Complementary Healthcare Council
of Australia

Food Standards Australia New Zealand
PO Box 7186
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AUSTRALIA

15 May 2009

Dear Sir/Madam,

CHC Submission – Proposal P293 Nutrition, Health & Related Claims – Consultation Paper for the First Review

Thank you for the opportunity for the complementary healthcare industry to provide comment on the above consultation paper dated 20 March 2009.

The Complementary Healthcare Council (CHC) is the national peak industry body that promotes the industry's interests by encouraging and advancing optimum community health. It does this by increasing awareness of the role played by the appropriate use of complementary healthcare and health food products in improving health and preventing sickness. The CHC membership includes raw material suppliers, manufacturers, exporters, importers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi-level marketers and consumers.

General Comments

- The CHC does not fully support Proposal P293 to allow foods to make 'health claims' which could be considered to be similar to 'therapeutic claims' used for complementary medicines (noting that Proposal P293 prohibits the use of therapeutic claims on food products). The CHC notes that many of the General Level Health Claims outlined in Schedule 2 are consistent with defined therapeutic claims under the *Therapeutic Goods Act 1989.*

- This proposal makes no reference to manufacturing controls. This will be a critical issue especially for foods making general and high level claims. The CHC questions how consumers or regulators can 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 and regulators are to be able to rely on the label and advertising claims for foods making health claims.

  Additionally, the vitamins and minerals allowed in food for health claims are at very low levels with respect to the food serving size. To make higher level claims, the CHC recommends there should be an obligation by the manufacturer of the product to show that the food does indeed deliver the quantities of the nutrient per serving. That is, manufacturing process does uniformly deliver the nutrient upon which these higher level health claims are being made.

  The CHC also notes that the issue of stability of food products has not been addressed; this is important to ensure the health claims being made can be justified for the shelf life of the product. This is particularly relevant to those foods containing biologically active substances, and where food products have a lengthy shelf life. The CHC considers it necessary to develop robust, validated, specific, transferable analytical testing for use in complex matrices i.e. finished food products.

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- Whilst noting that the options within the consultation paper address issues of enforcement, the CHC strongly urges that there be commitment from relevant State/Territory authorities to act in an appropriate and timely manner. The CHC cannot fully support any further development of a Standard relating to nutrition, health and related claims without being reassured that enforcement and existing complaints systems will be effective.

Specific comments

Does the new drafting improve clarity, and reduce the ambiguity of the draft Standard 1.2.7?

- The CHC does not believe that the drafting has reduced ambiguity within the draft Standard 1.2.7. There is currently ambiguity between requirements listed in Schedule 1 ('vitamins and minerals') and the conditions listed in Schedule 2 ('Permitted General Level Health Claims') for various vitamins and minerals as per clause 27 (2). In Schedule 1 of the draft Standard, it outlines the condition for making a nutrition content claim such that the food is not a food standardised in Standard 2.9.2, 2.9.3 etc. However, the CHC brings to your attention that if you refer to Schedule 2 of the draft Standard, most vitamins and minerals have a condition which states that '*the food meets the general conditions for a nutrition content claim about [stated vitamin/mineral]*'. This condition refers the user back to Schedule 1 where no claim can be made about a food in one of those identified Standards.

- Another issue with the draft Standard is in relation to formulated supplementary sports foods. Under Standard 2.9.4, clause 6 it states that '*unless specific permission is given in this Part, the label on 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 considers that this means that health claims are not permitted. However, the CHC points out that formulated supplementary sports foods provide a range of nutrients that would be of benefit as part of a balanced diet. This proposed draft Standard would therefore disadvantage sports food suppliers wanting to market a product containing vitamins and minerals for a particular health benefit.

  In addition to this, the CHC notes that clause 27 (2) of the draft Standard, states that foods standardised in Part 2.9 of the Code do not need to meet the nutrient profiling scoring criterion for making general level health claims suggesting that health claims can in fact be made for sports supplement foods as long as they meet the general level health claims conditions in Schedule 2. The issue with this is that the conditions for making a health claim in Schedule 2 refers back to Schedule 1 which clearly states that the food cannot be in Standard 2.9.2, 2.9.3 etc. The CHC considers that this is contradictory and requests that more clarity be given.

Will the new drafting be easier and less resource intensive to monitor and enforce and for industry to comply with? Does the new drafting facilitate compliance by industry and enforcement by regulatory authorities?

- The CHC notes that there is very little information relating to time frames or costs for submitting applications for general and high level health claims, particularly those claims relating to non-novel biological substances.

The CHC requests further information on the following:

- Industry will be given 2 years to comply with the requirements of the proposed draft Standard. What if a company submits information in the final 6 months and the processing takes longer than 6 months?

- The CHC also questions what costs will be involved with this new system? Consideration should be given to the regulatory impact this draft Standard may have on industry.

- What are the expected timelines for processing a submission for new health claims? Applications should be processed within a timely manner to ensure innovation within industry is not disadvantageous.

Please indicate your preference for the options presented above in Section 8, with your reasons.

In principle, the CHC would support the preferred option – Option 2, which would provide certainty around health claims on food products for industry, consumers and enforcement agencies. The CHC considers that this option is the most appropriate as all health claims would be pre-approved after evaluation by the Food Standards Australia New Zealand (FSANZ); this would minimise the number of unsubstantiated claims currently being made by food products. The CHC also considers that by having a list of pre-approved claims would assist with the issue of inconsistency with respect to enforcement within the different States and Territories for foods making illegal health claims.

The CHC however raises concern with the lack of description around what would be considered to be suitable evidence to support health claims for foods. The CHC believes that many of the health claims listed within the draft Standard would be considered to be similar to therapeutic claims used for Listed medicines (such as complementary medicines) under the *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990*, noting that Proposal P293 does not allow 'therapeutic claims to be made on foods'. For this reason, the CHC recommends that the level of evidence used to support health claims should be to the same standard as those applied to therapeutic goods and has concerns with the '*greater flexibility in the level of evidence that may be presented'* under this option.

The CHC notes that for simple nutrient content claims the company needs to hold evidence that the product contains the relevant component(s) in the amount(s) being claimed, and must meet any qualifying or disqualifying criteria specified in the draft Standard. The company who is manufacturing/marketing the product is not required to prove that the referenced nutrient is uniformly distributed throughout the food per serving or is present at the quantities claimed at the end of the products use by date. Furthermore, the manufacturer/marketer of the product does not need to show compliance with the claim for each batch and every batch nor that the process used to manufacture the product is validated and gives consistently reproducible results each and every time. The CHC therefore suggests that further consideration be given to the draft Standard to address these issues before the document is finalised.

To what extent does Schedule 2 of the draft Standard cover the GLHCs that are currently in the market place?

The CHC is unable to comment at this stage as to whether the listed GLHCs in Schedule 2 cover all those on the market however would like to ask that further consideration is given to the listing for Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA) (but not Omega 3) entry. The proposed general level health claim for this entry states as a condition

'*minimum of 50mg per serve*' will '*contribute to heart health'*. Whilst there are some conditions regarding saturated fatty acid, the population and context claim is '*500mg of EPA and DHA is recommended to be consumed per day to achieve the specific health effect'*. The CHC strongly recommends that this context statement be in a prescribed position in relation to the Nutrition Information Panel on all products.

The proposed approach for regulating GLHCs includes provisions for more GLHC relationships to be approved during the transition period via proposals and possibly applications. Please comment on the proposed system for transition including what else may be required during the transition period to ensure all valid claims can remain on the market?

The CHC considers it appropriate that all GLHCs should undergo the same evaluation process as proposed in the consultation paper.

Additional Comment

- The CHC raises great concern, as noted under general comments, with the matter of enforcement within the food industry. Without a commitment from all enforcement agencies, this complex and costly health claim proposal runs a serious risk of undermining the regulation of products at the food/medicine interface, introducing real public health risks as fraudulent claims are not dealt with in a timely and effective manner, and confusing consumers in their attempt to make informed choices based on balanced factual information.

  Before the complementary healthcare industry can fully support the draft Standard for nutrition, health and related claims for foods, there needs to be reassurance that enforcement will be implemented effectively and that the current complaint system for dealing with illegal food claims is acted upon in a timely manner. The CHC considers that a lack of an appropriate system for dealing with these illegal claims will result in jeopardizing any benefit to legal health claims. Consumers will lose confidence in the system as industry embarks upon a 'claims' race in the knowledge that there is unlikely to be any action taken against illegal claims because of a lack of resources or other reasons.

- Finally, the CHC advocates for a level playing field for advertising and labelling of both foods and therapeutic goods. All public interest issues that influence therapeutic goods advertising continue to be significant with food advertising. If there are accepted public health/safety/welfare reasons to impose particular advertising r labelling requirements on therapeutic goods, then they should also be applied to foods making health claims for risk reduction or serious disease. The CHC strongly urges that the food industry adopts the principles of the Therapeutic Goods Advertising Code for both general and high level claims. General level claims should require manufacturers/marketers to sign a statutory declaration stating that their advertising, labels and substantiation complies with the Standard which would help deter breaches of health claims for foods.

If you would like to discuss any of the matters raised in this submission, please do not hesitate in contacting me further.

Yours Sincerely,

Kristy Roberts
Scientific and Technical Manager