Australia New Zealand Food Authority
TE MANA WHAKARITE KAI MŌ ĀHITEREIRIA ME AOTEAROA

10/02
26 June 2002

INITIAL ASSESSMENT REPORT
(PREPARE A NEW PROPOSAL - SECTION 21)

PROPOSAL P235

REVIEW OF FOOD-TYPE DIETARY SUPPLEMENTS

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
7 AUGUST 2002
(See 'Invitation for Public Submissions' for details)

THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY

The Australia New Zealand Food Authority's (ANZFA) role is to protect the health and safety of people in Australia and New Zealand by maintaining a safe food supply. ANZFA is a partnership between the Commonwealth Government, Australian States and Territories governments and the New Zealand Government.

As an independent expert body, ANZFA is responsible for developing and reviewing food standards for both Australia and New Zealand. ANZFA makes recommendations to change the food standards to the Australia New Zealand Food Standards Council, a Ministerial Council made up of Commonwealth, State and Territory and New Zealand Health Ministers. If the Council approves the recommendations made by ANZFA, the food standards are automatically adopted as regulations into the food laws of the Australian States and Territories and New Zealand.

ANZFA's OBJECTIVES

In developing or varying a food standard, ANZFA is required by its legislation to meet three primary objectives, which are set out in section 10 of the *Australia New Zealand Food Authority Act 1991*. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, ANZFA must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry; and
- the promotion of fair trading in food.

OTHER REGULATORY OBJECTIVES

At the same time ANZFA must ensure that the regulations it develops are the most efficient and effective possible. It does this by looking at the possible impact that the regulation might have on consumers, business and other groups in our community or whether there are alternative options to formal regulations such as codes of practice. In addition, as Australia and New Zealand are members of the World Trade Organization (WTO), ANZFA must ensure that the regulations are consistent with the obligations of both countries as members of the WTO.

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FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984,* but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.*

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974,* and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

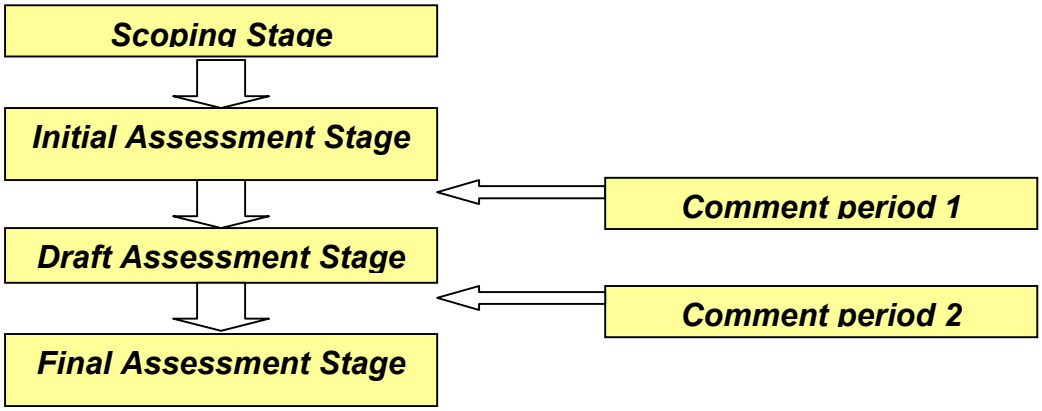
INVITATION FOR PUBLIC SUBMISSIONS

The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the ANZFA Act 1991. Open and transparent consultation with interested parties is a key element in the process involved in amending or varying the Code.

Any individual or organization may make an 'application' to the Australia New Zealand Food Authority (the Authority) seeking to change the Code. The Authority itself, may also seek to change the Code by raising a 'proposal'. In the case of both applications and proposals there are usually two opportunities for interested parties to comment on proposed changes to the Code during the assessment process. This process varies for matters that are urgent or minor in nature.

Following the initial assessment of an application or proposal the Authority may decide to accept the matter and seek the views of interested parties. If accepted, the Authority may then undertake a draft assessment including preparing a draft standard or draft variation to a standard (and supporting draft regulatory impact statement). If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the final assessment, which the Authority will hold to consider the draft standard or draft variation to a standard.

Comment opportunities in the usual assessment process
to change the Australia New Zealand Food Standards Code
(Note: this process may vary for matters that are urgent or minor)



Content of Submissions
Written submissions containing technical or other relevant information which will assist ANZFA in undertaking an assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organizations. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant; studies, research findings, trials, surveys etc. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions may provide more general comment and opinion on the issue although those framing their submissions should bear in mind ANZFA's regulatory role specifically relates to food supplied for human consumption in Australia and New Zealand. The ANZFA Act 1991 sets out the objectives of the Authority in developing food regulatory measures and variations of food regulatory measures as:

(a) the protection of public health and safety; and
(b) the provision of adequate information relating to food to enable consumers to make informed choices; and
(c) the prevention of misleading or deceptive conduct.

In developing food regulatory measures and variations of food regulatory measures
The Authority must also have regard to the following:

the need for standards to be based on risk analysis using the best available scientific evidence;
the promotion consistency between domestic and international food standards;
the desirability of an efficient and internationally competitive food industry;
the promotion of fair trading in food.

Submissions addressing the issues in the context of the objectives of the Authority as set out in the *ANZFA Act 1991* will be more effective in supporting their case.

Transparency
The processes of ANZFA are open to public scrutiny, and any submissions will ordinarily be placed on the public register of ANZFA and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to ANZFA, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires ANZFA to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonable be expected to be destroyed or diminished by disclosure.

Contact details for submitters are recorded so that the Authority can continue to keep them informed about progress of the application or proposal.

Deadlines
The deadlines for submissions are clearly indicated in the advertisements calling for comment and in the relevant Assessment Reports. While the Authority often provides comment periods of around 6 weeks, the periods allowed for comment may vary and may be limited to ensure critical deadlines for projects can be met. Unless the Project Manager has given

specific consent for an extension, the Authority cannot guarantee that submissions received after the published closing date will be considered.

Delivery of Submissions
Submissions must be made in writing and should be clearly marked with the word **'Submission'** and **quote the correct project number** and **title**. Submissions may be sent by mail to the Standards Liaison Officer at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2258
email: slo@anzfa.gov.au

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
email: anzfa.nz@anzfa.gov.au

Submissions should be received by the Authority by: 7 AUGUST 2002

Submissions may also be sent electronically through the submission form on the ANZFA website www.anzfa.gov.au. Electronic submissions should also include the full contact details of the person making the submission on the main body of the submission so that the contact details are not separated.

FURTHER INFORMATION
Further information on the application and submission process should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the above addresses.

Assessment reports are available for viewing and downloading from the ANZFA website or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@anzfa.gov.au.

EXECUTIVE SUMMARY

Volumes 1 and 2 of the *Food Standards Code* do not currently regulate many foods that are considered to be dietary supplements. Many such products are manufactured in or imported into New Zealand under the New Zealand *Dietary Supplement Regulations 1985* (NZDSR) and from there, into Australia under the Trans Tasman Mutual Recognition Arrangement (TTMRA). This Proposal (P235) seeks to develop food regulatory measures to manage these *food-type* dietary supplements (FTDS) within the context of the harmonisation of food regulations between Australia and New Zealand.

Viewed more broadly, foods such as those manufactured to the NZDSR represent a growing sector of the global food market and present a number of international regulatory challenges. Codex Alimentarius has not established a specific standard for these products and international regulatory measures differ markedly between countries.

