ATTACHMENT 4

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

Scope of the draft Standard

CONTENTS

1. APPLICATION OF THE DRAFT STANDARD

1.1 Decision

FSANZ recommends the following:

- The draft Standard will apply to food for retail sale, food for sale to the public; and to food prior to retail sale which is –

  (i) manufactured or otherwise prepared, or distributed, transported or stored; and
  (ii) not intended for further processing, packaging or labelling.

- The draft Standard will not apply to:

  - food for catering purposes and food not for retail sale (defined in Standard 1.2.1);
  - a meal delivered to a client of a delivered meal organisation;
  - food provided to a patient in a hospital or similar institution, when the food is not in a 'package';
  - infant formula products; and
  - claims about prevention or treatment of mild dehydration on electrolyte drinks (as permitted under subclause 8(3) of Standard 2.6.2).

- The draft Standard will not apply to a design on a food label that meets the definition of an *endorsement* and is made by an *endorsing organisation*.

- The draft Standard will regulate nutrition content claims, health claims, endorsements, cause-related marketing and dietary information that appear on either food labels or in advertising of food for retail sale.

The application of the draft Standard is outlined in clause 2.

1.2 Amendments to current standards/CoPoNC recommendations

Currently in the Code, Standard 1.1A.2 - Transitional Standard for Health Claims and Standard 1.2.8 – Nutrition Information Requirements regulate health and nutrition claims respectively. Both Standards 1.2.8 and 1.1A.2 apply to food for catering and food for retail sale, including meals sold to clients of delivered meal organisations and food provided to patients in hospitals and similar institutions. By excluding from the draft Standard, food for catering, meals sold to clients of delivered meal organisations and food provided to patients in hospitals or similar institutions, the application of this Standard is not as broad as the application of current nutrition and health claims conditions in the Code.

1.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report it was recommended that the draft Standard apply to foods for 'retail sale' as well as to 'foods for catering purposes', both as defined in Standard 1.2.1. Exemptions were not proposed for meals provided by delivered meal organisations or for food provided to patients in hospitals or similar institutions.

In line with the general application of the Code and in accordance with the FSANZ Act, the draft Standard applied to food labels and to advertising of food for retail sale in relation to the conduct of a food business. The draft Standard did not apply to other activities such as government health promotional campaigns or public health materials published by community based organisations.

Concerns were raised by submitters in response to the Draft Assessment Report that general dietary information provided in various media, for example, leaflets, recipe sheets that refer to branded products, and shelf wobblers, would be prohibited by the draft Standard. It was recommended that some of these information vehicles and/or content be exempt from the draft Standard. In addition, there was concern that due to the definition of 'advertising', food manufacturers would not be able to provide technical information to health care professionals.

Submitters from the alcohol industry were concerned that provision of information relating to the beneficial or harmful health and nutrition aspects of alcohol consumption including sensible drinking campaigns, even if not related to a particular product, would not be permitted.

There was also concern that the scope of the draft Standard was too narrow by focusing on foods that are sold or intended to be sold, and that there is a potential for foods to carry unregulated health claims when supplied (not sold) to vulnerable groups, e.g. donations to special needs people. One submitter commented that this differs to therapeutic goods regulation which regulates the supply of therapeutic goods in general.

1.4 Preliminary Final Assessment Report – approach taken and submitter comments

The application of the draft Standard was revised in the Preliminary Final Assessment Report. Exemptions were proposed for:

- foods for catering purposes (i.e. foods sold to catering establishments and not including food sold to the public by the catering establishment);
- packaged meals provided to clients of delivered meal organisations; and
- unpackaged foods provided to patients in hospitals and similar institutions.

Amendments to the definitions of 'food for retail sale', 'food for catering purposes' and 'package' being proposed under Proposal P272 –Labelling Requirements for Food for Catering Purposes Retail Sale[1] at that time, were taken into consideration. The reference to hospitals and similar institutions, as referred to under Proposal P272 was also relied upon.

A number of submitters indicated their support of the proposed approach, however, some believed that the draft Standard should apply to all packaged food and that by excluding certain types of sales, e.g., wholesale, claims could be used on ingredients when that claim could be prohibited in the final product (when sold to the public).
Some submitters considered that the draft Standard should also apply to foods for catering, in particular pre-packaged foods as they thought this exemption did not protect vulnerable consumers. This indicates some misunderstanding of this exemption, with some submitters appearing to incorrectly interpret it to mean that it did not apply to food sold to consumers by caterers.

Some submitters were unclear about the application of the draft Standard and it was suggested that this is clarified, either in the drafting or in a User Guide. It was questioned whether the draft Standard would apply to information such as brochures that have a reference to a brand of food or company name associated with food supplied for catering, and whether industry funded health promotion programs such as Nuts for Life, Go Grains and Dairy Australia would be exempt. Clarification regarding the use of dietary information and links to health information on the websites of food businesses was sought.

A few submitters stated that the 'exemption' for community based organisations creates an anomaly, as they could advertise 'foods for retail sale' that carry claims without the need to substantiate them.

