

Public Health Association of Australia submission on Draft Assessment Report Proposal P293 - Nutrition, health and related claims

31 March 2006

Thank you for the opportunity provided to the Public Health Association of Australia (PHAA) to make this submission on the Draft Assessment Report proposal P293 Nutrition, health and related claims (DAR). The PHAA is a leading professional organisation in Australia for public health nutrition practitioners and has a strong commitment to policies and programs associated with protecting and promoting the nutritional health of the population and sub-groups within the population.

Summary comments

The PHAA acknowledges the complex and substantial amount of work that FSANZ has undertaken since the Initial Assessment Report for P293 and that several important inclusions have been made in the proposed standard's development. The PHAA is concerned however that the proposed health claims standard does not pay sufficient attention towards FSANZs primary objectives of protecting public health and safety. In particular, the PHAA is concerned that the health claims standard will foster the marketing and consumption of highly processed, non-core foods while disadvantaging the promotion and consumption of core foods such as milk, bread and fruits and vegetables.

2.3 Limitations of the current arrangements

The PHAA questions the statement in the DAR that, "The current regulatory arrangements limit ... the benefits that might be achieved for consumers. ... and, potentially, could make better-informed food choices and achieve better health outcomes if a broader range of nutrition and health claims were permitted on food labels."(page 15). No evidence is provided to support this statement. Moreover, the statement fails to countenance whether or not there may be consumer and public health risks of such claims.

2.3.1 Folate/neural tube defects health claim

Page 16-17 of the DAR draws on the evaluation of the folate-NTD health claim trial to state, "Some of the recommendations from the pilot trial are relevant for consideration of options for drafting the new Standard. ... Some of the recommendations have not stood the test of time, in particular the recommendation for pre-approval of individual health claims on a product-by-product basis."

The PHAA questions this conclusion. It is acknowledged that the Pilot trial did provide some important information, but the conclusion presented in the DAR needs to be more circumspect in its commentary on the findings. For example, the validity of extrapolating findings from the Pilot health claim trial to all other health claims is tenuous. The folate-NTD health claim is peculiar in terms of the nature of the health relationship it describes, eg it relates to a specific sub-population group that requires an extra dose of a nutrient during a narrow window of time. Moreover, the "very tight time frame for introduction of the pilot and subsequent evaluation" (p16) and the limited

amount of resources invested in the Pilot placed exceptional constraints on the trial and raises doubt about the relevance of the findings for informing a regulatory framework for health claims in general.

4. Regulatory Option

The PHAA does not support the use of health claims as it believes there is a lack of scientific evidence to demonstrate that health claims will either benefit public health or not be a public health risk. However, as Ministers have given policy guidance on nutrition, health and related claims, the PHAA agrees with FSANZ in preferring Regulatory Option 3.

Within the scope of option 3 the PHAA urges FSANZ to conduct a public health risk and benefit analysis of including provision for mandating high level health claims from the perspective of ‘disease claims’ as integral components of the proposed standard. In this disease claim context a high level health claim would refer to the relationship between a food, or an ingredient in a food, as a contributing causal factor for a disease outcome, for example a claim that describes the relationship between a high sugar containing food and dental caries.

Within option 3 PHAA suggests that the following specific matters need to be addressed.

5.3.1. Nutrient content claims and disqualifying criteria

The PHAA disagrees with the statement in the DAR that disqualifying criteria are not required when foods make nutrition content claims and instead believes that the new standard should include disqualifying criteria for nutrition content claims as well as general level health claims and high-level health claims.

The PHAA believes that the application of disqualifying criteria to nutrition content claims is consistent with the Ministerial Council policy guidelines. The policy guidelines state that “The standard may also set out qualifying and disqualifying criteria for certain types of claims (eg. nutrient content claims)....” (Policy guidelines, pg 6, 1st bullet point). Moreover, two of the criteria FSANZ lists in setting their approach to the standard are to:

- protect consumers from misleading or deceptive claims; and
- assist consumers to select foods for healthy diets.

These aims will only be achieved if disqualifying criteria are applied to nutrition content claims as well as general and high level health claims.

The PHAA notes that FSANZ considers nutrition content claims as statements of fact (p 43). Nutrient content claims are not totally fact as they may omit important parts of the full factual picture. The PHAA is concerned that nutrition content claims have the potential to mislead consumers about the overall ‘healthiness’ of a product. While a label or advertisement may state that a food is high in particular vitamins and minerals that product may also be high in sugar and kilojoules, eg the recent CoCo pops advertisement. As FSANZ have stated, there should be less onus on the consumer to

interpret the healthiness of the food, particularly as there is likely to be a predominance of nutrition content claims. If disqualifying criteria are not required, the consumer could be misled into taking in a very large quantity of sugar or salt as they strive to get more of the added vitamin or mineral. Consumer research by FSANZ shows that consumers do not always distinguish between different types of claims relating to food, health and nutrition.

