences in uses of terminology also need to be taken into account due to impacts on interpretation and extent of direct comparability.

The major features of the nutrition and health claims regulatory systems are discussed and compared below: classification of types of claims, the regulatory approach applied to each claim category, disqualifying criteria/nutrient profiling requirements and substantiation. Refer to Table 2 in Chapter 4 for a summary of the regulatory systems.

1.1 Claims classification

Notwithstanding some definitional differences, all four regulatory systems bear similarities in the manner used to classify claims into categories. This is indicative of a common understanding of the level of public health risk inherent in each of the various approaches utilised to present claim-type information to the consumer. Each claim grouping is further discussed below, under the heading of the category used in the proposed system for Australia/New Zealand.

1.1.1 Nutrition content claims

These claims are the most simple of the various categories, and convey a relatively simple message about the presence, absence, or level of a nutrient (or energy) in a food product. An associated health effect is not described. All four regulatory systems identify this category in a similar manner as the least complex of the claim types. However, the apparent simplicity of the information presented does not necessarily translate into a negligible level of risk to the consumer. In keeping with this, some regulatory agencies have placed tight controls over which content claims may be used, and all four regulatory agencies have considered various risk management strategies for this category of claims. These aspects of nutrition content claims are discussed in section 2.1.

1.1.2 General level health claims

Under the regulatory system proposed for Australia/New Zealand, general level health claims are defined by exclusion. They are those health claims that do not fall into the high level health claim category; that is do not reference a 'serious' disease or biomarker of a 'serious' disease (for specific definition of these terms see the draft Standard). A broadly similar approach is taken under the EU system, where these claims are classified as those health claims that do not fit the definition of a 'reduction of disease risk claim'. It is foreseen that the EU will develop a list of permitted claims.

In applied terms, the type of claims that will fall within this category are statements that describe the role of a specific nutrient in relation to the 'normal' function or structure of the human body, or those that refer to a 'non-serious' disease. Some of these function or structure claims may be very specific in nature; drawing on the particular role of a nutrient in a specific bodily function or structure, whereas others may be more general in nature, for example, indicating that the subject nutrient is important for growth and/or maintenance of the body. Claims that address risk reduction of non-serious diseases could refer to non-serious diseases, such as constipation. Such a claim might be: *a healthy diet high in fibre reduces the risk of bowel irregularity*.

The Canadian and US regulatory systems take an inclusive approach to classifying the equivalent group of claims, reflecting the nature of the information conveyed, with the former defining the category informally as 'biological role claims' when they are about energy or nutrients, and the latter as 'structure/function claims'. Disease risk claims, whether serious or non-serious, are not included within this category in these jurisdictions. If a disease or health-related condition is included in the claim, the claim is classified as a health claim, not a structure-function claim.

In its policy development process, Canada is identifying a category of general claims about 'healthy choice'. This encompasses claims that do not refer to a specific health effect, disease or health condition, including claims that promote choosing a food for overall health, healthy eating. Under the Australian/New Zealand system general educative dietary information is not considered to be a health claim, but if it relates to a property of the food, dietary information must be directly associated with a nutrition content or health claim. Where dietary information directly relates to a food rather than a property of a food, the food is not required to carry a nutrition content claim or health claim. General health and well-being claims are not permitted by virtue of not meeting the required specificity for a compliant health claim.

1.1.3 High level health claims

The defining feature of this category of claim is that they link a specific nutrient to disease or disease-risk. Under the proposed system for Australia/New Zealand, the claims in this category relate specifically to serious disease or biomarkers of serious disease. Of the four regulatory systems under discussion, the Australian/New Zealand system is unique in its explicit definition and inclusion of the 'biomarker' concept. The definitions used under the three other regulatory systems do not use this term, instead focusing on a reduction in disease-risk. The US system permits surrogate endpoints to be used to determine risk reduction of a disease. Despite the difference in the terminology that is used to define the boundary of this group of claims, each regulatory system has a similar intent in identifying this category as that carrying the greatest level of potential health-impact. All four regulatory systems apply the tightest level of regulation to this category of claims, using a requirement for pre-approval to determine if and how each individual claim may be applied to food products.

1.1.4 Related claims

The proposed Australian/New Zealand system recognises and regulates three further types of claims – endorsements, dietary information and cause-related marketing. Equivalent categories of claims are not formally recognised under the regulatory systems of the US or Canada, however in Canada, they are considered implied health claims and are included in the consultation on managing health claims on foods. US regulations categorise certain third party endorsements (e.g. the American Heart Association symbol) as implied health claims. Like the Australian/New Zealand system, the EU system also recognises cause-related marketing statements, and proposes that in the future these statements must be linked to an appropriate health claim. The EU system also specifically prohibits the use of claims which reference the recommendations of individual doctors or health professionals. In addition the EU system prohibits the recommendations of associations other than national associations of medical, nutrition or dietetic professionals and health-related charities.

2. REGULATORY APPROACH

2.1 Nutrition content claims

Differing degrees of regulation have been applied to nutrition content claims by the different jurisdictions (referred to as nutrient content claims in the US and Canada systems and nutrition claim in the EU). Some groups have taken a more controlled approach, setting conditions for those claims which are permitted and prohibiting all other claims. This approach is used in Canada, where only those nutrient content claims listed in the Food and Drug Regulations are permitted. The EU regulations take a similar approach, with nutrition claims only permitted where they are included in the regulations and comply with the specified conditions. Scope for amendment of the permitted list to include new nutrition claims is provided in the regulations. The US regulatory system is once again similar, with permitted nutrient content claims specified in the regulations. An avenue for consideration of new nutrient content claims is also available under the US system, whereby a firm may submit a notification for a claim based on an authoritative statement by a US government scientific body or the National Academy of Sciences, and the regulator has a specific period in which to object.