This paper considers the current permissions of the NZDSR in the context of possible measures that could be used to regulate FTDS. Four main options for the regulation of FTDS are presented. Options 2 and 3 are based on the premises that:

a) the New Zealand *Food Regulations 1984* will be repealed at the end of the transition period (end 2002); and

b) the NZDSR will be revoked or amended in due course such that products presented as 'foods' could no longer be manufactured, imported or marketed specifically under these regulations.

Option 1 is based on premise a) only.

In the interests of exploring these options as fully as possible prior to the development of any draft regulatory measures, option 2 is further expanded into sub-options that address management of FTDS through either expansion of the general permissions of the current standards, or development of new standards in the *Food Standards Code*.

Any assessment of possible regulatory options requires consideration of the current permissions in the NZDSR and/or Volume 2 for: addition of certain substances to foods, in particular, nutritive substances and further botanical substances; novel foods; relevant products such as formulated supplementary sports foods and formulated caffeinated beverages (FCBs); and aspects of labelling and associated claims. These are outlined in Section 2.4. Furthermore, this proposal needs to carefully consider the boundary that exists between *food-type*- and *therapeutic-type* dietary supplements (TTDS) (such as complementary medicines).

At the same time that ANZFA is considering trans-Tasman harmonisation of foods, the Joint Therapeutic Products Agency (JTA) team (a preliminary working group formed between respective therapeutic products agencies in Australia and New Zealand) is also developing a proposal for harmonised regulation of medicines. This project will be specifically considering TTDS whilst, P235 considers FTDS i.e. foods. Furthermore, the New Zealand Ministry of Health will be considering the NZDSR, specifically in relation to foods that may be sold under these regulations.

Therefore, in order to provide a more 'complete picture', it is anticipated there will be three consultation documents released at a similar time for consideration by the community. Table 1 below summarises the respective documents and authoring agencies.

Table 1. Consultation documents relating to dietary supplements.

Topic	Authoring Agency	Key feature(s)
Food-type dietary supplements (Proposal P235)	ANZFA	Issues relating to regulatory principles, possible regulatory frameworks, and their relative impacts in respect of *food-type* dietary supplements
Therapeutic products	JTA	Consideration of harmonised approach to regulation of medicines, including *therapeutic-type* dietary supplements
New Zealand *Dietary Supplement Regulations 1985*	MOH	Consideration of foods manufactured to the NZDSR

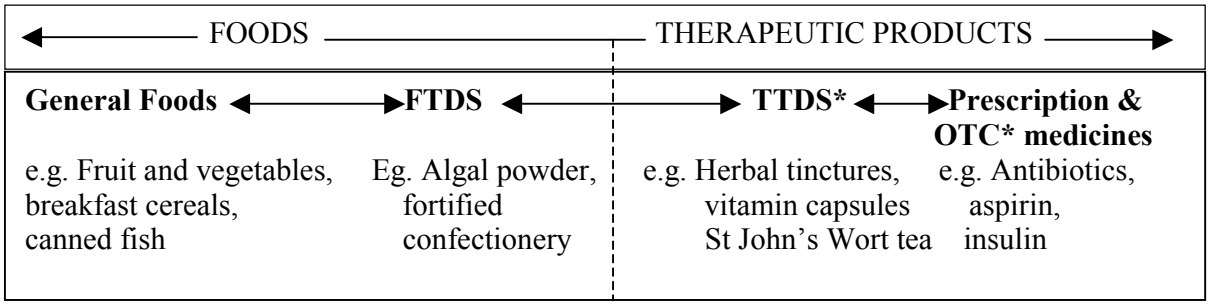
Following receipt of submissions to P235, proposed draft food regulatory measures will be prepared and circulated by ANZFA for further consideration within the context of the Draft Assessment Report for P235.

1. INTRODUCTION

P235 considers the need to develop food standards (or other food regulatory measures) that regulate, among other things, food-type products that are manufactured or imported under the New Zealand *Dietary Supplement Regulations 1985* (NZDSR) and, as appropriate, develop trans-Tasman food regulatory measures for these products. For the purposes of this paper, the term *food-type* dietary supplements (FTDS) will be used, where it is emphasised that the products under discussion are regarded as foods.

Figure 1 below describes the continuum that exists between foods and therapeutic products. In the middle of this spectrum are the products that approach the boundaries, or interface, between foods and medicines - FTDS have predominantly more food characteristics whereas *therapeutic-type* dietary supplements (TTDS) (known as complementary medicines in Australia) are more therapeutic in nature. The factors that are taken into account to determine whether a product is a food or not include representations such as claims, other labelling information, dosage form and certain compositional characteristics.

Figure 1. Continuum of foods to therapeutic products.



* Over-the-counter i.e. a prescription is not required.

New Zealand and Australian officials on the JTA project team are developing proposals for implementing a joint agency for the regulation of therapeutic products in Australia and New Zealand. A joint agency would provide the means for harmonising the regulation of therapeutic products in the two countries, thereby resolving the special exemption for therapeutic products under the Trans Tasman Mutual Recognition Arrangement (TTMRA). These proposals for a joint agency will be presented in a discussion paper, which will be distributed for public consultation in early May 2002.

Please note that TTDS are not the subject of P235 nor this consultation document.

2. ISSUES

Some foods that are manufactured or imported under the NZDSR are not currently permitted by Volumes 1 or 2 of the *Food Standards Code* and therefore, there are no harmonised regulatory measures for such products between Australia and New Zealand. As part of the overall review of the *Food Standards Code* and harmonisation of trans-Tasman food standards, consideration is being given to whether such products should be regulated within Volume 2 of the *Food Standards Code* (Volume 2).

The structure of Volume 2 is currently based on the purpose of the products (foods) that it regulates. This approach applies at both the broad i.e. general purpose level, and also at the more specific (special purpose) and individual standard level. These approaches are reflected in Chapter 1 and Chapter 2 of Volume 2 respectively. Chapter 1 includes horizontal standards that apply to all foods whereas, Chapter 2 consists of standards for specific food commodities (Parts 2.1 – 2.8 and 2.10 inclusive) and special purpose foods (Part 2.9). Many FTDS do not conform to the purposes currently inherent in these parts, which are based on appropriateness for the general population (i.e. general purpose foods) or dietary need based on essentiality (i.e. special purpose foods).

At the same time that ANZFA is considering trans-Tasman harmonisation of all foods, the Joint Therapeutic Products Agency (JTA) team (a preliminary working group formed between respective therapeutic products agencies in Australia and New Zealand) is also developing a proposal for joint regulation of therapeutic products, which will include therapeutic-type products made to the NZDSR. Because of the common link to the NZDSR, these related activities of the food and therapeutic products agencies need to be co-ordinated, at least in the first instance, to ensure a seamless food-medicine interface is adopted and that

the community is presented with a comprehensive proposal for its consideration. A further consideration in respect of this proposal is the need to recognise the interface that FTDS create with TTDS (such as complementary medicines) and to clearly articulate the boundaries.

The ongoing ability to manufacture or import foods to the NZDSR has the potential to severely undermine the harmonisation of food standards for FTDS therefore, it is important that the progression of P235 be closely linked to appropriate amendments or revocation of the NZDSR. Subject to the outcomes of the JTA proposal, it is anticipated that the NZDSR will ultimately be repealed. In the interim, ANZFA understands that The New Zealand Ministry of Health (MOH) is releasing, at a similar time to this report, a discussion document proposing that foods that may be sold under the NZDSR should no longer be able to do so.

