Complementary Healthcare Council of Australia

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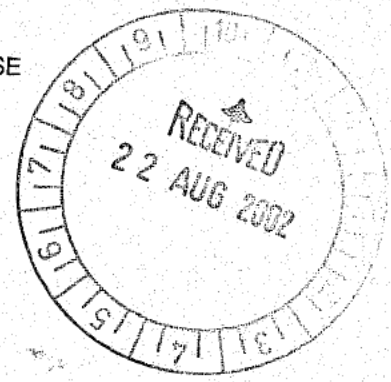

Australian New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610
Australia

Dear Project Manager,

Re : Submission on Proposal P235 – Review of Food Type Dietary Supplements (FTDS)

Please find enclosed the Complementary Healthcare Council Proposal P235 comments. Further comments will be provided at the draft assessment stage.

If you need any further information then please do not hesitate to contact the secretariat.

Yours faithfully,

[redacted]

Technical Director

August 21, 2002

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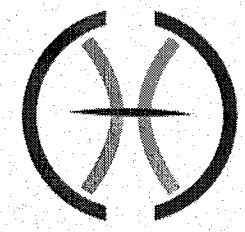

Complementary Healthcare Council of Australia

Enhancing Health and Wellbeing...naturally

Submission on Proposal P235 – Review of Food Type Dietary Supplements (FTDS)

The CHC thank the authority for the opportunity to comment on the proposal.

CHC understands that the proposal is a direct consequence of the harmonization of food regulations between Australia and New Zealand and intended to regulate foods that meet the New Zealand Dietary Supplement Regulations 1985 (NZDSR) and are permitted to be sold on the Australian market.

CHC supports measures that assist in regulation of these food type dietary supplements, and regulation that clearly differentiates these products from therapeutic goods. The food / therapeutic interface must be clearly defined and understood by all stakeholders. Difficulties were encountered in defining the FTDS. A contributing factor is that the proposed standard is being developed mainly to accommodate the Trans Tasman Harmonization process rather than being driven by a technical need for the products. The issue is further complicated by the emergence of 'functional foods', which could possibly, be included under the FTDS category. The CHC has some difficulty with the terminology as the term 'Dietary Supplements' is used internationally to refer to supplements in soled dosage form. Use of FTDS to cover products such as bars and liquids is confusing especially in the global context, and the CHC suggests that the terminology requires further consideration. Australia must have a clear definition that cannot be misinterpreted within the global markets. CHC members were unable to agree on a definition for FTDS and request more time to consider this important issue. Further comments will be provided at the Draft Assessment stage of the process.

CHC supports the establishment of a new regulatory model to cover the 'foods' (FTDS) currently coming into the Australian market via New Zealand and a standard liberal enough to accommodate the 'functional food' aspects.
The need for harmonisation is critical in view of the progress of a new joint trans–tasman regulatory authority of therapeutic goods.

CHC identified some issues which were not specifically addressed in the paper but which industry would be supportive of inclusion into the standard or consideration under existing standards.

These are:

- ***Mandatory notification of FTDS products to FSANZ.***

  This enables a data base to be established and where safety related issues are identified. Also, products can readily be identified and corrective action can be taken if safety concerns arise.

- ***Quality standards***

  The quality emphasis in the food industry has been, in the main, on hygiene in the production area. In the area of FTDS there are additional concerns about the quality of some ingredients. FTDS are at the high-risk end of the food supply.

  For example there is concern about the botanicals, where highly refined extracts may be used, that do not have a role as traditional foods and where there may be some doubt about their identity and purity. It may become necessary to include a quality standard in the new standard or amend existing standards.

- ***Advertising***

  CHC would be supportive of a co-regulatory system of advertising which would ensure that FTDS are responsibly advertised to consumers. Such an advertising code should contain key principles and ensure that claims are not expanded to become therapeutic claims. There must be equity between the claims that are permitted on complementary healthcare products and those permitted on foods with similar levels of evidence being required. A suitable model may be the New Zealand Advertising Standards Authority's Code for the Advertising of Foods.

- ***Compliance Management***

  The CHC is concerned about the ability and commitment of the States and Territories to monitor compliance of all aspects of the standard. The States and Territories must be adequately resourced and committed to enforcement of the standard. Uniform interpretive guidelines must be developed, as presently there are differences in interpretation and compliance approach by each state and territory. This causes confusion with Industry and Consumers. The CHC emphasis the need for monitoring and enforcement of any new standard.
  It is critical that the development of a new regulatory model for food-type dietary supplements includes mechanisms for ensuring compliance with the standard. FTDS are at the high-risk end of the food supply and States and Territories health departments must have adequate legislative underpinning and resource allocations

that allows them to act in a timely and effective manner in dealing with breaches of regulatory requirements.

