# Submission to FSANZ Proposal P293 Nutrition, Health and Related Claims

To:
Standards Management Officer
Food Standards Australia New Zealand
PO Box 7186
CANBERRA, ACT 2610
Australia
Tel +61 2 6271 2222
standards.management@foodstandards.gov.au

From:
Wendy Morrow
Executive Director
Complementary Healthcare Council of Australia
PO Box 450
MAWSON ACT 2607

Date:
Friday, 30th March 2012

**Introduction**

Thank you for the opportunity for the complementary medicines industry, through the Complementary Healthcare Council of Australia (the CHC), to provide comment on the Foods Standards Australia New Zealand Proposal P293 Nutrition, Health and Related Claims, dated 17th February 2012.

The CHC is the peak industry body for the Complementary Medicines (CM) Industry. The CHC is unique in representing the entire supply chain including; manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. We are the principal reference point for our members, the government, the media and consumers to communicate about issues relating to the complementary medicines industry.

Complementary medicines and natural healthcare products are vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals. Complementary medicines comprise traditional medicines, including Traditional Chinese Medicines, Ayurvedic, and Australian Indigenous medicines. Complementary medicines are generally available for self selection by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. The majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health[1].

There are over 300 complementary medicine companies in Australia generating around $2 billion in annual revenues. Australian companies export around $200 million in complementary medicines to more than 20 countries in Southeast Asia, Europe and The America's, and this continues to grow at higher rates than domestic consumption[2]. In Australia the industry generates around 5,000 highly-skilled manufacturing jobs, and indirectly supports a further 60,000 jobs. The global market has been estimated at $US 83 billion annually[3].

Production of complementary medicines in Australia is a substantial industry with 59 TGA approved manufacturing facilities for Listed medicines nationally (including complementary medicines, sunscreens and over-the-counter medicines). Over 75% of Australians use complementary medicines, so it is not surprising that the majority of consumers can name the exact CM product they purchase and why.[4]

Australia's complementary medicines industry continues to lead the world in the development of global benchmark standards in safety, quality and efficacy.

[1] Source TGA, http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm

[2] CHC Complementary Medicines Industry Audit May 2011, available by request

[3] The Australian National Audit Office, Performance Audit Report No. 3 2011-2012, Therapeutic Goods Regulation: Complementary Medicines, pp13

[4] My Opinions Research for CHC May 2011

**Key Recommendations**

| |
|---|
| 1. Does the revised drafting accurately capture the regulatory intent as provided in Attachment B? Please consider the clarity of the drafting, any enforceability issues and the level of user-friendliness. |

**Response:** The CHC does not fully support the draft Standard 1.2.7 as it allows foods to make 'health claims' which could be considered similar to 'therapeutic claims' used for complementary medicines (noting the draft Standard prohibits the use of therapeutic claims on food products). The CHC notes that many of the health claims outlined are consistent with and unable to be differentiated from therapeutic claims used for Listed medicines (such as complementary medicines) under the *Therapeutic Goods Act 1989,* and for this reason recommends that the level of evidence used to support health claims be to the same standard as those applied to therapeutic goods.

Without the establishment of a central, nationally run complaints body and reassurance from all enforcement agencies the health claims proposal runs the risk of undermining the regulation of products at the food/medicine interface, introducing a real public health risk if fraudulent claims are not dealt with in a timely and effective manner, and confusing consumers in their attempt to make informed choices. Commitment and guarantees are required that enforcement and complaints systems will be effective, timely and transparent with sufficient severity to deter further breaches.

**Structure and Regulatory Clarity of Drafting:**
The 2009 consultation on the draft standard raised concerns about the potential difficulties for compliance and enforcement due to the length, complexity and lack of clarity of the Standard. The comprehensive re-draft of the Standard by FSANZ to separate the concepts so that clauses deal with only one concept at a time and similar concepts are grouped together, has assisted with the readability of the Standard. The use of similar language throughout the provisions has overall simplified and clarified the document.

The re-drafting has not, however, provided any further information with regards to the time frames and costs for submitting applications for health claims, particularly those claims relating to non-novel biological substances. The CHC understands that a revised Regulatory Impact Statement (RIS) will be undertaken in line with targeted consultation, and the CHC requests involvement in this target consultation process.

The new drafting of the Standard does not address the inconsistency with regard to formulated supplementary sports foods, in that Standard 2.9.4, clause 6, states that "*unless specific permission is given in this Part, the label on a package of formulated supplementary sports food must not include an express or implied representation that relates to any property or proposed use of the food to enhanced athletic performance or beneficial physiological effects*". The CHC reiterates that for consistency this Standard would need to allow for amendments that provide the sports supplement industry with suitably qualified and substantiated health claims so as not to stifle innovation and marketing within this sector.