These types of claims, referred to as FDAMA (FDA Modernization Act) claims, can be modified subsequently through rule-making after the notification period, if necessary. In addition to this avenue, interested persons can petition the agency to define a new nutrient content claim.

In addition to the specific claims permitted within the US system, accurate quantitative statements may also be used, such as 'X grams of omega-3 fatty acids per serve'.

Under the proposed regulations for Australia/New Zealand a positive list is not provided. However, specific conditions and criteria have been set for a range of nutrition content claims and must be followed where applicable. Nutrition content claims that indicate the presence of a nutrient, for example 'contains…' or 'with…' may be made, providing they are true. Where criteria have not been set claims may still be made, noting generic fair trading provisions against false and misleading conduct apply. The use of certain descriptors, e.g. 'low', 'high', 'reduced' and 'increased', is permissible only in relation to those nutrients for which conditions are set, or, where applicable, a reference value is given in the regulations.

Specific food composition criteria are applied by each regulatory agency to specific content claims. Most commonly the criteria draws directly on the subject nutrient, for example: to qualify to carry a *low salt or sodium* content claim a food must contain no more than a specified amount of sodium (with this amount varying between the jurisdictions). However, the criteria for some content claims may also draw on nutrient/s other than that claimed, for example: the proposed criteria for omega-3 content claims in Australia/New Zealand include requirements around total, as well as saturated and *trans*-fatty acids.

A key difference between the regulatory systems under discussion is that some have chosen to apply compositional criteria for foods able to carry health claims (also known in some jurisdictions as disqualifying criteria) to nutrition content claims. Under the EU system, nutrient profiling restrictions (specifics yet to be developed) will be placed around all levels of claims, including nutrition claims. Under the US system a disclosure statement is required where the food contains one or more of specified nutrients at levels that exceed set quantities. This statement draws attention to that nutrient(s), for example: "see nutrition information for sodium content". The specified nutrient levels used for these criteria are detailed further in the section on nutrient profiling below. A more liberal approach towards nutrition content claim regulation has been taken by the proposed Australia/New Zealand regulatory systems and Canada, where no nutrition profiling restrictions are in place for this category of claims. Nutrition profiling, or disqualifying criteria, are further discussed in section 3.

Both the Canadian and US regulatory systems have implemented further risk management strategies around nutrition content claims to reduce the possibility that information is inappropriately presented. The Canadian system ensures that no one component of the claim is more visible to consumers, requiring that all words, as well as signs, numbers and symbols, are of the same prominence. In addition, the Canadian regulations ensure that information that is required to accompany the claim (such as a quantitative declaration of an energy or nutrient value) is presented in a manner readily visible to readers of the claim – the type used must be of equal prominence to that of the claim, and it must be positioned adjacent to the claim. The US regulator has placed restrictions on the format and style of the type used to express nutrition content claims, specifying that the claim may be no more than twice as prominent as the name of the food (statement of identity), and the style of the type may not make the claim unduly prominent compared to the name of the food.

Where disclosure statements are required under the US system, these are required to be presented adjacent to the claim and in a defined minimum type size.

2.2 General level health claims

Differing degrees of regulation are applied to this category of claims by different regulatory groups.

In the US, claims on food products which are referred to as structure/function claims are not subject to pre-approval or notification to the regulator, and are not provided in a 'positive list'. However, claims of this type must nonetheless be truthful and not misleading. Structure/function claims applied to dietary supplements are regulated by the FDA and products carrying them are required to have a specific disclaimer as well as be notified to the FDA.

Under the EU regulatory system this category of claims needs permission from the regulator, such as inclusion in the 'positive list'. In Canada, claims about well established functions of nutrients and energy, known as 'biological role claims', and only those specified by the regulatory agency, Health Canada, are permitted and a list of specific acceptable claims are listed in the *2003 Guide to Food Labelling and Advertising*. Other general health claims are also permitted as long as they are truthful, not misleading and do not bring the product within the definition of a drug as defined in Section 2 of the *Food and Drugs Act*. As claims of this type are reviewed and accepted, they will also be listed in the Guide. Again, management of this type of claim is an issue under consultation in Canada.

Under the EU system a 'positive list' of permitted health claims is currently being developed by the European Commission. Certain types of claims will be prohibited, such as claims which suggest that health could be affected by not consuming the food; claims which make reference to the rate or amount of weight loss; and claims which make reference to recommendations of individual doctors or health professionals and associations other than national associations of medical, nutrition or dietetic professionals and health-related charities.

Under the proposed Australian/New Zealand system, general level health claims are not restricted to a specified list, although a list of nutrient function statements is included in Schedule 2 of the draft Standard as a resource for both industry and enforcement agencies. In addition to 'structure-function' type claims, claims that refer to non-serious diseases will also be permitted under this category of health claim. The substantiation of any proposed general level health claim will be the responsibility of the manufacturer; using procedures set out in the regulations, and will be subject to post-market compliance requirements on request.

Qualifying compositional criteria are applied to all general level health claims by the proposed Australian/New Zealand system and the Canadian system, and are also proposed for the permissible claims that are included in the EU Commission's 'positive list'. Under the proposed Australian/New Zealand system, criteria are linked to nutrition content claim conditions for the relevant nutrient, with claims relating to risk-decreasing nutrients being required to meet the relevant conditions for making a 'source of' nutrition content claim as a minimum, and claims relating to risk-increasing nutrients being required to meet the conditions for making a 'low' nutrition content claim. In some cases conditions are not provided for making a nutrition content claim about a particular nutrient.

In these instances, a general level health claim may still be made about that nutrient, provided a nutrition content claim is permitted, and it is appropriately substantiated.