Viewed more broadly, foods such as those manufactured or imported under the NZDSR represent a growing sector of the global food market and present a number of international regulatory challenges. Variously called functional foods, nutraceuticals, designer foods etc, they may or may not encompass 'dietary supplements' depending on the definition and use of the terms in question. The Codex Alimentarius Commission (Codex) has not established a specific standard for these products and international regulatory measures differ markedly between countries.

Central issues pertaining to regulation relate to the:

- composition and associated safety of the products;
- provision of sufficient labelling information to allow for informed choice including appropriate use; and
- definitions insofar as they would differentiate these products from the general food (and therapeutic good) supply.

In respect of ANZFA's deliberations, further considerations are:

- current permissions afforded to New Zealand industry by the NZDSR
- current range of products available to New Zealand consumers;
- the potential harmonisation of regulations at the trans-Tasman level; and
- the development of a clear but consistent boundary between foods and medicines.

It is also noted that, in order to finalise the agreed harmonisation of food standards between New Zealand and Australia, P235 needs to progress within timelines identified by ANZFA, irrespective of the ultimate outcomes of the JTA proposal.

2.1 Nature of product

Due to the differences in meaning that may be ascribed to any terms used to refer to these products, it is difficult to nominate a suitable term that will not be open to differing interpretations by various readers. A number of definitions for 'dietary supplements' from domestic and international sources are in Attachment 1. The key element of these products appears to be a supplementary role (to the normal diet) and an intended function over and above that provided by the usual diet.

Whereas many associate the term 'dietary supplements' with tablets, capsules or other dosage forms of products that are normally viewed as complementary health care products or medicines, the NZDSR (refer to Attachment 2) have been used by manufacturers to develop/import products clearly presented as 'foods' e.g. beverages, powders, bars and confectionery, and fortified with vitamin, minerals and nutritive substances in a way that is not permitted under the *Food Standards Code*, except in a few defined circumstances.

There is further potential for confusion due to the different definitions of food within Australia in the respective jurisdictional Acts. There is a definition of 'food' in the ANZFA Act (refer Appendix to Attachment 3) however, when the States and Territories consider compliance, the definition of food within the relevant jurisdictional Act is used. The States and Territories have undertaken to amend their respective Food/Health Acts in line with the Model Food legislation and this will include adoption of the definition of food within that Act in due course.

Furthermore, it is essential that regulation of products that are regarded as foods are clearly differentiated from products that are regarded as therapeutic products (complementary medicines and corresponding New Zealand TTDS). The Australian *Therapeutic Goods Act 1989* effectively uses a defacto definition of foods by stating that therapeutic goods are <u>not</u>:

- *goods for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection3(1) of the Australia New Zealand Food Authority Act 1991; or*
- *goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.*

FTDS also sit within a broader domestic and international context where there is a rapidly developing functional food/nutraceutical industry. This industry has an estimated global value of $US 65 billion[1] and offers industry significant opportunity for the development of new markets and increased choice for consumers. The actual impacts on health-related outcomes remain to be seen and indeed, will be difficult to assess and monitor.

In view of this global trend towards these new types of foods, this review may need to extend beyond FTDS and also consider the regulatory implications for this conceptual category of functional-type foods. One of the inherent difficulties is suitably defining these products such that the chosen term is used consistently and with clear meaning for all readers.

In 1993, the [then] National Food Authority developed a preliminary working definition for this category of 'functional foods' which read '*similar in appearance to conventional foods and intended to be consumed as part of a normal (changed to 'usual' in 1996) diet, but have been modified to subserve physiological roles beyond the provision of simple nutrient requirements'.* Whilst some of the specific words could be debated, the fundamental purpose of *intending to provide health benefits beyond simple nutrition* appears to remain constant and be consistent with most international discussion on this concept.

[1] Lachance PA. 2002. Food Technology 56 (1) cited in the Functional Foodnet (FFNET)(January 30 2002). URL: www.ift.org/publications/docshop/ft_shop/01-02/01_02_pdfs/01-02-nutraceuticals.pdf

2.1.1 Market scan

In early 2001, ANZFA conducted a survey of the current FTDS market in New Zealand to provide a comprehensive overview of the types of product under consideration by this proposal (P235). The majority of these products were not compliant with the *Food Standards Code.* Given below is a summary of the key findings.

a) Composition
Liquid products and beverages comprised the largest category and ranged from sports-type beverages for the mass consumer market to herbal-based products making specific health-type claims, some of which contain restricted or prohibited botanicals under the *Food Standards Code*.

The second largest category was the powdered products. These were powders that are either added to juice, water or stirred into foods. This selection included spirulina, aloe vera, algae and cereal grass based powders. These appeared to be the main types in this category and many similar products were produced by a number of manufacturers. Other powdered products were milk and/or whey based.

There was also a miscellaneous category that was a mixture of more obscure products, ranging from an oral spray to mussel extract, honey, children's sweets and herbal tea bags. Again, some of these were found to contain prohibited or restricted botanicals (refer Standard 1.4.4, Volume 2) for example, St John's Wort. The bar-type products collected were mainly marketed as 'sports' or 'endurance' bars.

b) Labelling
Label information varied considerably by product and by manufacturer. Although label information was not specifically assessed in terms of compliance with the respective Australian and New Zealand legislation, the main area of potential concern would be the nature of the health/therapeutic-type claims made for some products and their constituent ingredients, which are prohibited by the *Food Standards Code* and New Zealand M*edicines Act 1981*.

Target market information tended to be implied (by the nature of the product and the on-pack advertising) rather than explicit although a few products were clearly designed for children.

Directions for use were mixed. Some provided 'dosage' advice (as is required by the NZDSR, refer to Attachments 2 and 5), others referred to serving size, and some used both i.e. dosage and serving size, which in some instances were inconsistent and thereby confusing.

c) Source of product
The majority of products in New Zealand can be purchased in supermarkets, health food stores and superettes (small suburban supermarket, larger than a corner store or dairy). A more limited range was found in dairies and service stations and tended to be the beverages labelled as 'dietary supplements'.

Traditional health food stores, previously found in malls and shopping centres, have largely been replaced by suburban health food stores. These new-age stores are more like health food supermarkets and mimic mainstream supermarkets in layout and product choice. It is these stores that stock the less familiar, imported lines of food products that fall into the dietary supplements category. These foods may or may not be clearly labelled as dietary supplements

or some may not need to be labelled as such but are, e.g. herbal teas, honey, spirulina powder, aloe vera products.

ANZFA invites further information in respect of the current market for FTDS, such as:

- What is the size of the FTDS market in Australia and in New Zealand:
  - In terms of the value of the market?
  - In terms of the range of products on the market, and each product's share of the total market?
  - What has been the growth in the value and range of FTDS products over the past 5 years?
- In supplying the FTDS products market in Australia and New Zealand:
  - What is the respective share of New Zealand industry and imports?
  - Has this share changed over the past 5 years?
  - What is the structure of New Zealand industry: number of companies, share of each company of total production.
  - What is the structure of imports: number of companies, share of each company of total production.

Do the New Zealand manufacturers or importers of FTDS products also produce/sell other functional, health or therapeutic products?

2.2 Current regulatory status

On 1 July 1996, an Agreement Between the Government of New Zealand and the Government of Australia Establishing a System for the Development of Joint Food Standards (the Treaty) came into force that established a joint Australian New Zealand Food Standards System. The Treaty served to underpin the development of Volume 2.

