Healtheries®

Submission on Proposed P235

Review of Food-Type Dietary Supplements

2nd September 2002

SUMMARY

The functional food market is the most rapidly growing food category in the world driven by consumer demand and marketers desire to add value in a stagnant highly competitive market.

New Zealand and Australia cannot afford to ignore this emerging category but must develop a regulatory framework which embraces it but ensures a necessary level of consumer safety.

Healtheries believes that Food Type Dietary Supplements are an alternative dosage form of a Dietary Supplement therefore should be treated and regulated accordingly.

Therefore option 2b(ii), a vertical approach, incorporating a new "Chapter" for FTDS's is the preferred regulatory option.

This would allow appropriate regulations to be developed incorporating labelling, claims, content and manufacturing standards which would effectively bridge the current gap between food and Dietary Supplements, which are presented in a pharmaceutical dosage form.

Dietary Supplements in controlled dose form are currently being reviewed as part of the Therapeutic regulations.

The review of FTDS's must be done in conjunction with this so both Australian and New Zealand Food, Food Type Dietary Supplements and Therapeutic products are aligned.

SIZE OF FTDS MARKET

Globally

Sales of functional foods worldwide are forecast to increase at a compound annual growth rate of more than 10% into the foreseeable future. Estimates of the current global market exceed US$26 billion, on average, with average projections for 2004 at US$40 billion and for 2010, US$47 billion.

For the United States, Nutrition Business Journal estimates year 2001 sales at US$18.5 billion and by 2010 its sales will reach US$31.2 billion. Total retail food sales were $453 billion in 1998, demonstrating just 2% growth over the previous year. Conventional foods grew just 1.7% in the 1997-98 period, compared to 14.8% growth for functional foods and 8.8% for natural/organic foods.

New Zealand/Australian Market

No report in New Zealand has broken the respective food categories into groupings such as organic, health and functional to any credible level which could be used at the time of writing this report.

Many unsubstantiated numbers have been used in estimating the size of the market, but for the purpose of this report we will estimate the size of the emerging Australasian market based on the US market. The New Zealand and Australian markets mirror US trends well, particularly in the 'health' type markets.

Therefore if the combined Australian and New Zealand market is 4% of the US market following the Nutrition Business Journal figures, the value of the market is anywhere up to NZ$1.5 billion dollars with an estimated double digit growth over the next 10 years.

Factors and trends driving rapid development in functional foods include:

- An aging population: In Australasia, the median age is projected to increase from 35 in 1999 to 45 in 2051! The over 65 population will more than double its current level to 26% of the population by 2051;
- Consumers who are more health conscious and inclined to self-medicate with natural preparations, and this is especially prevalent in the aging population;
- Healthcare providers becoming more aware of the relationship between diet and disease;
- A regulatory framework that is inching toward acceptance of health claims for foods and substances found in foods;
- Escalating healthcare costs (in the UK, it's been estimated that cholesterol-lowering plant sterol spreads could lower healthcare costs by $150 million there); and
- Food retailers and marketers who are seeking growth opportunities in a stagnant market.

Range of Products

Products which fall into the 'Functional Food' category are across the whole processed food spectrum and include varieties ranging from ready-to-eat cereals, bakery, probiotic dairy, bars, through to functional beverages.

In New Zealand the most established area is in probiotic dairy – principally yoghurt varieties, but the most rapid emerging market is functional ready to drink products which from 1995 to 2000 went from zero to $65 million dollars sales in New Zealand alone.

Because functional type foods are across so many categories it will depend on the type of product and regulatory environment to whether it is a locally manufactured or imported product.

For example, high value low cost ready to drink beverages such as Red Bull can be imported, but low value/margin products such as biscuits will be harder to justify importation costs.

Similarly the number of and type of companies involved in these products depend on the categories and the products within it. They can range from a small one man distributor company to a large multi-national either importing or manufacturing locally.

Product Range of Manufacturers/Marketers of FTDS

The range of manufacturers and marketers of FTDS depends on the category types in which the company operates.

For example, Griffins (largest biscuit manufacturer/marketer in New Zealand) see 'nutraceutical' type biscuits as a line extension to an existing range, e.g. Calci-Wine.