A similar, though more limited, approach to qualifying compositional criteria is used under the Canadian system. Under this system, biological role claims in relation to protein must meet the requirements for *source of protein*, and claims in relation to vitamins and minerals must have a minimum of five percent of the RDI for that vitamin or mineral. However, at present qualifying criteria are not specified in regulation for acceptable function claims relating to other nutrients, for example fat, DHA and carbohydrates.

Under the EU regulations, in addition to qualifying compositional criteria it is proposed that the risk management statements used for high level health claims are also applied to general level health claims. Where a general level or high level health claim is used the following information must be provided on the food label (or in the presentation or advertising where appropriate):

- the food product vehicle must bear a statement indicating the importance of a balanced diet and health lifestyle;
- the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;
- where appropriate, a statement addressed to persons who should avoid the food and/or warnings not to exceed quantities that may present a health risk; and
- an appropriate warning for products that are likely to present a health risk if consumed to excess.

The proposed Australian/New Zealand system also applies wording conditions to general level health claims – the claim must state the property of the food and the specific health effect in relation to the property of the food ('property' and 'health effect' are defined in the regulations), and the claim must be expressed in relation to the relevant population group (if any) and in the context of an appropriate healthy diet. The specificity required by these conditions effectively prohibits implied health claims. In addition to these general wording conditions, further wording requirements may also apply to certain general level health claims in Australia/New Zealand.

For the general level health claims permitted under the Canadian system requirements for the claim's presentation are the same as for nutrition content claims – all words, as well as signs, numbers and symbols, must be of the same prominence, and information that must accompany the claim must be positioned adjacent to, and be of equal prominence to, the claim.

In addition to qualifying compositional criteria and wording conditions, nutrition profiling criteria are also applied to general level health claims by two regulatory systems – the EU system (with specifics still to be decided) and the proposed Australia/New Zealand system. Nutrition profiling is further discussed in section 3.

2.3 High level health claims

This category of claim carries the greatest degree of regulatory control of all the systems discussed. This is consistent with their having the greatest potential for health detriment in the case of misuse.

All of the regulatory systems under discussion require that high level health claims are pre-approved by the relevant regulatory authority. The US system also provides an additional avenue for high level health claims to be based on an authoritative statement by a scientific body of the US government or the National Academy of Sciences (discussed further below). In addition to substantiation requirements, a range of compositional and wording requirements are also applied to these claims.

Food compositional criteria are applied to these claims under each of the regulatory systems. In the EU, nutrient profiling criteria, which are still to be developed, will apply to this category of claims. Further specific criteria may apply to individual claims; however, these have also yet to be determined. Under the Canadian system, specific compositional criteria are applied to health claims on a case by case basis. Under the Australian/New Zealand system food compositional criteria will be applied to high level health claims, also on a case by case basis. Specific qualifying criteria applying to individual claims will be set by FSANZ based on the substantiation evidence underpinning that claim, as well as the distribution of the claimed nutrient in the food supply. The generic disqualifying criteria for high level health claims are those that apply to general level health claims, based on nutrient profiling, and apply to all high level health claims unless an individual amendment is made. A similar approach is taken in the US, where either general or specific disqualifying criteria apply to high level health claims. However, in addition, general and specific qualifying criteria must also be met before a food may carry a claim of this type, making the US the most restrictive of the four regulatory systems in regard to qualifying/disqualifying criteria for high level health claims.

Wording requirements for high level health claims are included in the Canadian, the US and the Australia/New Zealand systems. Under the Canadian system, the exact wording for permitted claims is prescribed, with some alternative options provided for each claim. The Australian/New Zealand and US systems take a less prescriptive approach to wording, allowing for some flexibility. Under this proposed system, the essential claim elements are specified – the property of the food and the specific health effect - though the manner in which they are linked is not prescribed. In specific instances however, specific wording may be prescribed for individual claims, for example, where warranted by substantiation evidence underpinning the claim. Under the US system, claim wording may be varied provided that claim requirements are met, including a number of general requirements. Although specific wording requirements for the EU are yet to be developed a number of requirements are already described in the regulations– see Table 2 in Chapter 4 for details.

Additional wording elements are also required for high level health claims under those regulatory systems that do not prescribe exact wording. These are generally aimed at communicating the broader context around the health claim and thereby reducing or managing the potential for claims to be misleading. For example: the commonly used requirement is that the context of the claim is expressed in terms of a healthy diet (Australia/New Zealand), or a total daily diet (US), or a balanced diet and healthy lifestyle (EU). Further requirements of each jurisdiction are presented in Table 2 in Chapter 4.

2.4 Biologically active substances

Biologically active substances form one of the most rapidly growing areas of nutritional research and interest. For Australian/New Zealand regulatory purposes these are deemed to be substances other than a nutrient, with which health effects are associated.

Potential claims relating to these substances are regulated in differing ways by the jurisdictions under discussion.

Under the proposed Australian/New Zealand claims system the regulations allow scope for nutrition content claims and general level health claims relating to biologically active substances. Nutrition content claims for these substances must not contain a descriptor in relation to the level present, such as *high*, *source of*. General level health claims may also be made for biologically active substances but have additional wording requirements specifically designed to risk manage the absence of bi-nationally recognised reference values. Under the US system, structure-function claims around biologically active substances can also be made, as this type of claim does not require pre-approval or review by the regulator.