There was some concern expressed by submitters about the exemption for delivered meal organisations and hospitals. Specifically, it was questioned as to what would manage claims on foods supplied by delivered meal organisations that are under contract to a hospital. It was suggested that these exemptions should be clarified to ensure that these organisations can only make claims that are medically related, or that are about serious diseases only. It was suggested that a definition of 'delivered meal organisation' be developed and there was concern that commercial organisations such as Weight Watchers may come under this exemption. It was considered that if packaged meals provided to clients of delivered meal organisations are exempt, then packaged meals provided in hospitals and other institutions should also be exempt, noting that some foods are specifically prepared and packaged for use in hospitals only.

[1] The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has requested a Second Review of Proposal P272 - Labelling Requirements for Food for Catering Purposes and Retail Sale, consequently the amendments to the Code outlined in the Final Assessment Report for Proposal P272 have not yet been finalised.

1.5 Key changes from proposed approach in the Preliminary Final Assessment Report

FSANZ has considered all of these submitter comments and questions. However, the approach in the Preliminary Final Assessment Report has not been changed except for one minor amendment. This is that the exemption for meals delivered to clients of delivered meal organisations will apply to all meals rather than just packaged meals as was proposed. The reason for this is that many delivered meal organisations provide meals to clients other than in a package (according to the definition of 'package' proposed under Proposal P272[2]).

Because the reference to hospitals and similar institutions has not been incorporated into the Code under Proposal P272 as previously anticipated, Schedule 3 – Hospitals and Similar Institutions, has been added to draft Standard 1.2.7, to specify what is captured by the reference to hospitals and similar institutions.

In addition, the draft Standard has been amended so that the status quo for claims on infant formula products (under Standard 2.9.1) is clearly retained. This has been achieved by excluding products standardised under Standard 2.9.1 from the draft Standard rather than prohibiting claims on these products except as permitted under Standard 2.9.1, as was the approach in the Draft Assessment Report. The same applies to claims on electrolyte drinks about prevention or treatment of mild dehydration, whereby an exclusion for these claims from the application of the draft Standard has been added to ensure the status quo under Standard 2.6.2 for these claims is retained.

Other minor amendments have been made to the wording of the Application clause to improve the clarity and consistency with definitions in Standard 1.2.1.

1.6 Rationale for final decision

The application of the draft Standard to claims made on food labels and in advertisements is in line with the general application of the Code. Subclause 3(1) of the draft Standard provides for a general prohibition on claims on a label or in an advertisement for food unless permitted by the draft Standard. A label is defined in Standard 1.1.1 to mean 'any tag, brand, mark or statement in writing or any representation or design or descriptive matter on or attached to or used in connection with or accompanying any food or package'. Further, clause 13 of Standard 1.1.1 provides that advertisements for food must not contain any statement, information, designs or representations that are prohibited by the Code from being included in a label for that food. Thus FSANZ objectives in terms of the prevention of deceptive and misleading conduct and the provision of adequate information to consumers can be advanced.

The term 'advertisement' is not defined in the Code however it is a term that has been defined by the relevant State, Territory or New Zealand food legislation. Also, subsection 2(1) of the Model Food Act[3] defines advertisement to mean 'any words, whether written or spoken; or any pictorial representation or design; or any other representation by any means at all, used or apparently used to promote, directly or indirectly, the sale of food.'

[2] Note that the amendments to the Code outlined in the Final Assessment Report for Proposal P272 have not yet been finalised.

[3] The Model Food Act is annexed to the Food Regulation Agreement 2002. The model provisions have been broadly enacted by each jurisdiction in Australia with some variations.

The meaning given to the term in each jurisdiction is modified by the actual words used to define the meaning of advertisement in legislation, rules of statutory interpretation and judgments of the Courts that affect how the term will be interpreted in the circumstances. It is not within the scope of P293 to address the concerns of submitters in relation to the definition of advertisement in the food legislation of the jurisdictions and New Zealand.

The application of the draft Standard to food labels or advertisements appearing on an internet website is consistent with the application of the general labelling provisions in Standard 1.2.1. The definition of the term advertisement in the relevant food legislation will dictate whether or not the information about the food on a website or link on the website satisfies the meaning of advertisement for the purposes of that legislation.

Broadly, the offences relating to food outlined in Part 2 of the Model Food Act require circumstances where the conduct relates to food intended for sale or for sale and in specific circumstances relates to carrying on a food business.

Generally, the public health activities of community or government based organisations would not be in breach of the relevant food legislation in each jurisdiction and New Zealand. Public health information about food that is provided through activities such as government health promotion campaigns and public health materials published by community based organisations, for example Nutrition Australia and the New Zealand Dietetic Association are not subject to the draft Standard as these activities do not usually relate to food intended for sale or for sale and to carrying on a food business. Therefore, in the draft Standard the Purpose clause clearly articulates this intent and specifically states that public health information is exempt from complying with the draft Standard.

In circumstances, where corporate brands (and not branded products) are used on generic-type public health materials to indicate sponsorship, this act would not breach the relevant food legislation as the act of sponsoring public health information is not concerned with food intended for sale or for sale or the carrying on of a food business.

The application of the draft Standard to foods for retail sale (and not to foods that will be further processed or packaged prior to retail sale) is aimed at ensuring that when the food is ultimately sold to the consumer, the consumer is protected by the requirements of the draft Standard. Regulation of nutrition and health claims on food or ingredients sold prior to retail sale is not as critical, if the food undergoes further processing or packaging prior to sale to the consumer. This approach also allows for the exchange of important technical or dietary information relating to foods in certain circumstances. Examples include information provided in educational materials for schools, and information provided by ingredient suppliers to manufacturers or caterers, manufacturers to health professionals, or health professionals to manufacturers (when the label or advertisement does not apply to food for retail sale).