Response to specific Questions

SIZE OF FTDS MARKET IN AUSTRALIA AND NEW ZEALAND.

The information is hard to collect as many of the companies involved are not members of associations and the collection of data is not easy because of the diversity of products. The CHC estimates, from information received, that the approx value is $400 million

RELEVANCE OF ANZFA POLICY ON ADDITION OF VITAMINS AND MINERALS TO FTDS

CHC supports the proposal that all vitamins, minerals and nutritive substances currently permitted in Volume 2 should be permitted for use in FTDS. Generally the inclusion of Vitamins and Minerals as per National Health and Medical Research Council recommended dietary intake (RDI's) table should be permitted in FTDS provided the level of fortification does not exceed 50% of the recommended dietary intake.
The inclusion of other nutrients such as amino acids should be permitted. It may be necessary to set maximum levels for some ingredients to satisfy safety considerations.

The inclusion of other macronutrients such as fibre, fat, protein should be permitted in FTDS in reasonable quantities, as a supplement to the diet.

The use of any other substance should be subject to a safety assessment by Food Standards Australia and New Zealand (FSANZ) and may in fact be a 'novel food'

Some concern has been expressed over the availability in foods of substances that may have potentially adverse public safety risk. Mechanisms need to be developed to assess the safety of substances being considered for use in FTDS.

CHC supports a positive list for nutrients and believes that foods and ingredients without a history of safe use is evaluated for safety. Such new substances can be evaluated via the "Novel Foods" standard 1.5.1. Foods and food ingredients listed in Table 2 of Standard 1.5.1. would then be allowed to be used in FTDS products. Consideration should also be given to recognize, and give permission to use, substances that have been evaluated by CMEC and gazetted for use in complementary healthcare products.
It will be necessary for FSANZ to provide Industry with guidelines on the process and the type of data required for evaluation as a "novel Food'.

FTDS AS SPECIAL PURPOSE FOODS

CHC does not consider the FTDS to be special purpose foods which purport to fulfill a purpose beyond general nutrition, as they are not 'formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological need'. Some

FTDS are formulated to provide other 'functional benefits such as the promotion of health through provision of nutrients in addition to the normal diet and other physiological and psychological function which can put them into the special purpose food category. Many others contain substances which are more "therapeutic" in nature, such as botanical extracts that may contain highly selective compounds. It is difficult to establish dietary requirements for many of the substances present in the FTDS. This characteristic makes them different to Special Purpose Foods.

Purpose of Product

- CHC strongly supports a separate Vertical Standard for FTDS. It is recognised, that the reasons for, and the formulation of the product is uniquely different from other standards in Volume 2.

- To accommodate a two category food/therapeutic products system it is essential that there be definitions that clearly distinguish FTDS from therapeutic medicines. It is recognized that this is associated with some difficulties. In many instances there could be implied therapeutic benefits simply through the inclusion of medicinal type herbs e.g. St. John's wort in drinks.

- **Presentation.** FTDS must be presented in traditional food forms i.e. powder, liquid, bars, and confectionary and without therapeutic dosage instructions.

  Product in traditional therapeutic dosage form of *tablet and capsule and spray* should not be presented as FTDS. These dose forms are recognized as being "pharmaceutical" and should not be permitted to be confused with foods. The presentation of foods will be addressed by the TGA by the section 7 declarations and FSANZ must support this approach.

- **Claims/ Purpose of Use**. Where claims or therapeutic indications are made, directly or indirectly, about a FTDS then it should be deemed to be a therapeutic good. Health Claims will be addressed in Proposal P153. No health claim should be permitted that breaches the therapeutic goods advertising code. Again, we need a mechanism for addressing health claim breaches at the State and Territory levels.

- **Labelling**

  Where the label is presented to look like therapeutic medicine then the product shall be deemed to be a therapeutic. Labelling must provide the consumer with appropriate information to make informed health choices and is truthful and not misleading. If substances used in FTDS have warning statements applied under the therapeutic goods act then these warning must also be applied. It is important that there be consistency between the regulatory authorities in the area of management of safety issues. Daily intake conditions must also apply.

- **Promotion/Advertising**
  When promoted with therapeutic references, the product shall be deemed to be "therapeutic". CHC members strongly support the development of a co-regulatory approach to managing promotions and advertising. Including the development of an advertising code with appropriate and meaningful sanctions for breaches of the code.