Under the Canadian system, the regulations permit claims in the general level category must be made in respect of a nutrient or energy to the effect that the nutrient or energy contained in the food is generally recognised as an aid in maintaining the functions of the body necessary to the maintenance of good health and normal growth and development. 'Nutrient' for this purpose is defined according to the Institute of Medicine of the National Academies, Washington. Claims for other components of food, as lycopene or anthocyanins et cetera, may be made so long as they are truthful and not misleading and do not bring the product within the definition of a drug as defined in Section 2 of the *Food and Drugs Act*. In such cases, case-by-case evaluation is recommended so that acceptable claims can be clearly identified in a positive list.

It remains to be seen whether the positive list of claims developed by the EU will contain claims around any biologically active substances.

2.5 Regulatory prohibitions

2.5.1 Infant formula and foods for young children

Three of the four regulatory systems assessed have chosen to place restrictions around the application of health claims on infant formulas and foods for young children. This is consistent with the Codex *Guidelines for use of Nutrition and Health Claims*, which indicates nutrition and health claims should generally not be permitted for foods for infants or young children except as specifically provided for.

Within the proposed Australian/New Zealand regulatory system nutrition content and health claims are prohibited from use on infant formula products, unless specifically allowed in the relevant standard, and it is intended this approach be retained. In this instance 'infant formula products' includes breast-milk substitutes and follow-on formulae which are designed for infants up to the age of six and twelve months respectively. Similar restrictions do not apply to the use of nutrition content or nutrient function-type claims in relation to other infant food products, or other foods for young children over twelve months in age. As high level health claims require pre-approval, their application to such foods for young children would only occur with the express permission of FSANZ.

Both the US and Canadian systems also recognise that health information in relation to foods for young children requires particular attention. Under these systems a prohibition relating specifically to high level health claims is extended to cover a greater range of children's foods, encompassing all foods for children under two years of age.

However, the US system does allow for specific provisions to be made in the regulations for particular claims on these foods. The Canadian regulatory system does not prohibit general level health claims/structure function claims but allows only a limited number of nutrient content claims on foods for children under two years of age. Both regulatory systems allow nutrition content claims or general level health claims/structure function claims on foods for children less than two years of age. However, they deviate from the proposed Australian/New Zealand system in that they do not prohibit nutrition content claims and general level claims/structure-function claims on infant formulae. In Canada, claims require case-by-case evaluation before permission for use on infant formulae can be granted.

The EU regulatory system does not specify a prohibition in relation to foods for infants or young children. Claims relating to infant formulae are regulated under the specific legislation. However, for other foods, claims referring to children's development and health are to be treated in a similar manner to high level health claims (reduction of disease risk claims) which require authorisation by the European Food Safety Authority (EFSA) before use. A dedicated list of permissible claims referring to children's development and health is currently under development.

2.5.2 Foods and beverages containing alcohol

Both the Australian/New Zealand regulatory system and the proposed EU system consider it inappropriate for claims to be used to promote the consumption of products that contribute significantly to alcohol intake. Both regulatory authorities have placed similar restrictions on the use of nutrition and health claims for these products, with the proposed Australian/New Zealand regulations specifying that products containing 1.15% alcohol (by volume) or greater may not carry claims, and the EU regulations specifying 1.2% alcohol as the cut off point. However, both systems permit the use of nutrition content claims that refer to alcohol or energy content on these products. In addition, the Australian/New Zealand system is also proposing to permit nutrition content claims referring to carbohydrate.

Under the Canadian system there is no broad prohibition on claims in relation to products containing alcohol. However, as for each of the regulatory systems under discussion, all high level health claims require pre-approval and all approved claims include a prohibition for alcoholic beverages. Nutrient content claims are also technically prohibited for alcoholic beverages as the regulations do not specify any reference amount for such beverages on which these claims must be based. In the US, the labelling of alcohol beverages is regulated separately from foods, under the Federal Alcohol Administration (FAA) Act. Regulations for nutrition and health claims are not specifically included in the FAA Act, however it is required that label information be truthful, accurate and specific, and labels must be pre-approved (or specifically exempted from pre-approval), by the Bureau of Alcohol, Tobacco, Firearms and Explosives prior to the sale of most alcoholic beverages.

3. NUTRITION PROFILING REQUIREMENTS

Three of the regulatory systems under discussion have chosen to apply nutritional profiling requirements to nutrition and/or health claims. Canada is the only country which does not apply a common set of core nutrition criteria to all types of health and nutrition claims. Consideration to introducing such criteria is being given in the current consultation on managing health claims.

Under the EU regulations for claims, a nutrient profiling system is to be in place by 19th January 2009. The system will take into account the quantities of certain nutrients, such as fat, saturated fatty acids, *trans*-fatty acids, sugars and salt/sodium, as well as the overall nutritional composition of a food (including other nutrients with scientifically recognised health effects), and the role of the food in the diet of individuals and population groups. Nutrient profile requirements will apply to both nutrition and health claims, however two exemptions will apply to the former. Firstly, nutrition claims may be used for food products that contain one profile nutrient at levels exceeding the profile amount, providing they bear a statement reading 'High [nutrient] content'. This statement must be placed in close proximity to the relevant nutrition content claim. Secondly, nutrition claims referring to a reduced amount of fat, saturated or trans-fatty acids, sugars and salt/sodium will be exempt from nutrition profiling in relation to their subject nutrient.

The US regulatory body uses a graduated approach towards the issue of nutrient profiling. Four nutrients have been selected as those of interest, with levels of these specified per reference amount of food, as indicated in Table 1.