It is considered that many of the provisions in the draft Standard, for example compositional requirements of foods eligible to carry claims, may not be relevant for hospital meals because the use of claims on such foods is for medical purposes and is supervised by health professionals who have the relevant expertise to apply claims appropriately.

In practice, the exemption from the requirements of the draft Standard allows hospitals and similar institutions to continue to label unpackaged[4] meals making reference to disease states such as 'diabetic', and allows the use of claims such as *low fat* and *low sodium* on the meal label or tray ticket. This exemption will not extend to packaged foods, including those supplied pre-packaged by manufacturers. Some of these pre-packaged foods are branded and will also be sold as foods for retail sale to the general public, e.g. tubs of yoghurt and ice cream, and hence should be regulated consistently with these. Other pre-packaged foods served in hospitals are regulated as therapeutic goods or, in New Zealand, as foods for special purposes (Standard 1.1A.6 – Transitional Standard for Special Purpose Foods) and are therefore not regulated by the draft Standard. The reference to 'similar institutions' captures institutions such as nursing homes for the aged and hospices, and under Proposal P272 these intuitions are proposed to be listed in Standard 1.2.1.

The approach for all meals provided to clients of delivered meal organisations is similar to that outlined above for hospitals etc. The term 'delivered meal organisation' is considered to be commonly understood and therefore there is no need to define it. As outlined above in relation to hospital meals, the exemption for 'meals' provided by delivered meal organisations is not intended to capture individual pre-packaged single item foods such as juices and yoghurts.

The exemption for foods for catering purposes is intended to only apply to foods sold to catering establishments, not to food sold to the general public by the catering establishment. An example of food for catering purposes is pasta that is sold to a restaurant to be used in the preparation of a meal. When the meal containing the pasta is sold to the public it becomes food for retail sale and is captured by the draft Standard. This meets the primary objective of providing consumers with adequate information to make informed choices. Under Standard 1.2.1 the catering establishment can request the relevant information from the supplier to enable them to comply with the labelling requirements under the draft Standard. This is consistent with the application of the draft Standard to other situations where the food is not being sold to the general public, for example wholesale purchases of a food that will be further processed by a retailer.

As suggested by submitters, the application of the draft Standard will be clarified in a User Guide.

[4] The definition of 'package' as proposed under Proposal P272 will specifically exempt food served on a covered plate, cup, tray or other food container in prisons, hospitals or other similar institutions. Note that the amendments to the Code outlined in the Final Assessment Report for Proposal P272 have not yet been finalised.

2. FOOD INELIGIBLE FOR NUTRITION CONTENT AND HEALTH CLAIMS

2.1 Kava

2.1.1 Decision

FSANZ recommends the following in relation to kava:

- kava will be prohibited from making nutrition content and health claims.

Subclause 4(1) of the draft Standard prescribes a prohibition of claims on kava and kava containing products.

2.1.2 Amendments to current standards/CoPoNC recommendations

The labelling and sale of kava is currently regulated in the Code in Standard 2.6.3. (This Standard operates in conjunction with the National Code of Kava Management in Australia.) In relation to claims, the Code does not distinguish kava and kava containing products from products that do not contain kava. The draft Standard will explicitly prohibit claims on kava and its products.

2.1.3 Draft Assessment Report – approach taken and submitter comments

Permission for making claims on kava was not considered in either the Initial or Draft Assessment Reports. Submissions to the Draft Assessment Report recommended that kava, as regulated under Standard 2.6.3, be excluded from making nutrition content and health claims. This is because the rationale for excluding alcoholic beverages is equally applicable to kava.

2.1.4 Preliminary Final Assessment Report – approach taken and submitter comments

FSANZ proposed that kava be prohibited from making nutrition content and health claims. Those submitters who commented on this issue supported the proposed approach.

2.1.5 Rationale for final decision

The kava plant (*Piper methysticum*) is a member of the pepper family. The term 'kava' is primarily used to refer to the kava plant and the drink prepared from the fresh or dried roots of that plant. While recognizing the cultural significance of kava to South Pacific communities living in Australia and New Zealand, Standard 2.6.3 and the National Code of Kava Management were developed to minimize the detrimental effects associated with kava abuse. Prohibition of nutrition content and health claims on kava is consistent with FSANZ's approach for regulating alcohol claims and it is also consistent with the Australian, State and Territory Governments' restrictions on the promotion and advertising of kava.

2.2 Foods containing Alcohol

2.2.1 Decision

FSANZ recommends the following in relation to foods containing alcohol:

- nutrition content claims and health claims will be permitted on foods that contain equal to or less than 1.15% alcohol by volume (that meet the appropriate conditions for the claim);
- nutrition content claims in relation to energy and carbohydrate will be permitted on foods that contain more than 1.15% alcohol by volume; all other nutrition content and health claims on these products will be prohibited;
- claims about alcohol content are not considered to be nutrition content claims;
- a nutrition information panel will be required when a claim is made in relation to energy or carbohydrate; and
- voluntary nutrition information panels will continue to be permitted on foods and beverages containing alcohol.