  When reviewing the "Presentation" the questions to be asked should include "What is the intent of this FTDS?" If the intent is to promote the product as quasi therapeutic than the product should automatically be regulated as a medicine. This may occur where herbs are added that have no history of culinary/flavouring use, but that do have a history of medicinal use. FTDS are at the high risk end of the food supply. Guidelines on the classification of herbs as medicines or foods should be revised and updated.

Questions on Added Substances

Generally:

CHC considers that the risk based assessment in figure 2., section 2.4.1 does adequately address the safety concerns around FTDS.
One of the gaps identified by CHC is the omission of Botanicals and the purpose of their presence. Example: A Meal Replacement which contains an herb that functions as a *Diuretic* (therapeutic purpose). CHC believes that therapeutic herbs should not be permitted in FTDS.

Nutritive Substances

CHC believe that the definition of nutritive substance be extended beyond nutritional purpose i.e. to a functional purpose if the addition can be justified. Functional foods are considered to lie between FTDS and Listable complementary products. Functional foods may be considered to be covered by the Novel Food Standard e.g. Fructooligosaccharides added to a food. At this stage we have no further input into how that purpose may be described but will be pleased to review any proposals upon further progress by FSANZ.

Food Additives

- *Micronutrients that are not permitted or restricted under Standard 1.3.2. – Vitamin and Minerals that require further considerations for FTDS:*

CHC believe there may be some but as yet have not identified all the substances. Micronutrients identified were Stevia extract and Maltitol. Further comment will be provided at the next stage of the paper.

- *Botanicals:*

CHC believes there are botanicals that require further consideration but reserve comment at this stage. It will be important that there be consistency between the TGA and the FSANZ list. The CHC recommends that a botanical, that has only a therapeutic benefit, should be added to the list of prohibited herbs. This will assist the delineation between FTDS and Therapeutics. The CITES list should also be considered when revising Standard 1.4.4

Single and Mixed Foods

- *Permission for single ingredient FTDS foods*:

CHC supports permission for single food FTDS, provided they have been assessed for safety. It is likely that such substances/foods may fall into the Novel Food Standard and be assessed as such. CHC would not support a blanket approval for such substances, which may be marketed as FTDS to by-pass the Therapeutic Goods Regulatory system.

- *Should FTDS be generally permitted to be a mixture of foods i.e. are there particular foods that should be specifically excluded form mixing with FTDS?*

CHC supports permission but with some notable exceptions. Some exceptions identified are: Formulated Caffeine Drinks, Energy drinks. More may be identified at a later stage. It may not be appropriate to permit the fortification of staple food with certain substances since the foods are consumed by the population as a whole and may present some risk for certain groups, especially if the diet is then supplemented with FTDS . More consideration will be given at a later stage.

Novel Foods
Should permission for some substances, that may be 'novel', be given on the basis that they are currently included in a variety of products (outside the domestic market); or they occur naturally; or there is reasonable international evidence of tradition of safe human use?

CHC supports permission for some substances that may be considered 'novel' on the basis that they are currently included in a variety of products on the Australian market and on the market in New Zealand , or they occur naturally; or there is reasonable international evidence of tradition of safe human use. Such substance should not have to undergo an evaluation by FSANZ.

Questions on Labelling

What labeling statements are considered important for consumers to enable informed choice with respect to TFDS?

CHC supports the need for a

- Prescribed name
- Ingredient list

- Nutritional panel
- Vitamin and Mineral list
- Additives
- Labelling should comply with the Declaration of Ingredients in Standard 1.1.1
- Warnings for at risk groups are supported.
- Advisory statements such as: Suitable for Diabetics are also supported. There is merit in including additional strategies such as limits of intake for children. In this instance "Child" will need to be defined.
- Contraindications. Products may be contraindicated e.g. Vitamin K and Warfarin. Therefore it may be necessary to set limits for some vitamins or display mandatory warnings such as "Contains Vitamin K, Bioflavanoids etc".
- The same holds true for known allergens e.g bee pollen, royal jelly, nuts, crustaceans – these should be declared as being present.

The label of FTDS should permit consumers to make informed decisions about the product and decide if it is suitable for them.

As the issues are debated, identified and further developed it may become necessary to have a labelling guideline specifically for FTDS.

Claims for the presence of Vitamins and Mineral at less that 10% of the RDI should not be permitted.
No ingredient should be added at a level where it constitutes a risk to public health and safety. Substances at levels that have been marketed under the NZDSR regulations should be permitted, provided no safety issues have been reported.
International regulations could be considered for substances that have reference values in other countries.
CHC will consult with other stakeholders i.e. the Marketing division of its members on this matter and provide further input.

Should FTDS be exempt from nutrition information requirements of Standard 1.2.8. Volume 2? If so, why, and what alternative nutritional/content information would be appropriate?

FTDS should not be exempt from Standards 1.2.8 of Volume 2. To avoid consumer confusion these FTDS should be labelled similarly to other foods.
CHC supports Health and Nutrition claims for the components. Such health claims could be managed via the Advertising Code mechanism mentioned above.

Health Claims

Health Claims are currently reviewed in proposal P153.
If health claims are permitted in the future then they should also be permitted for FTDS's. It is important that they will be consistent with, and not exceed, claims and conditions that are permitted for Complementary Healthcare Products under the Therapeutic Goods Legislative provisions. A suitable mechanism to address breaches should be developed.

Contextual Statement- referring to the context of the total diet

FTDS should be exempt from the reference to the total diet as they are "complementary" to the normal diet. They may contain ingredients or nutrients that are not necessarily available in the general diet or contain nutrients that the consumer may wish to consume at elevated levels. Therefore it may not be relevant to refer to the context of the total diet.

Prescribed Name

CHC supports the use of a prescribed name but has some difficulty with the proposed nomenclature of :'Food type dietary supplements' or "Dietary Supplement" as this is not seen to appropriately describe this group of products. The CHC would like to consider this issue further.

Dosage instructions

Dose per se is not considered appropriate but terms such "Recommended use:" Serving size and frequency is considered to be more appropriate in providing advice to the consumer. The consumer must not be in the position to confuse the taking of FTDS with therapeutic goods. More work is required in the wording of such statements.

Any other general labelling issues

CHC supports the requirement of a minimum type size for Advisory statements, provided that consideration is given to the practicalities of label space with regards to mandatory information requirements. It may be necessary to have type size commensurate with the label size.
Mechanisms for exemptions in special circumstances need to be considered.

REGULATORY OPTIONS

Option 1 – Status Quo

There is no support for this option as it is considered to be inequitable to the Australian market. There is a belief that some products on the market do not comply with NZDSR 1985 and these will remain on the market. There is also a concern that some products on the market may not have been adequately assessed for public health and safety.

Option 2 – Full regulation

Full regulatory provision within Volume 2, and cessation of provision for production or importations of FTDS under the NZDSR.

CHC strongly supports **Option 2b.i**. A new Vertical Standard to be included in Volume 2 This option is preferred as it-

- creates a level playing field
- provides clarity for the industry,
- has strong legislative underpinning,
- opportunity for industry to contribute to the standard,
- opportunity to review current products on the market,
- opportunity to review for public health and safety,

Costs to Industry

- New labels
- May lose some products
- Possible reformulation of some products
- May shift some products to 'Novel foods" therefore increase in cost

Benefits to Industry

- Level playing field
- Opportunity to market meaningful products
- Will allow most products to remain on the market
- Improved public health outcomes
- Reduced compliance cost i.e. AQUIS will not have to be involved
- Permit innovative product development
- Equitable marketing opportunities
- Products more in line with some overseas markets i.e. USA
- Clarification of products in the food/therapeutic interface; if necessary through the use of Section 7 declarations of the Therapeutic Goods Regulations.

The industry supports the repeal of the New Zealand Food regulations 1984 once Option 2 has been implemented. This is seen a critical to the successful working of the new standard.

It will be necessary to have in place transition arrangements that allow products to be lawfully supplied in either country for a period of time.
Products in the form of tablets, capsules, sprays should transit to the therapeutic goods register whilst those products that will comply with the compositional standard for FTDS will have time to comply with all aspects of the new standard.
A transition period of two years would be consistent with the transition allowed for foods complying with Volume 1 to comply with Volume 2.

An important issue for the industry is the monitoring and management of the regulatory compliance for FTDS. The current system of states and territories each having their own standards and interpretation causes problems for Industry. Industry requires clarification and certainty in the regulatory status of these products.

States and Territories must develop a uniform standard of interpretation, akin to the SUSPD. This must state what is expected and what will be tested.
More importantly the States must be adequately resourced to carry out this function.
Industry would like to see adoption of Volume 2 by the States and Territories.

Many other issues will have to be considered in due course and CHC looks forward to being a part of the progression of this proposal, and to see it through to its final stage. We recognize its importance in relation to the total trans-tasman harmonization program and are committed to fully participate in the process.

If you require any further information or have any questions regarding the CHC submission then please do not hesitate to contact the Secretariat.