Table 1. Nutrient levels per reference amount of foods, main dishes and meal products (U.S)

	Foods	**Main dishes**	**Meal products**
Fat	13 g	19.5 g	26 g
Saturated fat	4 g	6 g	8 g
Cholesterol	60 mg	90 mg	120 mg
Sodium	480 mg	720 mg	960 mg

The reference amounts that are used for application of these nutrient levels are those presented on food labels, which in most instances must be calculated in relation to serving sizes that are standardised for various food categories. For foods with small reference amounts (defined as 30 grams or less, or 2 tablespoons or less) a size of 50g is also used. Where a nutrition content claim is made on a food product and one or more of these nutrients are present at a level that exceeds those set per serve, the food label must bear a disclosure statement that draws attention to this nutrient/s, for example, "see nutrition information for sodium content". Disclosure statements must be presented in accordance with requirements, which include a minimum type size, and positioning immediately adjacent to the relevant claim.

The proposed regulatory system for Australia/New Zealand takes a less restrictive approach towards nutrition content claims, with no nutritional profiling or generic disqualifying criteria applying to this category of claims. Furthermore, Australia/New Zealand does not standardise serving sizes.

Both the US and the Australian/New Zealand systems apply nutrition profiling to determine eligibility for food products to carry health claims. Under the US system, the nutrient disqualifying level outlined above are once again used, but are applied more rigorously to high level health claims than to nutrient content claims. In order to qualify to carry a health claim a food product must contain less than the specified levels of all four disqualifying nutrients (as well as qualify under any additional criteria that apply for individual claims).

The model that has been proposed for the generic nutrition profiling for health claims in Australia/New Zealand is a modified version of the UK Food Standards Agency Nutrient Profiling Model, which was developed for the restriction of advertising of foods during children's TV viewing times[1], and uses 100 g or 100 ml as the units for calculation. The model is more complex than that used in the US. In addition to considering energy and risk increasing nutrients (sugar, sodium, and saturated fat), the UK and Australian/New Zealand models allow counter-balancing points for fibre, protein, fruit and vegetable content. In order to allow potentially valuable claims (for example, in relation to calcium and various fatty acids respectively) further consideration in the Australia/New Zealand model has been given to some specific food groups, for example: cheeses and edible oils which would otherwise be eliminated because of their total fat content. This model will apply to all health claims – generically to general level health claims and as the default to high level health claims.

4. SUBSTANTIATION

4.1 Nutrition content claims

Evidence underpinning nutrition content claims is generally simple in form – demonstrating the level of the subject nutrient present in the food carrying the claim. These claims do not reference any nutrient function or health effect hence no evidence to support the role of the subject nutrient is applicable.

The nutrient content claim petitions submitted to the FDA need to include data to: demonstrate why use of the claim is of importance in human nutrition; show the amount of nutrient that is present in the types of foods for which the claim is intended; and analyse the effect of use of the claim on food consumption and any corresponding changes in nutrient intake. The proposed Australian/New Zealand and EU systems are very similar in their requirements for substantiation evidence. Under the EU system all nutrition and health claims must be substantiated by generally accepted scientific data, with responsibility for these data falling to the food business operator, who must produce the data to establish compliance on request. Similarly, under the Australian/New Zealand system the onus is also placed on manufacturers to analyse or calculate the nutrient content of the food. The *Nutrition Labelling Compliance Test* (www.inspection.gc.ca) outlines the Canadian requirements for assessing whether a food bearing a nutrient content claim or health claim meets the nutrient content criteria for the claim set out in the *Food and Drug Regulations*. These are similar to the proposed Australian/New Zealand system.

4.2 General level health claims

A range of approaches is taken towards substantiation of this category of claim. General level health claims (structure/function claims) are not pre-approved by the FDA for food products in the US. The FDA nonetheless makes explicit note that any of these claims made must be truthful and not misleading, and that the manufacturer is responsible for their accuracy and truthfulness.

[1] FSANZ gratefully acknowledges permission to use and adapt the UK Nutrient Profiling Model given by UK Foods Standards Agency. The development of this model was funded by the UK Food Standards Agency and was based on extensive work undertaken by Prof Mike Rayner and colleagues.

As discussed above, the approach used in Europe only permits use of those nutrient structure/function statements which are included in their pre-prepared lists or have been the subject of an approved application. This gives the regulatory authorities complete control over which statements they consider to be appropriately substantiated, and thereby relieves manufacturers from the requirement to hold evidence in relation to the function or role described. In Canada, nutrient structure/function claims that have been the subject of an approved application or were pre-approved are listed in a guidance document. Manufacturers using a particular statement nonetheless need to be able to demonstrate that their food contains a qualifying level of the subject nutrient. For example: to qualify to carry a biological role claim in relation to protein, a food product for sale in Canada must contain sufficient quantity of protein to qualify for a 'source of protein' content claim. Under the EU system food products carrying nutrition or health claims must contain the subject nutrient or substance in quantities defined by Community legislation, or where not defined, a quantity that will produce the effect claimed (as established by generally accepted scientific evidence).

The Australian/New Zealand system will also provide a guidance list of pre-substantiated nutrient function statements that can form the basis of a general level health claim without need for further substantiation by a manufacturer. This list is not exclusive, nor obligatory. In addition, further options are available to manufacturers for substantiation of other general level health claims, such as reference to a prescribed list of authoritative sources, or to base claims on the pre-approved food-disease relationships (that form the basis of high level health claims). Alternately, manufacturers may utilise the same process required for high level health claims, i.e. assessment of all the available relevant, suitable quality scientific evidence. A manufacturer must keep the review of the evidence available for inspection by the enforcement agency. Manufacturers will also need to hold evidence demonstrating the presence of the subject nutrient at appropriate quantities in the relevant food product.

By providing alternate avenues for the substantiation of general level health claims, this system provides maximum opportunity for manufacturers to present nutrient function information on their food product, whilst continuing to ensure that claims in this category are underpinned by appropriate scientific evidence.