The prohibition of nutrition content and health claims on foods containing alcohol is in clause 4 of the draft Standard.

2.2.2 Amendments to current standards/CoPoNC recommendations

Currently, Standard 1.1A.2 – Transitional Standard for Health Claims prohibits health claims[5] on foods that are standardised in Part 2.7 of the Code (Alcoholic Beverages). The Code does not prohibit nutrition content claims on foods containing alcohol, nor are these claims differentiated from claims on non-alcohol containing products. The draft Standard will place criteria around the use of nutrition content claims on such products, and will continue to prohibit health claims on products containing more than 1.15% alcohol by volume.

2.2.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report FSANZ proposed that general level and high level health claims would be prohibited on food containing 0.5% or more alcohol by volume. Nutrition content claims referring to alcohol content and energy content would be permitted on foods with an alcohol content of 0.5% or more. It was also proposed that these foods would be prohibited from carrying other nutrition content claims.

In response to the Draft Assessment Report, several submitters noted their support of the exclusion of alcohol from making claims, as proposed in the draft Standard. Several submitters representing industry recommended that nutrition content claims in general be permitted. A submitter sought specific permission for carbohydrate claims on alcohol. Other submitters believed that general level health claims should be permitted on alcohol-containing beverages.

[5] Note that 'health claim' in the context of the transitional standard is the equivalent to high level claims classification under the new regulatory paradigm.

2.2.4 Preliminary Final Assessment Report – approach taken and submitter comments

Based on submissions and stakeholder consultation, FSANZ proposed an amended approach for three issues in relation to claims on alcohol containing food and beverages in the Preliminary Final Assessment Report:

- Since the alcohol content of lower alcohol beverages such as brewed soft drinks can vary up to the maximum allowable level of 1.15%, FSANZ recommended the threshold for determining permissions for claims be increased from 0.5%. to 1.15% alcohol by volume.

- FSANZ recommended altering the approach proposed in the Draft Assessment Report to include permission to make carbohydrate claims on alcohol containing foods. This position was reached after further consideration of Policy Guideline principles in conjunction with FSANZ's objectives, in particular FSANZ's responsibility in the provision of labelling requirements that are commensurate with the risk posed to public health and do not unduly restrict industry's ability to innovate.

- FSANZ reconsidered the recommendation to exempt alcohol from declaring a nutrition information panel when a claim is made in relation to energy. This exemption was determined to be inappropriate due to enforcement and consumer information needs.

FSANZ did not change its position with regard to prohibiting health claims on foods containing more than 1.15% alcohol.

Several submitters supported the approach proposed in the Preliminary Final Assessment Report. Others supported nutrition content claims in relation to energy and alcohol on foods containing more than 1.15% alcohol, but did not support permission for carbohydrate claims. The main rationale for not supporting carbohydrate claims was the potential to mislead consumers given that many alcohol containing products naturally contain relatively small amounts of carbohydrate. The lack of criteria or national guidelines for determining carbohydrate claims was a concern for some submitters. Others were concerned that people with diabetes may interpret a *low carbohydrate* claim on alcohol as suitable for a diabetic diet, where this may not necessarily be the case.

Some submitters raised concern over the potential for a *high alcohol* claim. Others supported nutrition information panels on alcohol products provided serving size is defined according to the usual conventions for a standard drink. Several submitters recommended mandatory inclusion of nutrition information panels on alcohol containing products, not just when a claim is made.

2.2.5 Key changes from proposed approach in the Preliminary Final Assessment Report

The definition of 'nutrition content claim' has been amended to specifically exclude claims about alcohol content, i.e. claims about alcohol content are not considered to be nutrition content claims and will therefore not be subject to the requirements of nutrition content claims.

2.2.6 Rationale for final decision

In accordance with the Policy Guideline FSANZ is proposing to restrict the use of claims on alcohol. Given social issues regarding the abuse of alcoholic beverages, FSANZ considers that claims that attribute a health benefit are not appropriate on foods regulated in Part 2.7 of the Code. Therefore a prohibition on the use of general level health claims and high level health claims is warranted and will be reflected as such in the draft Standard.

FSANZ acknowledges submitters' concerns in relation to the permission for nutrition content claims about carbohydrate on foods containing more than 1.15% alcohol but maintains that nutrition content claims in relation to energy and carbohydrate should be permitted. These claims are established in the marketplace. Concerns over the potential to mislead consumers are addressed by the requirement to provide a nutrition information panel on any alcohol product carrying a carbohydrate and/or energy claim. This provides consumers and enforcement agencies with additional information about the product composition. This approach is also consistent with the provision of minimal effective regulation as required under the FSANZ Act. Regarding submitter concern about specific population groups such as diabetics being misled by carbohydrate claims on alcoholic beverages, FSANZ considers that this is better addressed through education rather than regulation.

By excluding claims about alcohol content from the definition of nutrition content claims, a nutrition information panel is not required on most alcoholic beverages (i.e. those standardised in Standards 2.7.2 to 2.7.5) that carry claims in relation to alcohol content. It is assumed that consumers choose products with claims about the alcohol content for reasons relating to potential intoxication rather than any perceived health benefit (as with energy and carbohydrate claims on alcohol products). Consumers will continue to have access to information to support a claim about the alcohol content from the requirement for percentage alcohol by volume labelling and parameters for *low alcohol* representations provided in Standard 2.7.1. The allowance for voluntary provision of a nutrition information panel remains and there is provision in the draft Standard that specifies that the information within a voluntary nutrition information panel would not be regulated as nutrition content claims.