Volume 2 came into effect in Australia in December 2000 and in New Zealand in February 2001. A transition period is currently in operation whereby Volumes 1 and 2 of the *Food Standards Code* are both in place so that food may comply with one or the other (but not both). Furthermore in New Zealand, food may also comply with the *Food Regulations (1984)*. It is expected that Volume 1 and the *Food Regulations (1984)* will be repealed at the end of 2002 such that Volume 2 becomes the sole set of food regulations for New Zealand and Australia.

Many FTDS fall outside the current provisions of both Volume 1 and Volume 2 but are nonetheless lawfully available for sale in both New Zealand and Australia. Products that are lawfully manufactured or imported into New Zealand, may as a result of the Trans Tasman Mutual Recognition Act (1997), which gives effect to the TTMRA in Australia, be lawfully imported and sold in Australia, provided they are not considered to be therapeutic goods (which must comply with the *Therapeutic Goods Act 1989*).

Attachment 3 provides further detail on the respective bi-national legislative systems, pertaining to both foods and therapeutic products, and a summary of the current definitions used in these sets of legislation.

2.3 International Regulations

One of the difficulties facing this area is the lack of international consistency in the regulatory management of dietary supplements *per se*. In some countries regulation is effectively based on a 3-category system i.e. foods, medicines and dietary supplements (or alternate term) although, the regulations pertaining to dietary supplements (or other) generally sit under a broader [2-category] legislative umbrella for either foods or medicines. By way of example of the potential confusion inherent in some of these systems, the NZDSR regulates products that are predominantly therapeutic products in Australia, yet the NZDSR places them under the *Food Act (1981)* in New Zealand. Countries that have instituted a 3-category approach include New Zealand, the United States, Canada (proposed system), Europe and Japan whereas, countries such as Australia and the United Kingdom use a 2-category system i.e. foods and medicines (under therapeutic products).

The complexities of the various regulatory systems, and hybrid presentation of many of the products, often make it difficult to clearly identify whether such products are intended to be used as foods or therapeutic products. A further complication is lack of consistency in relation to the terminology used and its application. For example, the types of products included in the international 'supplementary' categories may differ eg restricted to only certain forms of products eg tablets and capsules, or be applied more broadly, and/or be difficult to determine as 'foods' or 'therapeutic products'. This situation is becoming increasingly complex as foods and pharmaceutical companies merge and new styles of food products emerge whereby foods essentially deliver substances traditionally found in the therapeutic domain.

Attachment 4 provides further detail on various international approaches to the regulatory management of functional/dietary supplement foods, looking specifically at Europe, the United Kingdom, the United States, Canada and Japan.

Codex is an international intergovernmental body that is responsible for implementing the Food and Agriculture Organization (FAO) and World Health Organization (WHO) Food Standards programme. The primary objective of Codex is *to guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in their harmonisation, and in doing so, to facilitate international trade.*

Codex currently does not have an applicable term or definition *per se* that covers these products, but has defined foods that have a special purpose in the human diet (CODEX STAN 146-1985[2]).

Foods for Special Dietary Uses (eg infant formulae, meal replacements) are defined as:

> *those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such foods exist.*

[2] URL (8 March 2002) http://www.codexalimentarius.net/standard/volume4/vol4_e.htm

At this point in time, this definition relates more closely to Special Purpose foods in the *Food Standards Code* (refer to Section 2.4.2 for further detail); any direct applicability of the definition to FTDS within an Australian and New Zealand regulatory framework remains to be seen.

Fortification with vitamins and minerals is integral to the discussion on FTDS and is discussed further below (refer Section 2.4). It is therefore relevant to note at this point, the Codex Committee on Nutrition and Foods for Special Dietary Uses' (CCNFSDU) draft proposed Guidelines for Vitamin and Mineral Supplements is at an early stage of consideration and addresses acceptable and unacceptable ingredients, minimum and maximum quantities, labelling and claims. It proposes to exempt such supplements where they are nationally regarded as drugs/medicines[3].

2.4 Regulatory framework

The *Food Standards Code* is underpinned by a regulatory framework based on the application of risk analysis, which includes the three steps of risk assessment, risk management and risk communication. In order to assess the risk, hazards need to be identified through a variety of means including traditional knowledge within the community, available scientific data and associated risk-exposures. Inherent in this process is a variable degree of scientific uncertainty that calls for judgement, and transparency and consistency in decision-making. The degree of risk (or on the other hand, caution) that a community is prepared to accept is also a matter of judgement, and may be significantly influenced by community and cultural values.

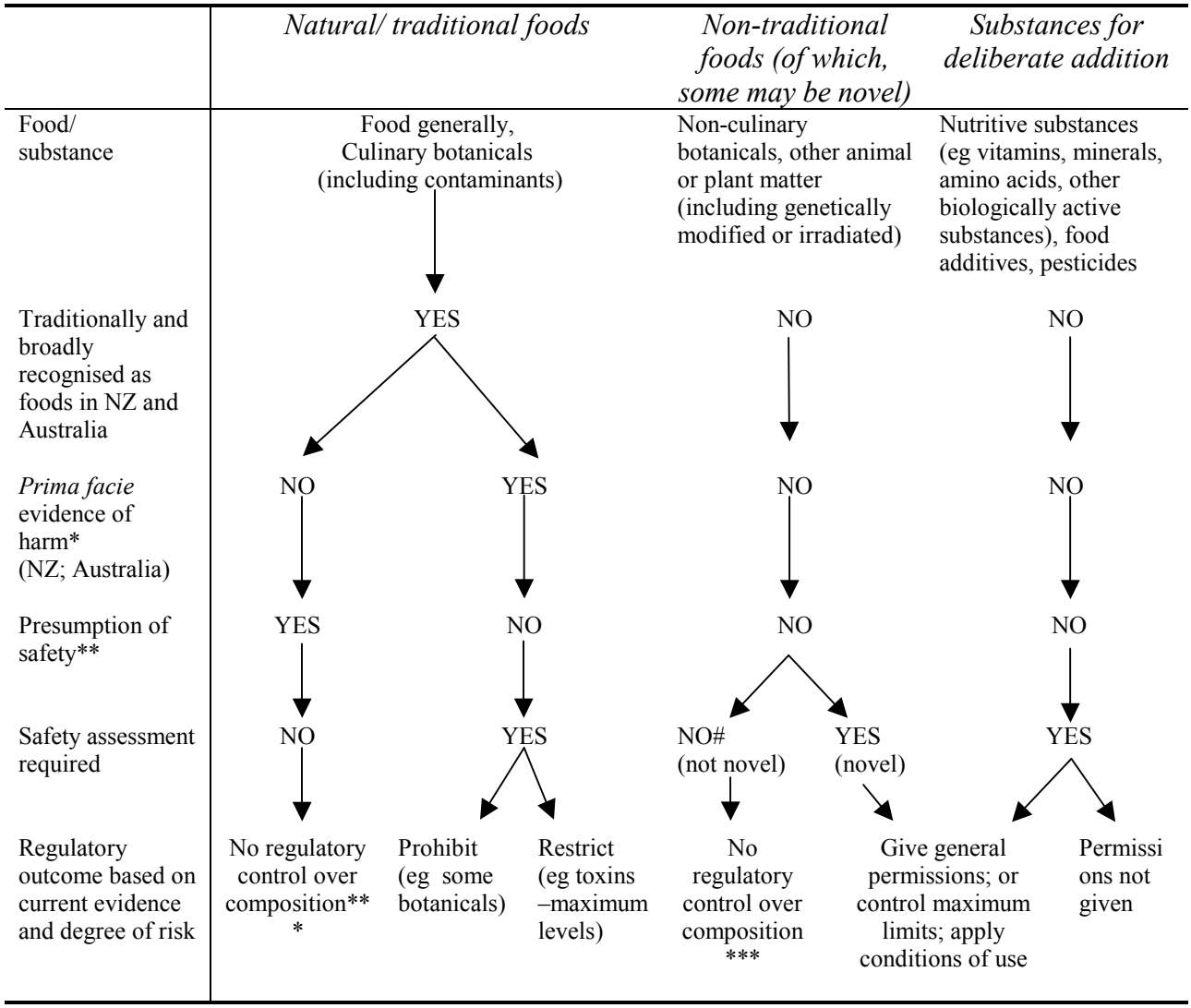
FTDS challenge many facets of this process due to a lack of community knowledge and lack of data on many of the substances involved, the potentially unpredictable and high levels of exposure (by virtue of being in the food supply), accompanied by the difficulties of identifying an appropriate 'yard stick' (or precedents) against which possible permissions may be assessed, particularly in respect of whole foods.