4.3 High level health claims

Claims in this category require the most rigorous substantiation evidence. Three of the four regulatory systems under discussion – the EU, Canada and Australia/New Zealand - require that all high level health claims are approved by the appropriate regulatory body before use. Once a claim in this category is approved and listed in the appropriate regulation, manufacturers may use it for their food products, provided any qualifying and disqualifying criteria are met. Manufacturers may also apply to the relevant regulatory body for approval of a new high level health claim, providing a review of the totality of the relevant evidence to substantiate the claim, following the procedures set out in the regulation.

Under the proposed EU system, an application for a reduction of disease claim or children's development and health claim will be examined by the European Food Safety Authority (EFSA) and must include certain evidence – relevant, independent, peer-reviewed studies and any other relevant scientific studies.

Detail around the evidence required to underpin a high level health claim under the Canadian system was made available in an interim guidance document published in 2002 (www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam) that described the framework for evaluating foods with health claims, and outlined the general requirements for the type and quality of evidence required for new health claims for foods. These requirements are along the same lines as those outlined for the EU system, involving 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.

Under the proposed Australian/New Zealand regulatory system, the totality of evidence must be sufficient to substantiate a food-disease relationship before a food-disease relationship (which can form the basis of a high level health claim) will be pre-approved. The key elements in evaluating the overall strength of scientific evidence are:

(a) The evidence must support a consistent association between the property of the food, the food, or the group of foods and the claimed health effect;
(b) The evidence must comprise a number of acceptable quality human studies, preferably including some experimental studies;
(c) The evidence must support a food-disease relationship that is biologically plausible;
(d) There must be a causal relationship in which it is shown that consumption of the property of the food, the food or the group of foods causes the health effect independent of other factors; and
(e) To assess causality and the weight of evidence, most weight is given to well-designed experimental studies in humans.

When seeking regulatory approval for a food-disease relationship, two methods for substantiating a food-disease relationship will be available. The first requires a comprehensive review of all available relevant scientific evidence and is similar to the processes outlined above that are currently used in Canada, and proposed for use in the EU. The specific requirements around the type, quality, and amount of evidence that will be required to support an application are outlined in detail in the regulator's *Application Handbook* (a document that lists information requirements for applications to amend the food regulations). The alternative method available under the proposed system will be to make an application to the regulator based on updating a suitable existing review conducted by an authoritative body, for example: evidence from comparable claims approved by overseas regulatory agencies. This option has been included with the aim of streamlining the process and avoiding duplication of equivalent processes undertaken elsewhere. The same standard of scientific rigor will be applied to the review of applications based on this streamlined approach as applies to the comprehensive review process, and in both cases it will be necessary to show that the requisite intake to achieve the claimed effect would be practicable in Australia and New Zealand within the context of a varied, balanced diet.

As a pre-emptory step to the introduction of the new health claims Standard, FSANZ has pre-approved a number of food-disease relationships upon which high level health claims can be based, ready for use at the time the new Standard is gazetted.

Under the US regulatory system high level health claims can gain approval in one of three ways. The first is also common to those described above, requiring that a manufacturer petition the FDA, submitting the appropriate scientific evidence to support their petition.

Evidence must meet a standard of 'significant scientific agreement' for a claim to be approved. In addition, the US system since 2003 has provided for qualified health claims which only need to be supported by credible scientific evidence and so can be based on preliminary, inconclusive or very limited amounts of evidence, provided the wording of the claim is qualified with statements about the level of scientific support, the claim is not misleading, and the substance, at levels necessary to justify a claim, is safe and lawful. For example: the qualified claim in relation to omega-3 fatty acids and coronary heart disease starts – "*supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease*". Claims that meet the significant scientific agreement standard are authorised through rule-making while qualified health claims can be used through the agency's enforcement discretion. The third avenue available in the US is basing the claim on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences. These claims may be used after submission of a health claim notification to FDA. At present, five health claims in the US have been substantiated using this mechanism.

Table 2: International Benchmarking on claims – comparison of four regulatory agencies

Claims Classification

Level of public health risk	Australia/New Zealand	EU	Canada	US
Lowest	Nutrition content claims	Nutrition claim	Nutrient content claim	Nutrient content claim
	General level health claims – includes: • function claims, • claims that reference 'non-serious' diseases.	Health claims that are not 'reduction of disease risk' claims	Healthy Choice claims, including logos and endorsements; Biological role claims; and 'Other function' claims not considered drug claims	Structure /function claims
Highest	High level health claims - includes 'biomarker' concept	Reduction of disease risk claim	Health claims that are disease risk reduction claims or function claims that are considered drug claims.	Health claim

Regulatory Approach

Regulation of Nutrient Content Claims

	Australia/New Zealand	EU	Canada	US
Permissions	Claims with specific conditions and criteria included in the regulations permitted. Claims using certain descriptors ('low', 'high', 'reduced', 'increased') permitted only for nutrients with set criteria, or which have a reference value in the regulations. Other nutrition content claims indicating the presence of a nutrient (e.g. 'contains…' or 'with…').	Only claims listed in the regulations permitted.	Only those claims listed in the regulations permitted.	Only claims listed in the regulations permitted. New claims require pre-approval by the regulator. Or, nutrient content claims may be based on an authoritative statement by a scientific body of the US 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'
Nutrient profiling restrictions	Only specific disqualifying criteria for some claims	Will apply – specifics yet to be developed	None	Disclosure statement required where the food contains one/more of specified nutrients at levels that exceed set quantities.
Wording conditions	Some relating to 'reduced', 'light' and 'increased' claims only.	None, except for the following claims: "light" the claim shall be accompanied by an indication of the characteristic(s) which make(s) the food "light" "no added sugar": If sugars are naturally present in the food, the following indication should also appear on the label: 'contains naturally occurring sugars"	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.	Claim may be no more than twice as prominent as name of the food. Style of type may not make the claim unduly prominent compared to name of the food. Where disclosure statement required it must be adjacent to the claim and in minimum type size.