At present the Code has no provision to prevent the use of *high alcohol* claims. FSANZ is not aware of common usage of such claims in the market place. Furthermore there is no evidence that *high alcohol* claims increase alcohol intake in the population. Therefore FSANZ considers there to be no need for further regulation of *high alcohol* claims. This approach is consistent with minimal regulation in accordance with the FSANZ Act 1991.

As the Code does not mandate serving sizes, it is considered inappropriate for FSANZ to mandate a serve (as declared in the nutrition information panel) be equal to, for example, a standard drink, as suggested by submitters. It would be the responsibility of suppliers to ensure that the labelling of alcohol containing products was appropriate with respect to serving size.

It is outside the scope of Proposal P293 to consider mandatory nutrition information panels on alcohol containing products. This issue may be considered further in the forthcoming general labelling review. Meanwhile, a nutrition content claim on an alcohol containing product will continue to trigger the requirement for a nutrition information panel.

FSANZ considers the proposed approach to be consistent with the Policy Guideline by excluding alcohol containing foods and beverages from permission to carry health claims and limiting the nutrition content claims permitted on these products.

2.3 Infant Formula Products and Infant Foods

2.3.1 Decision

FSANZ recommends the following in relation to infant formula products and infant foods:

- nutrition content claims and health claims on infant formula products (designed for infants under 12 months) will not be subject to the draft Standard but will be regulated under Standard 2.9.1; and
- foods for infants will be exempt from the nutrient profiling system but will be required to meet the qualifying criteria within the draft Standard in order to make a general level health claim.

The application of the Standard with respect to infant formula products is outlined in clause 2 of the draft Standard. Claims on foods for infants will be regulated under Standard 2.9.2 and the draft Standard.

2.3.2 Amendments to current standards

Currently representations made in relation to the nutritional composition of infant formula products are prohibited unless expressly permitted in Standard 2.9.1 - Infant Formula Products. Standard 2.9.2 - Food for Infants, provides for the compositional (including nutritional) and labelling requirements of food intended and/or represented for use as foods for infants. Clause 8 of Standard 2.9.2 provides for the regulation of claims in relation to vitamins and minerals however these relate primarily to nutrition content claims. There are no specific provisions in Standard 2.9.2 restricting the use of other nutrition content claims or health claims. There will be no amendments to these standards as a result of the draft Standard.

2.3.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report FSANZ proposed that nutrition content and health claims be prohibited on infant formula products (except as permitted under Standard 2.9.1). FSANZ also proposed that claims on infant foods be permitted, and that these foods must comply with the conditions in clauses 6, 7 and 11 of the draft Standard.

Several submitters to the Draft Assessment Report noted their support of the ineligibility of infant formula products in making nutrient content and/or health claims. Some submitters recommended that infant foods should be prohibited from making claims, as infant formula alone does not meet the policy guidance which referred to ‘baby foods’. These submitters were concerned that health claims on baby foods may encourage their use instead of breast milk, at an earlier age and over reliance on these rather than fresh foods. Some submitters stated that both infant formula and food should be permitted to make nutrient content and health claims. This latter view came primarily from the baby food and/or formula industry.

2.3.4 Preliminary Final Assessment Report – approach taken and submitter comments

The eligibility for infant formula products and infant foods to carry claims was not specifically consulted on in the Preliminary Final Assessment Report, although some comments were received. Submitters continued to be divided over whether infant formula/foods should be permitted to carry nutrition content and/or health claims.

Some submitters considered that failure to extend the permissions for claims for infant formula products was in conflict with domestic and international policy, specifically the WHO International Code of Marketing of Breast Milk Substitutes which requires signatories to ensure '…the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information and through appropriate marketing and distribution'. Other submitters reiterated that the Policy Guideline states that 'infant foods' be excluded from making claims under the draft Standard. Furthermore, some submitters believed it inappropriate to base claims on infant food on Recommended Dietary Intakes devised for adults.

2.3.5 Key changes from proposed approach in the Draft Assessment Report

Draft Standard 1.2.7 has been amended so that the status quo for claims on infant formula products (under Standard 2.9.1) is clearly retained. This has been achieved by excluding products standardised under Standard 2.9.1 from the draft Standard rather than prohibiting claims on these products except as permitted under Standard 2.9.1, as was the approach in the Draft Assessment Report.

2.3.6 Rationale for final decision

Given that nutrition content claims may act against policies to promote breast-feeding, FSANZ considers there is no justification to relax the current requirements of Standard 2.9.1 Infant Formula Products This is further supported by the lack of international or policy support for the use of health claims on infant formula.