Whereas Healtheries (largest manufacturer/marketer of Natural Health products in New Zealand) use FTDS as an alternative Dietary Supplement dosage form to increase the offer or convenience for the consumer for a particular indication.

For example, people may prefer to drink Echinacea as a tea versus taking a tablet. In fact, the historical usage of Echinacea was a tea made from crushed up roots. Healtheries Lollipops have proven to be an effective dosage form in giving immune boosters such as Vitamin C and Echinacea to children who typically cannot or will not take tablets. Many bars currently on the New Zealand market do not fall within either the Sports Food Standard or Volume 2 of the Code. However, they do provide a useful source of nutrients for persons who prefer this dosage form.

RELEVANCE OF THE ANZFA/NZDSR POLICY ON FTDS

If we consider FTDS as an alternative dosage format of Dietary Supplements, the current ANZFA policy on the addition and amounts of Vitamins and Minerals is too restrictive. However, as they are a Dietary Supplement the NZDSR regulations are the appropriate standard to apply.

The permissions in the NZDSR do not need to be further restricted regarding types or amounts of nutritive substances but should be controlled as currently listed in the regulations.

FTDS AS 'SPECIAL PURPOSE FOODS'

'Special Purpose Foods' are intended to address specific nutritional deficiencies or disease states, and as such, have very directed formulation and composition.

As FTDS's are intended to provide a wide range of nutrients and nutritive substances, it is not appropriate to include them in this category.

ADDITION OF NUTRITIVE SUBSTANCES

The ANZFA policy on the addition of vitamins and minerals to FTDS, in its current form, is not relevant as the code only allows addition of limited amounts of a restricted number of vitamins and minerals to certain foods.

The need to provide alternative convenient and effective dosage forms for dietary supplements requires a far more comprehensive and broader list of permissions, similar to that of the NZDSR.

Where a 'Nutritive Substance' is defined by Volume 2 (of the code as: a substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which, after extraction and/or refinement, or synthesis, is intentionally added to a food to achieve a nutritional purpose, to include vitamins, and minerals, etc. Then the current permissions in the NZDSR are the most appropriate standard to apply. This uses a 'black list' which details substances not allowed to be used. This could similarly apply to the FTDS.

The permissions in the NZDSR do not need to be further restricted regarding types or amounts of substances, but should be controlled as currently listed in these regulations

PURPOSE OF PRODUCT

'Horizontal' permissions should not be allowed. Because FTDS's are an alternate dosage form for dietary supplements, they should be kept separate from general foods and become a subset in the same manner as 'special purpose' foods.

'Horizontal' permissions would make it impossible to distinguish between FTDS and normal Foods permitted by the Code.

FTDS's differ to foods in the quantity and/or types of substances contained within them, and normal food manufacturing standards will not give sufficient assurance that the dosage of nutrients will be sufficiently controlled. Therefore, it is the controls pertaining to the manufacture and labelling that need to be differentiated, as is the case with TTDS and the NZDSR.

ADDED SUBSTANCES

General

As long as appropriate levels of science and evidence are applied, the risk-based assessment process reflected in Figure 2, section 2.4.1 of the proposal, in conjunction with current HSNO regulations, would address the necessary safety concerns.

Nutritive Substances

For the purposes of regulating FTDS, the definition of nutritive substance needs to be broader to incorporate the additional benefits that may be derived from such products.

Food Additives

The list is fairly extensive and therefore should cover all necessary food processing aids that are used for technical reasons. However, there is one specific exception that needs to be included, which is polyvinyl pyrolidone, present in many FTDS's in the New Zealand market and legal under the current NZDSR.

Botanicals

There are no particular botanicals that should be further restricted. The current list incorporates the latest information on botanicals. As new information becomes available, either on safety or efficacy, the list can be updated (as was the case for Kava).

Single or Mixed Foods

Where it is appropriate to deliver a dietary supplement in the form of a single food, then this should not be explicitly excluded from the code, as this may be the most effective dosage form for this product. e.g. Kelp or Spirulina which may be taken "as is" or incorporated by the end user into other foods such as a soup or a drink.

In general FTDS will be a mixture of foods, and as long as appropriate labelling standards are applied (to ensure the consumer is adequately informed as to the content of the product and that it is a Dietary Supplement) no particular foods need to be specifically excluded from being utilised as a dosage form for Dietary Supplement.

Novel Foods

As currently is the case with Novel Foods, the current regulations of the ANZFA code should continue to be applied.

Labelling

Important labelling statements on FTDS should be a combination of the NZDSR and ANZFA as it is a Dietary Supplement in a recognised Food Form.

The criteria for the contents claim for added nutritive samples should be based on documented efficacies dosage and possibly be similar to that of food claims. I.e. a 'source' claim must contain at least 10% of the efficacious dose or a 'good source' 25%.

There is a plethora of literature based on Botanical and other nutritive substances from which efficacious dosages can be derived.

Labelling should contain general advisory statements or warning statements if required.

FTDS should have the nutritive information requirements of Standard 1.2.8.

Health Claims should only be allowed in the future with rigorous substantiation, with scientific validation.

The contextural statement referring to the context of the total diet is appropriate for FTDS.

As we believe FTDS should be separated into a vertical subset with its own regulatory framework, it should be required to carry a 'prescribed name' which further highlights to the consumer its difference from everyday food items.

Instructions regarding dosage must be used for FTDS as they currently are in the NZDSR.

REGULATORY OPTIONS

The preferred regulatory option is 2.b(ii) – a new "chapter" in Volume 2 of the ANZFA code that treats FTDS as a discrete class of products, as FTDS do have a unique intent different to that of normal foods in that they look to provide a benefit over and above that of the base food which they are composed. However, to ensure efficacy and safety of these products, there is the need to provide substantiating data for usage and any claims made, as well as a code of practice for manufacturing and quality control standards.

Since the level of promise is higher than that for non-fortified foods, so too the manufacturing standard should be higher than that for normal foods. The food license could be modified to include specific permissions to manufacture or pack dietary supplements (in the same way a medicines license gives various levels of permissions based on required compliance to an agreed standard). Compliance to these standards would need to be audited. It is proposed that this be performed by the Food Safety Program Auditor.

The benefits of this option are:

- The ability to provide consumers with an alternative and more convenient dosage form of supplementation. For example, people that are unable to take tablets such as the elderly or young children. It would be preferable to take a daily dosage in a liquid or everyday food.

  An example of this would be in the case of osteoporosis. This disease is becoming endemic in all developed nations. Research (Healtheries of New Zealand conducted by Fast Forward Research) has shown that women find it onerous taking a daily calcium tablet but would readily substitute a food, such as a bar/chew which would supplement their daily calcium intake. While nutritionists would argue that a balanced diet will provide the necessary calcium, evidence shows that women (on average) only consume between 17-20% of the necessary calcium RDI. With the decrease in consumption of dairy products and the increase in caffeine and fast food intake, the level of calcium intake will decline even further. As many women find tablets unpalatable, there is a requirement for a food-based form of calcium supplementation which as taken as an every day form of food will enable consumers to achieve the RDI easily.

- To provide the necessary standards for manufacturers and suppliers to ensure the necessary level of safety and efficacy with the products provided

- To provide a level playing field for industry with respect to the standards (and code of practice) they need to comply with. There would be increased costs to the manufacturer/supplier due to the need to comply to the higher standards than that applied to normal foods, and the associated audit costs. This is a required cost for those currently complying to the required dietary supplement standards (internationally as opposed to New Zealand). Therefore, as it is proposed that FTDS's are an alternate dosage form they should be subject to the same standards and hence incur similar costs.

Experience would show that industry-based monitoring of a code of practice that encompasses a wide spectrum of regulations we are proposing, such as manufacturing standards, labelling, safety and stability data, would be ineffective. Hence, the need for an independently monitored regulatory environment and the associated costs that this entails, such as provided for the Dairy, Meat and Fish Industries.

Prepared on behalf of Healtheries of New Zealand Limited by:

[redacted]
Managing Director

[redacted]
Technical Manager