Regulation of General Level Health Claims

	Australia/New Zealand	EU	Canada	US
Permissions	The nutrient subjects of general level health claims restricted to those for which a nutrition content claim may be made. Health claims that refer to non-serious diseases also permitted.	Claims will only permitted if specified by the regulator – the 'positive list' is yet to be developed. Until the 'positive list' is published member countries will use their own national safeguards.	Two types of function claims not considered drug claims: (1) 'Biological role claims' are expressly permitted in regulations. (2) 'Other function claims' are not expressly prohibited if they are truthful and not misleading. Acceptable claims of each type are listed in the guidance document. 'Healthy choice' claims also permitted (do not refer to a specific health effect, disease or health condition, 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 by the regulator. All claims are regulated to ensure that they are not false or misleading.
Qualifying compositional criteria	Will apply. Claims relating to risk-decreasing nutrients required to meet the relevant 'source of' criteria for nutrition content claims as a minimum. Claims relating to risk-increasing nutrients required to meet the 'low' criteria for nutrition content claims as a minimum. Where there are no 'source' or 'low' criteria for a particular nutrient a general level health claim may be made if a nutrition content claim for that nutrient is permitted, with no specific qualifying criteria.	Will apply – yet to be developed.	Apply. Claims around protein must meet the requirements for 'source of protein', claims around vitamins and minerals must have a minimum of five percent of the RDI for that vitamin or mineral. Qualifying criteria not specified for claims relating to other nutrients. 'Healthy choice' claims are expected to be bases on meeting one or more nutrient content claim criteria.	N/a

	Australia/New Zealand	EU	Canada	US
Nutrient profiling restrictions	Will apply	Will apply – specifics yet to be developed	None	N/a
Wording conditions	Will apply. Claim must state the 'property' and the specific 'health effect' of the in relation to the property of the food. Claim must be expressed in relation to the relevant population group and must be expressed in the context of the appropriate 'healthy diet'. Further wording conditions may apply to individual claims.	The following information must be provided: • food product vehicle must bear a statement indicating the importance of a balanced diet and health lifestyle; • quantity of the food and pattern of consumption required to obtain the claimed beneficial effect; • where appropriate, a statement addressed to persons who should avoid the food and/or warnings not to exceed quantities that may present a health risk; and • an appropriate warning for products that are likely to present a health risk if consumed to excess.	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

Regulation of High Level Health Claims

	Australia/New Zealand	EU	Canada	US
Permissions	Require pre-approval of the food-disease relationship that forms the basis of the claim, by the regulator	Require pre-approval by the regulator	Require pre-approval by the regulator and regulatory amendment.	Only claims listed in the regulations are permitted. New claims require pre-approval by the regulator. Or, high level health claims may be based on an authoritative statement by a scientific body of the US government or the National Academy of Sciences
Qualifying compositional criteria	Specific criteria will apply to individual claims.	May apply – yet to be determined.	Specific criteria apply to individual claims	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, and fibre
Nutrient profiling restrictions	Default will be that generic criteria based on nutrient profiling will apply. Specific criteria may be applied to individual claims.	Will apply – specifics yet to be developed.	None	Specific disqualifying criteria apply to individual claims. General disqualifying criteria also apply: - a food cannot exceed specified levels of total fat, saturated fat, cholesterol, or sodium.

	Australia/New Zealand	EU	Canada	US
Wording conditions	Essential claim elements specified – property of the food and specific health effect – but exact wording not prescribed. Exact wording may be prescribed for individual claims where considered necessary. Context of the claim is expressed in terms of a 'healthy diet'. Claim must be expressed in terms of the relevant population group. Additional advisory statements or labelling information may be required as deemed necessary.	Specific wording conditions are yet to be developed. Context of the claim is expressed in terms of a 'balanced diet and healthy lifestyle'. The following information must be provided: • food product vehicle must bear a statement indicating the importance of a balanced diet and health lifestyle; • quantity of the food and pattern of consumption required to obtain the claimed beneficial effect; • where appropriate, a statement addressed to persons who should avoid the food and/or warnings not to exceed quantities that may present a health risk; and • an appropriate warning for products that are likely to present a health risk if consumed to excess. • for claims relating to reduction of disease risk, 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 beneficial effect.	Exact wording prescribed, with alternative options provided. Specific nutritional information required for some claims.	Exact wording for entire claim not prescribed, but required elements of the claim are specified. 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.

Regulation of Related Claims

Type of claim	Australia/New Zealand	EU	Canada	US
Endorsements	Will be permitted in accordance with regulations.	Endorsements by individual medical practitioners prohibited.	Not specifically regulated. Must comply with general provisions of the *Food and Drugs Act* (i.e. be truthful and not misleading). Guidelines have been provided.	Not regulated as a specific type of claim, except in the case where an endorsement may indicate an implied claim.
Cause-related marketing	Will be permitted in accordance with regulations.	Will be permitted – in future must be linked to an appropriate claim.	Not specifically regulated. Must comply with general provisions of the *Food and Drugs Act* (i.e. be truthful and not misleading). Guidelines have been provided.	Not regulated as a specific type of claim.
Dietary information	Will be permitted in accordance with regulations.	Not regulated.	Not specifically regulated. Must comply with general provisions of the *Food and Drugs Act* (i.e. be truthful and not misleading). Guidelines have been provided.	Regulated as 'dietary guidance'. Not considered a health claim because does not refer to a relationship between a substance and a health related condition, may contain one element or another.