The CHC recommends that FSANZ provides clear guidance to industry as to how it will deal with indiscrepancies between standards, in particular Standard 2.9.4 (noting this standard will soon be

considered for review), and how Sponsors of sports supplements can ensure they are compliant with transitional arrangements.

**Enforceability:**

Whilst noting the provisions for the substantiation of claims to enforcement agencies, the CHC strongly urges that there be commitment from the relevant State/Territory authorities to act in an appropriate, transparent and timely manner. Under the current proposal, enforcement would involve determining whether a particular claim was permitted by FSANZ, and whether the product claiming a particular benefit contained sufficient amounts to assess the evidence to substantiate the claim. However, compared with complementary medicines, the penalties for non-compliance under the Food Act are less substantial. Further, the current situation of inconsistent interpretation, unknown or complete inaction of complaints creates an un-level playing field for the complementary medicines industry.

The CHC notes that statements considered to be misleading can potentially be addressed by Australian and New Zealand Consumer Law, and that for the protection of the Australian public complaints should be handled in a transparent and timely manner.

The CHC suggests that to improve consistency, transparency and traceability of food complaints, a national complaints body be established. This body could function as a central point of contact to analyse the complaint and determine, for example, if the complaint would be considered to be misleading, and come under Australian Consumer Law or dispersed to the relevant State/Territory agency for action within a specified timeframe. Such an agency could display the receipt, status and outcome of each complaint, as well as the regulatory status of products that fall within the food/medicine 'grey area' as well as those being considered by the government external reference group (FSANZ, TGA, State and Territory).

In relation to enforceability of the Standard, the CHC believes the main priority of the food regulatory system must be to meet broader public health objectives. Food regulation, particularly labelling law and policy, should protect and promote public health by ensuring safe and high quality foods are available and promoted to the Australian population in such a way that promotes informed consumer choice. The CHC continues to state that enforcement of the labelling requirements needs to be improved. This remains an important issue, as current enforcement of food standards is inconsistent and not adequately applied, which in turn creates an un-level playing field for the complementary medicines industry due to the similar nature of the claims being used.

It is important to note that for Listable medicines to qualify as low risk they may only include low risk ingredients that have been pre-evaluated for safety, and may only be promoted for use in non-serious disease conditions, aliments or defects. The Therapeutic Goods Administration (TGA) considers indications and claims relating to biomarkers to be high level and not suitable for use with listed medicines, unless the claims are suitably qualified to refer to maintaining normal levels in healthy individuals. The CHC, therefore, strongly recommends that a condition-of-use be established for foods making claims related to biomarkers (cholesterol, blood lipids, blood glucose, blood triglycerides and blood pressure,) to specify their use in a dietary context representative of a healthy population.

The CHC strongly recommends that if permitted health claims are to be allowed for foods, enforcement needs to be applied consistently, and in particular, the claims made need to be substantiated by appropriate scientific based evidence that demonstrates a commensurate level of manufacturing standard to that of the permitted health claim.

Further, health claims should require manufacturers/marketers to sign a statutory declaration stating their advertising, labels and substantiation complies with the Standard in order to deter breaches of health claims for foods, and provide a level of consumer assurance. The CHC suggests that this could be a function of the national complaints body mentioned above - to record receipt of such declarations.

The interface between foods and medicines has become wider and further hindered with inconsistent interpretation or complete inaction. A key issue is how to secure a continuum in relation to health claims across the food products and therapeutic claims across complementary medicines. The introduction of health claims in the food regulatory regime will make more urgent the resolution of these interface problems.

The 2009 proposition that food-health relationships be pre approved by FSANZ, and this list included in the draft standard, does provide a level of certainty for consumers that food-health relationships are valid, and goes some way to reduce the burden on enforcement. However, the proposal makes no reference to manufacturing controls. Therefore, how can consumers or regulators be confident that the ingredient or properties are in the food and that the ingredient is consistently mixed throughout the food? To monitor these elements will require considerable expertise and resources if consumers or regulators are able to rely on the label and advertising claims for foods making health claims.

**Without manufacturing controls and therefore stability of the food product being addressed there is no assurance that the health claims being made can be justified for the shelf life of the product, or that higher levels of nutrients are being delivered per serving for foods making health claims.**

It should be a priority to incorporate robust, validated, specific, transferable analytical testing for use in complex matrices, for example, finished food products, and these costings should be incorporated into the revised RIS.

The CHC advocates for a level playing field for advertising and labelling of both foods and therapeutic goods. Public health interest issues that influence therapeutic goods advertising continue to be significant with food advertising. If there are particular health and safety reasons to impose certain labelling and advertising requirements for therapeutic goods, then consideration should be given to those that are applied for foods making health claims for risk reduction or serious disease.

**The CHC strongly recommends that the food industry adopt the principles of the Therapeutic Goods Advertising Code for making health claims.**

2. What evidence can you provide that shows consumers are purchasing foods of lower nutritional quality because they are being misled by fat-free or % fat-free claims?

The CHC cannot comment directly as to the impact fat-free or % fat-free claims have on consumers. However, the CHC strongly encourages further investigation, and greater dialogue with consumer and community members, to gather a large sample of current evidence with regard to the impact of this labelling claim. In particular, more research is required as to whether fat-free and % fat-free claims cause substitution behaviour, in that it may cause consumers to purchase foods of lower nutritional quality in place of foods of higher nutritional quality.

The CHC does, however, note research undertaken by the University of Wollongong, which found that many Australian consumers are sceptical about, and influenced by, claims about fat on food labels, and in particular many claims were seen as advertising that could be misleading, deceptive or confusing. [5] The CHC agrees that there may be merit for changes to the regulations governing nutrition/health claims on food labels to enhance creditability, and support the role of assisting consumers to make healthier informed choices.

The CHC supports the public health message that in addition to recommending a reduction in total fat intake, recommendations be made to limit intake of sugars and foods containing added sugars, as recommended by the Ministry of Health and the National Health and Medical Research Council (NHMRC) 2003[6,7].

The CHC supports further and ongoing education in industry as an important element required to assist consumers and other stakeholders to appreciate the role food labelling plays, and to understand and consider the information provided in a whole-of-diet context.

3. Do you support option 1 (status quo), option 2 (voluntary action through a code of practice), or option 3 (regulate with additional regulatory requirements for fat-free and % fat-free claims)? Please give your reasons

In the absence of the FSANZ literature review on the available evidence in relation to fat-free claims, the CHC in principle supports option 2- voluntary action through a code of practice that incorporates option 3(b), a disclosure statement if above a particular sugar concentration threshold.

Option 2 would allow industry the option to self regulate by limiting the use of fat-free and % fat-free claims on a particular range of foods and to establish conditions for making claims of this type. The CHC supports the development of an industry code of practice that incorporates a complaints mechanism, and

[5] University of Wollongong. (2005). Australian Consumers are Skeptical about but influenced by claims about fat on food labels.
[6] Ministry of Health. (2003) Food and Nutrition Guidelines for Healthy Adults: A background paper. Ministry of Health, Wellington.
[7] NHMRC. (2003) Dietary Guidelines for Australian Adults. NHMRC, Commonwealth of Australia.

promotes ongoing consumer education around food claims and overall dietary messages. Recognising that industry codes of practice are voluntary and 'cowboys' exist in every industry, a code of practice would allow for a complaints mechanism and a degree of consumer confidence. The CHC supports that food advertising be enforced in a similar manner to the Australian Food and Grocery Council's voluntary Code of Practice – Food Labelling and Promotion, and supports the publication of breaches and sanctions applied as deterrence to other manufacturers.

The addition of a disclosure statement such as - *this food is high in sugar* or this *food contains x% sugar,* would be considered consistent with EU food regulations. The additional disclosure statement should stipulate the font size requirements. That is, the font size for the fat free and sugar content claims be equivalent.

**General comments**

The CHC recognises that there has been increasing pressure on governments to reform food labelling regulations because of concerns that they do not assist consumers in making informed decisions. Regulatory action with regard to Country-of-Origin (COO) labelling, a consumer value issue, should be addressed and incorporated via consumer protection legislation. That is, a specific consumer information standard for foods should be provided for within consumer protection legislation rather than in the Code.

The CHC supports mandatory COO labelling on all food products and seeks further clarification on the phrase '*Made of Australian and Imported Ingredients*' (defined as at least 50% by weight (excluding water) of ingredients and components of Australian origin). The CHC suggest this clarification could be:
Australian Ingredients 65%
Imported Ingredients 35%

The CHC believes that all foods coming into Australia from New Zealand (NZ) be labelled with COO, noting that in NZ there is no mandatory requirement for COO and suppliers can opt to supply the information on labels. This means that under the Trans Tasman Mutual Recognition Agreement (TTMRA), foods sold in NZ with no COO can be legally imported into Australia, constituting a way of avoiding the Australian COO labelling requirements. Imported goods must meet the regulatory standards of the exporting country, and similarly the 10 jurisdictions covered by the Food Standards Code should use a risk based system to evaluate and monitor food products, whether locally produced or imported.

**Conclusion**

The CHC values the opportunity to make this submission. In general, the CHC is not supportive of the draft Standard 1.2.7, as without the appropriate manufacturing standards and enforcement considerations the Standard will exacerbate the un-level playing field that currently exists between foods and medicines, and will be misleading to consumers.

The CHC encourages a closer examination of the intersection between food and medicines and the development of evidence-based industry-focused research and robust policy to achieve lasting outcomes that will provide for improved population health.