Although the Policy Guideline refers at different times to 'baby food' and 'infant food', FSANZ assumes only one category of food was meant and has interpreted these terms to refer specifically to 'infant formula product' as defined in Standard 2.9.1. In response to submitter concerns regarding potential for nutrition content claims on infant formula, although it has never been intended that such claims be permitted, FSANZ will be seeking to consequentially amend through other processes aspects of Standard 2.9.1 to ensure clarity regarding the intent that nutrition content and health claims are not permitted on infant formula products

In response to submitters concerned that health claims on infant foods may encourage over reliance on these rather than fresh foods, FSANZ requires that the wording condition should include an age appropriate statement to satisfy the healthy diet context requirement, for example, *'...when consumed as part of a healthy diet appropriate for infants'*.

Consumer research conducted on behalf of FSANZ by TNS Social Research in May 2004 during the assessment of Proposal P274 - Review of Minimum Age Labelling of Foods for Infants, found that label information on infant foods had 'little if any influence on the decision to start solids' (FSANZ, 2004). This research suggests to FSANZ that claims on infant foods will not necessarily result in early weaning of infants from breast milk. Additionally food intended for infants aged 4 to 6 months are currently required to include the following warning statement 'Not recommended for infants under the age of 4 months'.

FSANZ considers that it is not appropriate to apply the nutrient profiling scoring criteria where general level health claims are made in relation to infant foods because compositional requirements for infant foods are specified in clause 2 of Standard 2.9.2. In particular, these compositional requirements take into account sugars and salt, two of the three risk increasing nutrients for the nutrient profiling scoring criteria. In addition, the Dietary Guidelines for Children and Adolescents in Australia (NHMRC, 2003) specify that low fat diets are not suitable for infants and therefore imposing a saturated fat disqualifier around the use of general level health claims is not appropriate.

Criteria for claims on infant foods and foods aimed at young children will be further considered when the Code is reviewed in terms of the 2006 nutrient reference values.

3. IMPLIED CLAIMS

3.1 Decision

FSANZ recommends the following for the regulation of implied nutrition content and health claims:

- the definition of 'claim' includes reference to 'implied claims', therefore the definitions of nutrition content claim and health claim capture implied claims; and
- nutrition content claims and health claims are prohibited by the draft Standard unless they meet certain pre-requisites:

    - the claim must be substantiated;
    - the claim must make reference to a specific property of the food; and
    - health claims must explicitly state the specific health effect claimed in relation to the property of the food (or in relation to the food).

'Claim' is defined in clause 1 of Standard 1.1.1. 'Nutrition content claim' and 'health claim' are defined in clause 1 of the draft Standard and are prohibited under clause 3 unless they meet the substantiation requirements in clauses 5 (nutrition content claims) and 6 (general level health claims) and the wording conditions for health claims in clauses 6 and 7 of the draft Standard.

3.2 Amendments to current standards/CoPoNC recommendations

'Claim' is defined in the Code however this current definition does not explicitly include reference to 'implied claims'.

The Transitional Standard – Health Claims (Standard 1.1A.2) does not explicitly mention implied claims except in relation to claims that could be interpreted as advice of a medical nature, i.e. it currently prohibits implied words, statements or claims that could be interpreted as advice of a medical nature, and designs that by implication could be interpreted as advice of a medical nature.

3.3 Draft Assessment Report – approach taken and submitter comments

The approach recommended in the Draft Assessment Report for regulating implied health claims was the same as that now presented (above) in this Final Assessment Report.

Submitters raised some concerns about the proposed regulation of implied claims. These related to the difficulty in determining whether a representation was an implied claim, and lack of clarity around the regulation of implied claims. Some specific comments were:

- the approach would prohibit wellbeing claims which are justified because consumption of food adds to wellbeing;
- a reference to 'implied claims' in the definition of 'claim' would be problematic, as 'implied' is open to interpretation;
- the issue of whether or not a statement or graphic is in fact a claim is problematic;
- the term 'implied' in the definition of 'claim' in Standard 1.1.1, and the term 'indirectly' in the definitions of 'general level health claim', 'health claim' and 'high level claim' in the draft Standard creates a lack of clarity;
- FSANZ's intent to capture all implied claims under the draft Standard is not clear from the current drafting; and
- the requirement to state a specific health effect within a claim will have an impact on some claims that in the past may have been considered as 'marketing puffery'.

The suggestion was made to develop a definition of 'implied claim' and to limit this to those claims which imply a health benefit relating to a serious disease, as this would allow enforcement agencies to focus on those implied claims with the greatest potential to have a negative impact on consumers.

3.4 Rationale for final decision

Potential implied nutrition content/health claims include those represented through graphics, symbols, key words, brand names, vague terms and generally loosely worded claims. FSANZ's qualitative and quantitative consumer research (FSANZ, 2005a, FSANZ, 2005b) has indicated that key words and graphics have a similar impact to explicit claims in terms of attracting attention and conveying information pertaining to health effects. FSANZ therefore considers it is important that implied nutrition content and health claims are regulated in order to ensure the provision of specific rather than vague information, and to reduce the potential for consumers to be misled.

In order to be regulated by the draft Standard, implied nutrition content and health claims firstly need to be captured by the Standard. This has been achieved by including reference to implied claims in the definition of 'claim' in Standard 1.1.1 to ensure it captures all potential claims, whether express or implied.

The definition of claim, also includes reference to 'representation' and 'words or reference in relation to a food' which captures graphics, brand names, keywords and express statements with implied meanings that may be construed as 'implied' claims. In order for something to constitute a nutrition content claim or a health claim, it must first meet the definition for a 'claim'. An implied claim in relation to a food or property of a food is picked up in the definition of claim. Implied claims are then managed by the draft Standard as they are required to meet the same conditions as equivalent express claims, for example substantiation of the claim and reference to a specific property of the food and health effect (as appropriate).

Internationally, 'implied claim' does not have an agreed definition or consistent use. Codex does not provide any express provisions or prohibitions for implied claims. Canada suggests certain words should be avoided or 'used with caution', such as healthy, nutritious, wholesome, good for you, and there is specific policy around the use of heart symbols and the term 'heart'. In the European Union, claims that refer to general, non-specific benefits may only be made if accompanied by a specific permitted health claim. In the United States it is likely that many implied claims fall under structure/function claims which are unregulated.

The recommended approach is consistent with the Policy Guideline which provides a definition of 'claim' for consideration for inclusion in the draft Standard and this definition refers to implied nutrition, health or related claims. The Policy Guideline also notes that claims must communicate a specific rather than a broad benefit. It therefore follows that claims that refer to performance or wellbeing must convey a message about a specific health effect that may be gained by consuming the food. For example, the claim: *has a positive effect on wellbeing* could more appropriately be represented in the following way: *this product is high in X which, when consumed as part of a balanced diet, may help improve immune function.*

4. NUTRITION CONTENT CLAIMS AND HEALTH CLAIMS POTENTIALLY REGULATED BY BOTH DRAFT STANDARD 1.2.7 AND OTHER STANDARDS IN THE CODE

4.1 Decision

In relation to nutrition content claims and health claims that are regulated by draft Standard 1.2.7 and other Standards in the Code, FSANZ recommends the following:

- Claims of 'isotonic' and the health claim relating to availability of energy and prevention or treatment of mild dehydration permitted under subclause 8(3) of Standard 2.6.2 – Non-alcoholic Beverages and Brewed Soft Drinks, will not be regulated by the draft Standard.

- The draft Standard 1.2.7 will not apply to Standard 2.9.1.

- Certain claims will be subject to draft Standard 1.2.7 and also be regulated by specific clauses in Standards 2.9.2 – Foods for Infants, 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods, and 2.9.4 - Formulated Supplementary Sports Foods.

- Where there is a direct inconsistency in relation to labelling or compositional requirements between the draft Standard and a specific clause in another standard then the latter would prevail to the extent of the inconsistency (including qualifying criteria for both nutrition content claims and health claims).

- A specific exemption from the nutrient profiling scoring criteria is provided for foods standardised under Part 2.9 (Special Purpose Foods).

The exclusion of foods standardised under Standard 2.9.1 is provided in subclause 2(2) of the draft Standard 1.2.7. The exemption from the nutrient profiling scoring criteria is provided in clause 6 of the draft Standard.

4.2 Amendments to current standards/CoPoNC recommendations

The status quo applies to claims regulated under Standards 2.9.1 and 2.6.2. For claims that are currently regulated by other Standards (not Standard 1.2.7) then additional provisions may be placed on some of these claims by the introduction of Standard 1.2.7, for example, some function claims currently permitted under Standard 2.9.3 will now need to include the dietary context statement required under draft Standard 1.2.7. For other claims, such as vitamin and mineral nutrition content claims on foods for infants, the current conditions will not be affected by the introduction of draft Standard 1.2.7. Only minor consequential amendments have been proposed to Standards 2.9.2, 2.9.3 and 2.9.4.

4.3 Draft Assessment Report – approach taken and submitter comments

In the Draft Assessment Report the approach taken was the same as that outlined in the Decision section above, except that infant foods (standardised in Standard 2.9.2) were the only foods specifically exempt from the nutrient profiling scoring criteria (referred to then as disqualifying criteria), and claims about mild dehydration on electrolyte drinks (under Standard 2.6.2) were subject to the draft Standard.

Submitters made comments in relation to the eligibility of foods regulated by Part 2.9 to make claims, particularly in relation to formulated supplementary foods because they did not meet the disqualifying criteria (now referred to as nutrient profiling scoring criteria). It was suggested that these foods are exempt from the disqualifying criteria. Some of the comments from submitters were that:

- the link and need for consistency between draft Standard 1.2.7 with other existing standards, e.g. Standards 2.9.3 and 2.9.4, and proposals, e.g. Proposal P242 – Foods for Special Medical Purposes, should be considered;
- within Standard 2.9.4 there is a prohibition on certain claims being made which is inconsistent with the draft health claims Standard. This should be amended to permit claims in the same way as other foods; and
- Foods for Special Medical Purposes have been in the market place for many years and legitimately carry the names of serious diseases. These foods should not be regulated by the same standards applied to conventional foods or foods advertised directly to consumers. Gazettal of the Standard for Foods for Special Medical Purposes should proceed prior to gazettal of the health claims standard or transitional arrangements should be provided to exempt those foods under the draft health claims Standard, until the Standard for Foods for Special Medical Purposes is finalised.

4.4 Preliminary Final Assessment Report – approach taken and submitter comments

The approach in the Draft Assessment Report was unchanged in the Preliminary Final Assessment Report.

Submitters raised similar concerns to those raised in response to the Draft Assessment Report. The time taken for FSANZ to review Standard 2.9.4 and develop draft Standard 2.9.5 and progress other relevant Proposals was considered unacceptable and it was considered that jurisdictions will need to continue to be lenient on products in the Foods for Special Medical Purposes category. It was recommended that conditions for claims on foods for infants in relation to nutrients such as protein, dietary fibre and omega-3 be reconsidered as the criteria in Standard 1.2.7 are based on adult requirements. Similar concerns were raised around formulated supplementary foods for young children (division 4 of Standard 2.9.3) and the conditions for vitamin and mineral claims, including the declaration of %RDI.

4.5 Key changes from proposed approach in the Preliminary Final Assessment Report

Since the release of the Preliminary Final Assessment Report, FSANZ has looked more closely into the relationship between draft Standard 1.2.7 and the Part 2.9 Standards. This has resulted in the decision to exempt foods standardised under Standards 2.9.3 and 2.9.4 from the nutrient profiling scoring criteria, in addition to foods for infants which were already exempt.

It was also decided to state in the draft Standard that a claim that an electrolyte drink is isotonic and claims that an isotonic electrolyte drink promotes the availability of energy and prevents or treats mild dehydration (as regulated under Standard 2.6.2), should not be regulated by draft Standard 1.2.7.

4.6 Rationale for final decision

FSANZ maintains that the specific Proposals that have been established to review Part 2.9 Standards are the most appropriate Proposals under which to make any amendments to these Standards, rather than Proposal P293.

Draft Standard 1.2.7 will apply to claims regulated by other standards in the Code, except for those permitted under Standards 2.6.2 and 2.9.1. As outlined above, where there is a direct inconsistency in relation to labelling or compositional requirements between Standard 1.2.7 and a specific clause in another standard, the latter prevails to the extent of the inconsistency. For example, criteria for protein and vitamin and mineral claims in Standard 2.9.2 – Foods for Infants, will override the adult-based criteria in draft Standard 1.2.7. Where specific conditions do not apply to claims on foods for infants, for example dietary fibre and omega-3, the conditions in Standard 1.2.7 will apply. However, criteria for certain claims on foods for infants may be incorporated during the planned review of such values in the Code due to the 2006 NHMRC nutrient reference values. It is not considered appropriate to amend the Part 2.9 Standards under Proposal P293.

Foods standardised under Standards 2.9.2, 2.9.3 and 2.9.4 will be specifically exempted from the nutrient profiling scoring criteria as these foods are specially formulated for specific dietary purposes and it is not considered appropriate for these foods to also meet the nutrient profiling scoring criteria that have been developed for general purpose foods (see Chapter 3 – Exemptions from Nutrient Profiling Scoring Criteria in Attachment 6 for further detail).

Under Standard 2.9.4, only certain claims (in relation to sports performance) are permitted and in order to make these claims, the food must meet certain compositional conditions depending on the claim made. The suggestion by a submitter that the prohibition of claims not specifically permitted under Standard 2.9.4 be lifted will not be carried out under this Proposal. The removal of this prohibition, combined with the exemption from the nutrient profiling scoring criteria would effectively open up the opportunity for claims on these products without the need to meet any food vehicle eligibility criteria. A large range of Formulated Supplementary Sports Foods are sold in supermarkets in addition to specialty retail stores and these are often represented in a very similar way to general purpose foods. If such products were eligible to carry health claims without being subject to nutrient profiling scoring criteria they may be misleading as to the overall health value and purpose of this range of products, i.e. as a supplement to the diet to assist sports people to achieve specific nutritional or performance goals. This would also be inconsistent with the conditions for health claims for the rest of the food supply. It is recommended that the ability for Formulated Supplementary Sports Foods to make health claims beyond those already permitted by Standard 2.9.4 is considered under the review of that Standard rather than Proposal P293.

It is acknowledged that the condition for making a *low lactose* claim in Standard 2.9.1 (0.3 g per 100 ml) differs to that in Standard 1.2.7 (2 g per 100 g). As infant formula is intended for a vulnerable population group, FSANZ considers it more appropriate to review the conditions for making a *low* lactose claim in Standard 2.9.1 as part of a future review of the infant formula standard.

FSANZ notes that foods for special medical purposes are currently not explicitly recognised in the Code. This matter will be subject to further consideration under Proposal P242 – Foods for Special Medical Purposes, which has proposed a draft Standard to specifically regulate the composition and labelling requirements for these foods in the future.

Electrolyte drinks carrying *isotonic* claims are regulated under Standard 2.6.2. Currently, under this Standard, these claims are not considered to be nutrition claims. This approach will continue under Proposal P293 for consistency and because FSANZ considers that isotonic claims are adequately regulated under this Standard.

Claims that isotonic electrolyte drinks are designed to promote the availability of energy or prevent or treat mild dehydration that may occur as a result of sustained strenuous exercise, are also currently permitted in the Code in Standard 2.6.2. This claim meets the definition of a health claim but would be prohibited under draft Standard 1.2.7 because it refers to the prevention of a condition (i.e. a 'therapeutic' claim). However FSANZ sees no reason to rescind this provision at this point in time. The additional requirements in draft Standard 1.2.7, such as the nutrient profiling scoring criteria and the requirement for the healthy diet context to be included as part of the wording of the claim, are not considered appropriate and will therefore not apply to this claim.

5. REFERENCES

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