Regulatory Prohibitions

	Australia/New Zealand	EU	Canada	US
Infant formula & foods	All claims prohibited on infant formula unless permitted by the Standard that regulates infant formula products.	Claims on infant formula are regulated through specific legislation. In the general legislation on nutrition and health claims, claims referring to children's development and health require authorisation by the European Food Safety Authority (EFSA)	High level health claims prohibited on all foods for children under 2 years age. General level health claims/structure function claims require case-by-case evaluation. Narrow scope of nutrient content claims permitted.	High level health claims prohibited on all foods for children less than 2 years age unless provided for in the specific requirements for that claim.
Alcohol content	Food products containing 1.15% alcohol by volume or greater may not carry claims, except claims about energy or carbohydrate content.	Food products containing 1.2% alcohol or greater may not carry any claims, except nutrition claims related to low alcohol content and reduced alcohol or energy content.	No broad prohibition. All approved disease risk reduction claims include a prohibition for food products containing 0.5% or more alcohol. Nutrient content claims may not be made on alcoholic beverages.	No specific prohibition

Nutrition Profiling

	Australia/New Zealand	EU	Canada	US
Required, system	Yes, nutrient profiling scoring criteria. Will use 100 g /100 ml units. Takes into account energy and risk increasing nutrients (sugar, sodium, saturated fat), and risk decreasing nutrients (fibre, protein, fruit & vegetable content). Special category for specific food groups with high fat levels e.g. cheese, edible oils.	Yes, yet to be developed. Will take into account: • quantities of certain nutrients, such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium; • the overall nutritional composition of a food; • role of the food in the diet of individuals and population groups.	None (concept currently being consulted on).	Yes. Four nutrients considered - fat, saturated fat, cholesterol, sodium - with levels set per serve.
Nutrition content claims	Will not apply	Will apply with 2 exemptions: • food products that contain one profile nutrient* at levels exceeding the profile amount may carry a claim, providing the food bears a statement in close proximity to the claim, reading 'High […*] content; • claims referring to a reduced amount of fat, saturated or trans-fatty acids, sugars and salt/sodium exempt from nutrition profiling in relation to their subject nutrient.	N/a	Food products containing one or more of the target nutrients (total fat, saturated fat, cholesterol and sodium) at the set levels must carry a disclosure statement drawing attention to this nutrient/s. Disclosure statements must comply with requirements - a minimum type size, positioning immediately adjacent to the relevant claim.
General level health claims	Will apply	Will apply	N/a	N/a

	Australia/New Zealand	EU	Canada	US
High level health claims	Will apply (as determined on a case-by-case basis)	Will apply	N/a	Food product must contain less than the specified levels of all four disqualifying nutrients, as well as qualify under any additional criteria applied to individual claims. Six nutrients considered for qualification - 10 percent or more of the Daily Value of vitamin A, vitamin C, iron, calcium, protein, or fibre per serve.

Substantiation

	Australia/New Zealand	EU	Canada	US
General	Manufacturer must provide substantiation evidence upon request.	Claims must be substantiated by generally accepted scientific evidence. A food business operator must produce data and relevant elements to establish compliance on request. Food products carrying nutrition or health claims must contain the subject nutrient or substance in quantities defined by Community legislation, or where not defined, a quantity that will produce the effect claimed (as established by generally accepted scientific evidence).	Manufacturers are responsible for ensuring that claims are truthful and not misleading under the *Food and Drugs Act*. Where there are no specific regulatory requirements for premarket assessment, voluntary premarket consultations are encouraged.	All claims made must be truthful and not misleading. Petitions to authorise a specific claim must include all information and data to substantiate that claim.

	Australia/New Zealand	EU	Canada	US
Nutrition content claims	Food must on average contain the component that is the subject of the claim at levels that are referred to in the claim.	No explicit requirements	Guidance provided on compliance requirements with respect to levels of nutrients declared and required to meet content claims.	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.
General level health claims	Four substantiation options: 1. Use of list of nutrient function statements without need for further substantiation by a manufacturer. 2. Use of prescribed list of pre-approved food-disease relationships for high level health claims. 3. Use of a prescribed list of authoritative sources. 4. Systematic review of the literature.	No requirement regarding role/function of subject nutrient as only claims on pre-prepared (positive) list permitted.	Pre-approved list established for 'biological role claims' for known nutrients and well established functions. List can be updated for validated claims outside the scope of 'biological role claims'.	Any claim made must be truthful and not misleading. The manufacturer is responsible for their accuracy and truthfulness.

	Australia/New Zealand	EU	Canada	US
High level health claims	Three options to meet substantiation requirements: 1. Use of pre-approved food-disease relationship. 2. Assessment by the regulator via comprehensive review of all available relevant scientific evidence. There are specific requirements around the type, quality, and amount of evidence that will be required. 3. Assessment by the regulator based on updating a suitable existing review conducted by an authoritative body, e.g.: evidence from comparable claims approved by overseas regulatory agencies.	Substantiation evidence must be presented to the regulator who will seek the advice of the risk assessor (EFSA) for examination before consideration for approval. Evidence must include relevant, independent, peer-reviewed studies and any other relevant scientific studies.	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.	Three options: 1. Manufacturer petitions the regulator, submitting the appropriate scientific evidence to support their application. Evidence must meet a standard of 'significant scientific agreement' for approval. 2. Manufacturer petitions the regulator with preliminary, inconclusive or very limited amounts of evidence, which do not meet the standard of 'significant scientific agreement', but is sufficient for a 'qualified health claim' supported by credible scientific evidence (there must not be any over-riding safety issues and the claim must not be not misleading). Wording of these claims must be "qualified" with statements about the level of scientific support. 3. Submission of a health claim notification to the regulator, where the claim is based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences.