National Council of Women of Australia Inc Ltd

Affiliated with the International Council of Women

National Secretariat
1st Floor, 6A Thesiger Court
Deakin ACT 2600

Telephone: +61 2 6285 2337
Facsimile: +61 2 6285 2652
Email: ncwa@bigpond.com
Website: ncwa.org.au

ACN 061 777 937
ABN 46 061 777 937

5 August, 2002

INITIAL ASSESSMENT REPORT
PROPOSAL P235
REVIEW OF FOOD-TYPE DIETARY SUPPLEMENTS

The National Council of Women Australia makes this submission on the basis of the protection of public health and safety through the provision of adequate information relating to food to enable consumers to make informed choices. For example, malnutrition is a global problem with obesity a major issue. This issue alone shows how difficult it is to convince people to eat an appropriate diet. Food-type dietary supplements would represent a challenge for manufacturers in trying to combat malnutrition. Given the parameters of this problem it is important that food regulatory measures to manage food-type dietary supplements are developed. Any regulations related to food for maintaining and promoting health and development must be effective. This submission will provide more general comment and opinion on the issue.

We would support the view that the key element of dietary supplement should be a supplementary role to the balanced diet with an intended function over and above that provided by the usual diet for specific conditions or groups of people. It is also important that essential regulation of products that are regarded as foods are clearly differentiated from products that are regarded as therapeutic products. These foods must be clearly labelled as dietary supplements to allow for maximum consumer choice. It must be easy for potential consumers to identify whether products are intended as foods or therapeutic products through the use of consistent terminology. There is a lack of community knowledge on foods and the role nutrients they contain play in maintaining health and development.

The way Codex has defined foods that have a special purpose in the human diet is clear and useful

This submission makes no response to the invitation in respect of the current market for FTDS as this is beyond our resources.

A conservative approach has been taken with respect to the addition of nutritive substances to foods. This should be considered until scientific data is available to

support the addition of nutritive substances to foods. There is still limited knowledge of the safe levels for nutrients.

ANZFA's current policy in relation to voluntary addition of vitamins and minerals to general purpose foods is appropriate. The addition of calcium and iron to orange juice as seen at present is questionable in its benefits to diet and ultimately health. The interrelationships between intake and absorption should be taken into account. Safety levels for the intake of some vitamins and minerals must be known before additions to foods are allowed. There is evidence that high intakes of Vitamin C may cause kidney stones, for example. Maximum levels should be prescribed. The Australian Recommended Dietary Intakes should be used rather than those developed for the U.S.A.

ANZFA's definition of special purpose foods is firmly grounded within a traditional nutrition paradigm. This definition should be maintained. Any supplements should have as a basis dietary adequacy and be designed to deliver nutrition to at-risk groups whose dietary requirements cannot be satisfied by a normal diet. Any FTDSs beyond this should remain within the domain of therapeutic products. The FTDS should be kept separate from the general purpose and/or special purpose foods to enable clear consumer choice. Therapeutic foods should be confined to those that are beyond the recommended Dietary Intakes for Australians. The novel food standard should be maintained as a thorough risk assessment must be made before these foods are offered for retail sale. Substances present in FTDS that are considered to be 'novel' must undergo a pre-market safety assessment. The use of botanicals and/or extracts must be assessed for safety as food ingredients and must be shown to be beneficial to health. Their safety in foods is unknown in many cases therefore there is a need for research, development of standards and careful categorisation.

The approach to risk-based assessment should adequately address safety concerns around FTDS. The definition of nutritive substances should not be extended beyond nutritional purpose. No clear knowledge is held on food additives that may be considered for FTDS nor are particular botanicals that require further consideration. Permissions for FTDS should include single-ingredient and a mixture of foods to enable greatest consumer protection. Permission should not be given for novel foods on the basis that they are currently included in a variety of products outside the domestic market or they occur naturally or international evidence of safe human use. They should be compared with Australian foods whose composition may differ.

Labelling should be required – percentage labelling and allergen labelling.

Rigorous substantiation of health claims should be required to ensure that efficacy is taken into account. Any claims must be underpinned by rigorous research. Any health claims should require an advisory statement to the effect that the food about which the claim is made needs to be consumed within the context of the total diet.

Effective labelling is an important tool in risk-management. The statement presented on page 31 about misleading communications provides an excellent framework for appropriate labelling. Labelling is important to consumers to enable them to make decisions about appropriate use of products. Labelling statements that would be important to consumers is the use of clear language, the inclusion of scientifically

substantiated information about the FTDS and the prohibition of representations that may be judged as misleading to particular groups. Only nationally accepted reference values should be used for content claims. Labelling of products with general advisory statements that warn against consumption by vulnerable groups is an appropriate risk-management strategy for FTDS. Allergens require an advisory or warning statement to allow consumers to make appropriate choices to benefit their health and wellbeing. FTDS should not be exempt from the nutritional information requirements as they purport to be nutritional supplements. Neither a prescribed name nor an advisory statement as set out is really appropriate. An advisory statement is a coercion if you believe one amount is beneficial, double the amount is more efficacious. There is a problem too with the possible interpretation that you can substitute the FTDS for a regular food with no worries.

The lack of clarity of the regulatory structure presents a risk of inadequate protection of public health and safety. Information must be sufficient for consumers to make informed choices.

Options – We do not support Option 1. The status quo is inadequate for consumers at present. The present situation does result in considerable consumer and public health confusion.

We support Option 2 where the relevant provisions would be reviewed and amended as appropriate. The underpinning principles as set out in Section 2 are valid and should be maintained. Option 2b is preferred as any risk management strategies for FTDS should maintain separateness from the general food supply. FTDS should be treated as discrete products that would be subjected to targeted risk-assessment most likely resulting in specific compositional permissions and labelling requirements. We would support Option 2bii. We would not support Option 3 Co-regulation. Industry codes of practice can create problems for consumers in their access to adequate information to make informed choices.

One of the potential impacts on consumers is in the area of advertising. Advertising is often used to convince consumers that they need these often more expensive products when eating a wide variety of basic foods is the best diet for health at a minimal cost. An example is the advertising of phytoestrogens to menopausal women with little scientific support at present. Another is where supplements are sold as cancer preventing. The key is that consumers are primarily concerned with product safety and the provision of accurate and adequate information for informed choice when purchasing products. An example mentioned earlier is the addition of calcium and iron to orange juice as a dietary supplement. No information is provided as to why <u>all</u> consumers need extra iron or calcium or the benefits of combining orange juice and iron –the ability of orange juice to enhance the absorption of iron is not described. Perhaps the money invested in developing, producing and marketing FTDS could be better used in promoting foods and the relevant health benefits of eating a wide variety of foods. Few nutrient deficiencies are seen in Australia.

Prepared by [redacted]
Acting National Advisor, Nutrition
National Council of Women of Australia, Ltd.