The PHAA and CHAFS representatives on the Nutrition and Health Related Claims Standard Development Advisory Committee have notes of meetings indicating that disqualifying criteria were to be applied to all claims. At no time was it suggested that Content claims would not be included in applying disqualifying criteria. As the Draft Assessment clearly includes Nutrient Content Claims within the standard, they should be included in all applications of disqualifying criteria.

5.3.2.1 Disqualifying criteria

The PHA is concerned about the levels established for disqualifying criteria and the use of one set of disqualifying and qualifying criteria for all foods, ie we believe that is problematic to adopt a 'one size fits all' approach. Modelling indicates that this does not achieve the aims of the disqualifying criteria, with many core foods captured and therefore disqualified from making health claims (e.g. large serves of some fresh fruits, cheeses and other dairy foods).

The PHAA believes that FSANZ needs to give further consideration as to how disqualifying criteria apply to unprocessed core foods vs. processed non-core foods. It does not seem in keeping with standard dietary advice to restrict the use of claims on core foods such as milk, yoghurt, fruit and bread.

Table 5.3.4 in attachment 5, page 105 shows how the disqualifying criteria can be applied to various foods. It is particularly concerning that foods such as cocoa pops and sponge cake do not meet the disqualifying criteria and yet other foods are disqualified, such as baked beans in tomato sauce or large serves of fruit.

The PHAA recommends that standard serve sizes should be developed in consultation with key stakeholders and incorporated into the Standard 1.2.7 to avoid potential consumer confusion and deception. However, expressing disqualifying criteria as per 100g rather than per serve would negate the need for standard serve sizes and at the same time prevent some energy dense products from carrying health claims.

5.3.1.2 Biologically active substance

The PHAA is concerned about the proposed regulation of claims for biologically active substances. There are no recommended reference intakes for biologically active substances. This leads to problematic outcomes.

It is particularly concerning that the DAR suggests that food manufacturers may be able to set the levels for what is an effective daily amount. The PHAA believes this is meaningless and may result in a high risk for misleading and confusing consumers. FSANZ has stated that claims involving biologically active substances must state the amount of the substance that provides the health effect. This is a concern as for

many biologically active substances there is no evidence for what is an effective level for achieving a health effect

FSANZ also proposes that a food manufacturer may make claims for biologically active substances based on the food containing a minimum of 10% of the manufacturer nominated per day amount. Most consumers are unlikely to regularly consume foods containing biologically active substances. Allowing manufacturers to establish appropriate amounts and then make a claim on a product that contains as little as 10% of that efficacious amount may result in consumers never eating or drinking enough of that substance to have the effect claimed or implied on the label or in advertising.

The PHAA suggests that there should be generic disqualifying criteria applied to any nutrition content claims related to biologically active substances, i.e. foods high in saturated fat, added sugar or sodium, not just general level claims. The PHAA recommends:

- that FSANZ establish effective levels of biologically active substances; and
- the percentage required for a claim to be made should take into account the likely consumption of other foods containing that biologically active substance.

5.3.2.3 Ineligible foods

The PHAA supports the exclusion of infant formula and alcoholic beverages from making any health claims.

5.3.3.5 Positioning of claim elements

The PHAA believes that all essential elements of a claim need to be in the one place. This appears to be supported by FSANZ but confusion arises when the recommendations against split claims permit a brief claim on the front of the package and directions to see the full claim on the back. This permission is effectively a split claim. The PHAA suggests that FSANZ requires the entire claim to be listed in one place.

5.5.3 Weight management claims

The PHAA believes that overweight is a serious disease and is a biomarker for obesity and should be considered a high level claim.

6.3 High level health claims

The PHAA is concerned that no high level health claims for pre-approval involve fresh foods. For example, fruit and vegetable consumption is positively associated with reduced risk of cancer. Assembling high level claims to assist this process would seem a priority, especially in view of the fact that individual growers of various fruit and vegetables are unlikely to have the funds to mount a subsequent submission. This is an area where FSANZ could assist the campaigns by State, Territory and Commonwealth governments to increase consumption of vegetables and fruit.

9 Implementation, enforcement and monitoring

The PHAA believes that strict enforcement of the nutrition, health and related claims standard is vital to protecting public health. We are concerned that enforcement of the new standard will not be sufficient to deter food manufacturers from breaching the standard and therefore will not adequately protect consumers from misleading claims and advertisements.

The proposed approach is primarily complaints based, but we would urge that there should be greater proactive compliance monitoring and enforcement at the Commonwealth level. While the proposed approach establishes a health claims watchdog which sits under the Implementation Subcommittee (ISC), this watchdog is little more than a secretariat, co-ordinating and reporting on complaints received across all jurisdictions.

Under the current proposal enforcement and compliance is likely to vary depending on the capacity of the individual state jurisdictions, placing greater burden on the states where most manufacturers are based. The level of monitoring and enforcement will vary between jurisdictions based on the willingness and capacity of these agencies to take action.

Although it would deviate from standard food enforcement processes, we suggest an enforcement system similar to the Therapeutic Goods Administration, which is a Commonwealth-led approach. Such an approach could be funded through an industry levy and include appropriate penalties (such as fines, retraction of labelling or advertising and corrective advertising) which will be a more effective deterrent against misleading practices. Another key element of a successful enforcement system is a publicly accessible complaints procedure that makes it easy for the general public to know who to complain to and how to make a complaint.

In addition the proposed approach is problematic in terms of the timeliness of enforcement action. If an advertising campaign contravenes the health claims standard, the campaign could be over by the time enforcement action is completed. In this case the marketing objective of the campaign would have been achieved, yet the message sent to consumers may be misleading. Those enforcing the standard must have the capacity to stop an advertising campaign immediately.

9.4 Monitoring and review

The current role for the watchdog is largely a summarising and reporting function. The PHAA recommends that the watchdog role be greatly expanded to act pro-actively and search for compliance with the standard.

9.5 Education

The PHAA believes that FSANZ should ensure there is an adequate education campaign for both consumers and health professionals about the changes to nutrition and health claims from two perspectives.

- Education about the nutrition, health and related standard

It will be essential for FSANZ to inform and educate public health professionals on the changes to nutrition and health claims. For example, the PHAA suggests that FSANZ disseminate education materials through stores and supermarkets in order to support a comprehensive education campaign. Also, it will be essential for FSANZ to improve consumer understanding about how to interpret food labels, as well as address consumer understanding of nutrition and health claims and to ensure that the public are aware of the complaints processes.

Nutrition education about healthy eating

A well resourced and sustained education campaign funded by the Commonwealth and state governments and based on the key messages within the Australian Dietary Guidelines is required in order to protect public health and minimise potential risks associated with health claims, including promoting the over-consumption of certain foods, displacing core foods from the diet and generating consumer confusion.

9.6 Review of health claims

The PHAA recommends that panels reviewing the standard must be independent. In addition we recommend that expert review committees:

- Always include representations from public health and consumer groups;
- Involve scientists without a vested interest in the products likely to be involved; and
- Should be subject to transparent selection processes.

11.3 Exclusivity of claims

The PHAA has significant concerns about the proposed legislative changes to the FSANZ Act 1991 agreed by the Food Regulation Ministerial Council in relation to proposed changes to FSANZ assessment and approval processes that will affect the management of health claims applications. These specific amendments to the Act resulting from work conducted by the Food Regulation Standing Committee Working Group in 2005, appear to be driven by a perceived need to protect commercially valuable information at the expense of public health and consumer interests. It has been proposed that the standard for health claims would be developed with full consultation, but applicants, such as the food industry, could seek pre-market approval of high-level health claims with no public consultation. Instead, an expert panel will consider applications for these claims.

The PHAA believes it is important that there are open consultation processes for the assessment and approval of all health claims applications in order to help protect public health and consumer interests and not solely commercial interests.

If the reason for permitting health claims is to benefit public health, the PHAA believes that there is a particular need for greater and wider public consultation during the approval process for health claims, not less or as is proposed, none. The PHAA disagrees with the justification provided in the FRSC working group discussion papers that health claims are not an issue of public health safety, but only an issue of consumer

choice. Health claims are indeed an issue of public health safety as they have the potential to contribute to over consumption of unhealthy foods and under consumption of healthier food choices.

The development of the health claims standard has been a complex and controversial process. The amendments to the approval process will create a system for assessing health claim applications that will reduce transparency relative to the current arrangements. The system will become vulnerable to conflict of interest concerns, eg in the selection of experts, with less checks and balances and accountability built into the approval process. An open and transparent process is essential to allow all public health and consumer stakeholders to have input that assists FSANZ in delivering on its primary objectives.

The PHAA recommends that where an application is assessed, participation in the assessment process should include public health and consumer representatives who have no conflict of interest. Such participation should entail a fee being paid for the time and expenses incurred by the public health or consumer group representatives. Representations on any assessment panel should be open and transparent.

11.5 Interface between food and medicines

The PHAA supports moves to prohibit comparison of foods and therapeutic goods.