Figure 2 below is a schematic representation of this risk-assessment based framework, incorporating the regulatory responses that currently underpin the *Food Standards Code*. This diagram endeavours to describe the steps taken in respect of different foods/added substances that determine whether a safety assessment is undertaken and the ultimate regulatory response, which may range from total prohibition to broad general permissions, with a number of intermediate responses along this continuum.

Many FTDS would relate to the second and third columns of this diagram i.e. *Deliberate addition/supply* because of the substances that compositionally characterise FTDS i.e. nutritive substances, particularly vitamins and minerals, non-culinary (or 'medical') botanicals and/or novel foods.

[3] URL (25 March 2002) ftp://ftp.fao.org/codex/Alinorm03/al03_26e.pdf

Figure 2. **Conceptualisation of risk assessment-based framework that currently supports the *Food Standards Code*.**



Notes:

* Assumes acceptance of '*prima facie* evidence of harm' as the appropriate underpinning principle, rather than a requirement for 'evidence of safety'; and is based on available data.

** Subject to the comprehensiveness of evidence collection and integrity of the surveillance systems (eg reporting of adverse reactions) and extent to which a population is exposed to the food/substance.

*** Underpinned by generic labelling and other requirements in *Food Standards Code* and jurisdictional Food Acts.

Based on definition of 'novel' (see Section 2.4.4, or Standard 1.5.1-Novel foods, Volume 2)

A significant proportion of the foods in the FTDS category contain nutritive and/or botanical substances <u>not currently permitted</u> within Volume 2, or the levels of nutritive substances are <u>in excess of the current prescribed limits.</u>

The purported purpose behind the addition of some of the nutritive substances to FTDS extends beyond established physiological need to other 'functional' benefits more

traditionally associated with therapeutic products than foods. Such purposes include promotion of health through to 'boosted' physiological and psychological function.

Consideration of the addition of nutritive substances at levels beyond generally accepted nutritional need requires a significant paradigm shift from the current nutritional principles applied to general purpose foods (in the *Food Standards Code*). In saying this however, it should be noted that an anomaly has recently arisen with the newly developed standard for FCBs - these beverages may contain vitamins in excess of general permissions. This issue is discussed further below in Section 2.4.1.

The sub-sections below address some of the principles that support the *Food Standards Code* in its current form and that bear particular relevance to this proposal. Specific consideration is given to the application or otherwise of these principles to FTDS.

2.4.1 Addition of nutritive substances

A conservative approach has traditionally been taken in both Australia and New Zealand with respect to the addition of nutritive substances[4], predominantly vitamins and minerals, to foods. To date, with the exception of the recently developed food standard for FCBs, the addition of nutritive substances to foods has been largely based on the four Codex – principles[5] for adding nutrients to food of which the first three apply to foods generally*:*

1) restoration [to moderate fortification levels];
2) nutritional equivalence of substitute foods;
3) fortification [to address public health need]; and
4) ensuring the appropriate nutrient composition of a special purpose food.

Volume 2 provides permissions for nutritive substances, which tend to be predominantly vitamins and minerals, to be added to certain foods at specific levels (for general purpose foods in Standard 1.3.2; and for special purpose foods in the specific standards outlined in Part 2.9). Some nutritive substances have a significant history as low risk substances (because their counterparts naturally occur in other foods) or even as dietary supplements (eg complementary medicines) in defined dosages, whilst others do not.

Nutritive substances also differ [from contaminants and additives] insofar as, there is no safe baseline of 'zero' - many may be essential at one level but potentially toxic at another. This particular characteristic means that broad permissions, either minima or maxima, cannot be applied generally but rather, an approach may need to be used that provides for ranges of substances, depending on the specific substance, the form in which it is presented, the manner in which it is likely to be used and by whom. Where there are potential public health and/or safety concerns due to excessive intakes, maximum limits are imposed and controlled through either upper maximum permitted levels, or more indirectly through maximum permitted content claims.

[4] 'Nutritive substance' is defined in Volume 2 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, and include vitamins, minerals, amino acids, electrolytes and nucleotides.*

[5] Codex General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 09-1987). URL (8 March 2002): http://www.codexalimentarius.net/standard/volume4/vol4_e.htm

Whether fortification permissions are ultimately voluntary or mandatory depends on the level and extent of the health problem to be addressed, and the capacity and willingness of the targeted industry sector to volunteer specific nutrient addition to relevant 'general purpose' foods. From a public health perspective, permission for voluntary addition cannot be relied upon to achieve major improvements in public health because manufacturers may not utilise the permission(s).

ANZFA's current policy in relation to voluntary addition of vitamins and minerals to general purpose foods is:

- Vitamins and minerals may be added, subject to identified risks to public health and safety, at moderate levels (25% RDI/ reference quantity) to some basic foods providing the vitamin or mineral is present in a marker food in the food group to which the food belongs. The vitamin or mineral must be naturally present at a level which would contribute at least 5% of the Recommended Dietary Intake (RDI) in a reference quantity of the food (eg vitamin C in fruit juice).

- Specified foods may be fortified with vitamins and minerals to address situations where there is reasonable evidence for a nutritional need in the population (eg folate in breads and cereal products).

- Vitamins and minerals may be added, for the purpose of nutritional equivalence, to specified foods, which substitute for certain basic foods (eg calcium to soy beverages).

In total, sixteen vitamins and minerals are permitted to be added to a range of general purpose foods, with the specific provisions outlined in Standard 1.3.2 of Volume 2. The philosophical direction of this approach is established in the context of:

- controlling risks to health;
- preserving the nutritional integrity of the food supply; and
- and supporting food-based nutrition education activities.

Furthermore, it aims to:
- improve the nutritional content of some commonly consumed foods;
- permit consumer choice; and
- address public health need.

Application to FTDS

The permissions afforded by the current vitamin and mineral standard in Volume 2 (i.e. Standard 1.3.2 – Vitamins and Minerals) are relatively conservative and do not cater for many of the formulations currently seen in FTDS.

Some vitamins and minerals may have a history of safe use in foods at certain levels, eg those naturally occurring in foods, but when added to other foods in higher concentrations there is no such history.

The NZDSR provides a list of substances that are referred to as *vitamins* or *mineral*s. Minimum levels of these nutrients are not required in the dietary supplements however, maximum limits are specified for only some vitamins and minerals (refer to Attachment 2 for

specific details). If minerals are added to the dietary supplements, other than the 15 minerals listed in regulation 19(1) of the NZDSR, then a maximum 'daily dose' of the current US *Recommended Dietary Allowances* is specified. It should be noted that of the 15 minerals listed in 19 (1), maximum levels are prescribed for only 4 (refer to table to subclause 3(1)). Other nutritive substances, i.e. other than vitamins and minerals (eg free amino acids), may also be added to dietary supplements and there are no restrictions on the levels that can be added. This is significantly different to Volume 2 where such substances can only be added where there are positive permissions to do so. For example, free amino acids for nutritive purposes are only permitted to be added to Formulated Supplementary Sports Foods (refer to Standard 2.9.4) to the maximum amount specified in Volume 2.

ANZFA invites comment on:

- the relevance of the current ANZFA policy on the addition of vitamins and minerals to FTDS;
- the appropriateness of the current permissions in the NZDSR for nutritive substances; and
- should these [NZDSR] permissions be restricted regarding:
    - the types of substances (please give name and reason); and/or
    - amounts of substances (please give details).

Initial assessment

Volume 2 treats added nutritive substances in the same way as food additives in that they require explicit pre-market assessment and permission to be added to foods. Many FTDS regulated under the NZDSR contain amounts and/or types of nutritive substances, specifically vitamins and minerals, not currently permitted by Volume 2.

2.4.2 Special Purpose foods

Special purpose foods, as standardised in Volume 2, are underpinned by the policy basis that they are '*… foods that are specially processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological need'* [6].

ANZFA's definition of special purpose foods is firmly grounded within a traditional nutrition paradigm that has as its basis, dietary adequacy (which includes essentiality) to support physiological growth, development and maintenance of health.

In the Australian and New Zealand context, the phrase *particular dietary requirements* refers to nutritional requirements that cannot be met by consumption of a normal diet. *Physical and physiological need* includes reference to normal states in the life cycle such as pregnancy and lactation, as well as physical (including lifestyle) and physiological conditions that require the use of special purpose foods.

These foods differ from general purpose foods because they are designed to deliver nutrition to at-risk groups whose dietary requirements cannot be satisfied by a normal mixed diet.

Maximum limits for nutritive substances are determined in accordance with the specific intention of the special purpose food, and the risk to the target group. Because there are

[6] Lewis J et al. 2002 Food Control [in press]. *Nutrition Considerations in the Development and Review of Food Standards, with Particular Emphasis on Food Composition.*

potential risks from consumption of excessively fortified products, a cautious approach underpinning the regulation of special purpose foods requires, for every special purpose food standard, the establishment of maximum micronutrient levels expressed in terms of maximum claim (lower risk) and maximum amount for higher risk micronutrients.

Application to FTDS

The above principles are founded on meeting specific dietary needs and the related standards (Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods and Standard 2.9.4 – Formulated Supplementary Sports Foods) have quite specific permissions around composition and labelling, many of which may or may not be applicable in the context of many FTDS currently on the market.

Initial assessment
It is debatable as to whether FTDS (or at least some) are special purpose foods. Some of the possible arguments include:

FTDS may be special purpose foods because they are:

- Specially formulated.
- Designed to meet the health needs of particular sub-group(s) of the population.
- Designed to deliver nutrients and other substances in a convenient form to those whose dietary requirements are not readily satisfied by a normal diet.

Most FTDS are not special purpose foods in that:

- The purpose is not scientifically defined and the target group not well defined.
- It is not possible to establish scientific dietary requirements on which to determine minimum levels.
- Many substances, or the levels at which they are present, are not well supported in respect of efficacy.
- The intent of many FTDS is, arguably, 'medicinal' in nature and therefore, should remain within the domain of therapeutic products (rather than foods, including special foods).

ANZFA invites submitters' views on FTDS as 'special purpose' foods.

2.4.3 Formulated caffeinated beverages

The standard regulating formulated caffeinated beverages (FCBs) (*viz* Standard 2.6.4[7], a general commodity standard) is an anomaly to the above (refer Section 2.4.1) insofar as it permits the addition of nutritive substances outside the current nutritional paradigm that underpins other general purpose foods. The permissions were developed within the context of harmonisation (i.e. to address issues round inequality in trade) and, in so doing, recognised a purported 'purpose' beyond the traditional view of nutrition and dietary need. The approach taken was to apply a risk-based approach through compositional safety assessments and the use of labelling provisions as a risk-management tool.

[7] Standard 2.6.4 arose from the recently completed Application A394 – refer to the ANZFA website for further detail – www.anzfa.gov.au or www.anzfa.govt.nz.

Application to FTDS

At the time of the development of Standard 2.6.4 the underpinning principles were not clearly articulated, deferring instead to this review (i.e. P235) and noting that further attention would be given to these issues within this context. FCBs and FTDS have in common their manufacture to the NZDSR, and that they purport to fulfil a purpose beyond general nutrition.

Initial assessment
The progression of P235 and associated development of regulatory principles that underpin any food regulatory measures arising from this assessment, may have consequential implications for the regulatory management of FCBs, if relevant commonalities are identified.

QUESTIONS RELATING TO 'PURPOSE' OF PRODUCT:

- If FTDS, as they are currently on the market, are to be regulated by the *Food Standards Code*, do you consider that the relevant permission should be made applicable to all foods (i.e. be 'horizontal' permissions) or do you think FTDS should be kept separate (i.e. 'quarantined') from the general purpose and/or special purpose foods (refer Section 2.4.2 above)?

- On the basis of a 2-category food/therapeutic products system, what are the distinguishing characteristics that should be taken into account in order to clearly distinguish between foods and medicines (such as complementary medicines or TTDS)?

2.4.4 Novel foods

The Novel Foods Standard (Standard 1.5.1 of Volume 2) was gazetted on 16 December 1999 and came into effect on 16 June 2001 following an 18-month implementation period. Under Standard 1.5.1, a novel food is prohibited from being sold by way of retail sale as food, or for use as a food ingredient, unless it is listed in the Table to clause 2 of the Standard, and complies with any special conditions specified in that Table. ANZFA is required to assess the safety for human consumption of each novel food prior to its inclusion in the Table to clause 2 of Standard 1.5.1.

In the context of Standard 1.5.1, the following definition is used:

> ***novel food*** *means a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account -*
>
> *a) the composition or structure of the product;*
> *b) levels of undesirable substances in the product;*
> *c) known potential for adverse effects in humans;*
> *d) traditional preparation and cooking methods; or*
> e) *patterns and levels of consumption of the product;*

where a non-traditional food is defined as:

a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.

Traditional foods of a particular community may be considered novel if they are made available to a new or wider community without adequate information regarding applicable presentation and use. Novel foods can take on many forms and not all are natural substances. There is an increase in the number and variety of novel foods on the market as a result of technological developments, trade opportunities, scientific advances and increasing ethnic diversity of the population.

Some examples of novel foods assessed or being assessed under Standard 1.5.1 that illustrate the broad scope of the novel foods standard include phytosterol esters derived from vegetable oils, some DHA-rich marine micro-algae and hemp-based foods.

Similarly, some dietary supplements traditionally used as therapeutic substances are now being presented in food forms or incorporated into other foods. The purpose of the Novel Food Standard is to ensure that non-traditional foods, which may have characteristics that raise safety concerns, will undergo a risk-based assessment before they are offered for retail sale in Australia and/or New Zealand.

Application to FTDS

Whether FTDS, or the substance(s) they contain, are novel foods and novel food ingredients under Standard 1.5.1 will depend on a number of factors including the nature of the substance and how it is being used in foods.

FTDS regularly include a range of ingredients that have a variety of origins, purported physiological roles and/or technological use (for example, colostrum, chitosan, chlorella, hydroxy citric acid (HCA) sourced from *Garcinia cambogia*). Some of these may need to undergo pre-market assessment as novel ingredients as they are not currently addressed by the *Food Standards Code.*

Initial assessment
Substances present in FTDS that are considered to be 'novel' may need to undergo a pre-market safety assessment.

2.4.5 Botanicals and natural toxicants

Standard 1.4.4 – Prohibited and Restricted Plants and Fungi, of Volume 2 regulates the use of certain botanicals (including fungi, herbs and spices) in foods. The Standard consists of two schedules: Schedule 1 provides a list of plants and fungi that are prohibited in foods; and Schedule 2 provides a list of plants and fungi that have restricted use in foods. Those plants and fungi that appear in Schedule 2 are restricted in terms of the natural toxicant/s they contain, which are further regulated in Standard 1.4.1 – Contaminants and Natural Toxicants, Table to clause 4. It should be noted however, the standard is not all inclusive – there will be many botanicals that would not be safe in food but are not included in the schedules.

The Novel Food Standard provides a mechanism that requires ANZFA to consider the safety of all non-traditional foods (defined above in Section 2.4.4), including plants, fungi and their extracts. The absence of a plant or fungi in either Schedule 1 or 2 of this Standard therefore

does not preclude the herb from being considered a novel food and subject to the pre-market approval requirements of Standard 1.5.1 – Novel Foods.

In recent years, there has been an increase in both the number and extent of use of botanicals including medicinal (or 'non-culinary') herbs, in food products. Many of these food products are permitted under the NZDSR and enter Australia under the TTMRA. The majority of these botanicals and/or extracts have never been assessed for safety as food ingredients, although they may have permission for use in complementary medicines. Their use in foods is considered to present a greater health risk since risk management options are fewer and the potential for high exposure to a broader segment of the population is greater.

The use of botanicals and their extracts in FTDS raises issues regarding tradition of safe use and the level of community knowledge, and the expectation of a 'benefit' from the product (even in the absence of explicit functional/health claims).

Some of the considerations that are raised are:

- *Botanical as a whole food versus extracts* – the traditional use of the total botanical (comprising primary bioactive ingredients, secondary compounds and other ancillary compounds) compared with a refined extract of isolated constituents. A refined botanical extract may or may not be considered a food, as it is difficult to determine at which point along the continuum of increasing refinement/extraction the 'extract' becomes an 'additive' or 'nutritive substance'. For example; herbal infusions compared with tinctures of biologically active ingredients;

- *Potential adverse effects* – consideration needs to be given to the traditional manner of use by the respective populations and the possibility of adverse effects if used incorrectly or inappropriately; and

- *Quality assurance and characterisation* – botanicals may be grown and harvested in various geographical locations around the world, and processed in different ways with varying degrees of quality assurance. Similarly, different botanical species with the same common name or different parts of the plant (e.g. root, leaf, seed, stem, or bark) may be used. Without the application of good manufacturing practice or similar assurance of product integrity, the final product may potentially result in varying profiles and consequent characteristics and/or greater or lesser degrees of adulteration.

Application to FTDS

Various FTDS contain botanicals, mainly herbs, and/or their extracts many of which have been more commonly found in the medical domain. Some botanicals may contain naturally occurring toxicants that are considered conditionally safe in the therapeutic environment (subject to various risk management strategies such as dosage restrictions or labelling requirements) and are managed within therapeutic products legislation, but are restricted in the general food supply. These substances may have a tradition of use as medicines and be safe when presented and used as such, but may not be safe when presented in foods. For example, there are safety concerns about certain components of passionflower however, when the whole plant is used as a therapeutic substance there are no particular safety concerns. Passionflower has recently been identified in food products and depending on the part used and the degree of extraction, may or may not pose safety concerns.

Botanicals may potentially be in the form of powders, liquids, infusions, or dried foods that are added to traditional foods or developed into new food products. Similarly, many of the botanical substances used in FTDS may currently be used by sub-groups within the community but when presented in a different form and/or consumed by the population more generally issues regarding tradition of safe use and level of community knowledge are raised. An example of this is kava. This product has a history of traditional use for ceremonial purposes by Pacific Islanders however, kava extracts (still portrayed as kava) are now being seen in the general food supply (eg formulated beverages) and in complementary medicines. Recent reports from Europe have identified a number of cases of liver toxicity associated with the consumption of kava in therapeutic dose form. These problems are believed to be associated with either the origins of the plant or the parts or preparations used. The same problems have not been identified with the traditional use of kava.

Initial assessment
Recent experience in the US where there is growing use of herbal substances in foods has raised some safety concerns within the US Food and Drug Administration. This issue is also of particular concern to ANZFA as herbal substances present more extensively in the food supply. A preliminary scoping exercise by ANZFA has identified a variety of products, readily found in supermarkets and health food shops that carry approximately 60 different herbal substances. The relative potential risks posed by these, will be partly dependent on the amount of herbal substance used, the preparation of this substance, the manner of presentation and intended uses of the products.

As identified earlier in Figure 2 (refer Section 2.4.1), these substances may not be able to be presumed safe and therefore, require pre-market safety assessment.

2.4.6 Food additives and processing aids

Food additives are used for a technological purpose (eg flavouring) in the final product and processing aids are used fulfil a technological purpose during the treatment or processing of food (and generally do not appear in the final product).

Applicability to FTDS
Food additives and processing aids that are included in the respective (horizontal) standards in Volume 2 would be applicable to any standard(s) addressing FTDS in Volume 2.

Initial assessment
Pre-market approval would need to be sought for any other additives or processing aids not already included in Standards 1.3.1- Food Additives and 1.3.3- Processing Aids.

QUESTIONS ON ADDED SUBSTANCES:

Generally

- Does the approach to risk-based assessment reflected in Figure 2, Section 2.4.1 adequately address safety concerns around FTDS?
- Are there 'gaps' in Figure 2 such that there are categories of 'added substances' in FTDS that are not captured by the framework and thereby, current standards?

Nutritive substances

- Should the definition of nutritive substance be extended beyond *nutritional purpose* to broader eg 'functional' purposes? If so, how should that purpose be described?
- Are there particular micronutrients that are not permitted, or are restricted under Standard 1.3.2- Vitamins and Minerals, that require further consideration in relation to FTDS?

Food additives

- Are there food additives (i.e. added for a technological purpose) that are not currently permitted in Standard 1.3.1 – Food Additives, that may need to be considered for FTDS?

Botanicals

- Are there particular botanicals that are not prohibited or restricted under Standard 1.4.4- Prohibited and restricted Plants and Fungi that require further consideration in relation to FTDS?

Single and mixed foods

- Should permissions for FTDS include single-ingredient foods (eg barley/wheat grass powders; conjugated linoleic acid; creatine)? Please explain your answer.
- Should FTDS be generally permitted to be 'a mixture of foods' i.e. are there particular foods that should be specifically excluded from mixing with FTDS (eg general purpose foods such as soft drinks, breakfast cereals, biscuits, confectionery)? If so, which foods and why?

Novel foods

- Should permissions for some substances, that may be considered '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?

***If you wish ANZFA to consider any potentially 'novel' substances further within the context of this proposal, sufficient data would need to be provided in order to carry out the appropriate assessments.**

In broad terms, such data would include:

- Substance/food: - source, history of use, known effects;
- Exposure: - current levels of use, current levels in foods, which foods; and
- Safety – know toxicity, clinical (or other) studies, benchmarks.

It would be particularly important to specifically characterise any botanical substances in question in respect of species, alternate names, plant part or any isolated actives.

More specific guidance can be found in the ANZFA guidelines for applications (refer to www.anzfa.gov.au or www.anzfa.govt.nz then foodstandards/novelfoodsappguide.cfm)

2.4.7 Labelling and claims

2.4.7.1 General labelling

Volume 2 contains generic labelling requirements that apply to all foods however, these differ from those relating to FTDS under the NZDSR. A description of the Volume 2 and NZDSR requirements of particular relevance to FTDS is included in Attachment 5. There are a number of differences between these labelling requirements of which those of particular interest are outlined in Table 1 below.

Table 2. Some differences in general labelling requirements for foods (Volume 2) and dietary supplements (NZDSR)

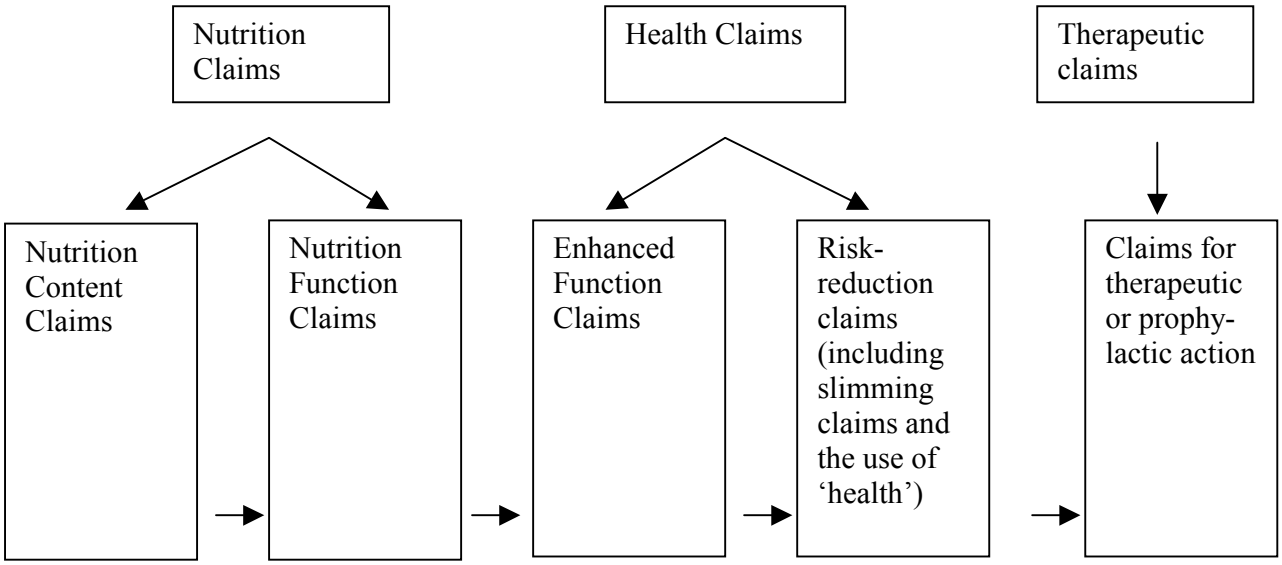
Type of information	Foods	Dietary Supplements
Content	Nutrition information panel (NIP)*	Consumer information panel*
'Percentage labelling'	Characterising ingredient identified as a percentage	Not required
Instructions for use	Serve size specified (as part of the NIP*)	Dosage (amount and frequency) specified
Allergen labelling	Required for cereals containing gluten, crustacea, egg, milk, fish, peanuts, other nuts, sesame seeds, soy beans, sulphites, Royal Jelly and other bee products	Not required (except for Royal Jelly**)
Prescribed name	Not applicable (for FTDS)	'Dietary Supplement'
Genetic modification	Labelling required	No labelling required

* Further information is provided at Attachment 5.
** By virtue of the *New Zealand Food Standard* (1996), Amendment No. 11

2.4.7.2 Specific labelling - Claims

'Claims' are a particularly important type of labelling. The claims that can be made about a product are integral to successful marketing, consumer understanding and appropriate use of the product. There are a number of types of nutrition and health-related claims that relate to food, which can be described in a theoretical continuum (noting that health-related claims, and the criteria underpinning nutrition content claims, are currently under review by ANZFA through Proposals P153 and P234, refer www.anzfa.gov.au or www.anzfa.govt.nz). Such a theoretical continuum is demonstrated below in Figure 3.

Figure 3. Theoretical continuum of nutrition and health related claims.



The following definitions have been proposed (refer Proposal P153) for these categories of claims:

nutrition content claim means a claim in relation to food which describes or indicates the presence or absence of a nutrient, energy content or biologically active substance in that food.

nutrition function claim means a claim in relation to food which describes the physiological role of a nutrient, energy content or biologically active substance in the food, in the growth, development, maintenance and other like functions of the human body.

health claim means a claim that a relationship exists between a food or a constituent of that food and a disease or health related condition and includes a -

(a) enhanced function claim;
(b) reduction of disease risk claim; and
(c) claim that a food is a slimming food or has intrinsic weight-reducing properties;

but excludes a –

(d) nutrition function claim; and
(e) nutrition content claim; and
(f) claim of therapeutic or prophylactic action.

enhanced function claim means a claim about the specific beneficial effects of a food or constituent of a food on the physiological, psychological or biological functions other than the role of the nutrient or biologically active substance in the normal growth, development, maintenance and other like functions of the human body.

reduction of disease risk claim means a claim in relation to food that a relationship exists between the consumption of a food or food constituent and the reduced risk of developing a disease or health related condition.

Nutrition claims
Content claims, such as nutrition content claims, are permitted under the *Food Standards Code* and are also subject to overarching fair trading requirements in that such claims must not be misleading or deceptive. In other words, the product should contain the claimed substance(s) in the amount(s) that it says it does. The majority of nutrition content claims are currently managed by the Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC) in Australia. In New Zealand, similar claims are regulated under the New Zealand Food Regulations 1984 (NZFR). Volume 2 of the *Food Standards Code* also has provisions for some nutrition content claims in Standard 1.2.8. Further detail on the relevant New Zealand and Australian legislation can be found in Attachment 5.

Furthermore, vitamin and mineral claims have specific criteria around them, which are articulated in Standard 1.3.2, Volume 2. One key feature is that a food must contain a certain minimum amount of the claimed substances, in order to be able to make a claim. A 'source' claim (eg *this food contains*…..) can only be made if the reference food contains at least 10% of the RDI Recommended Dietary Intake (RDI) or Estimated Safe and Adequate Daily Dietary Intake (ESADDI) preserve, and a 'good source' claim (eg *this food is rich / high/ etc in*….) if the reference food contains at least 25% of the RDI or ESADDI per serve. However, in the case of some nutritive substances found in FTDS (such as non-nutritive bioactive substances eg phytoestrogens, and botanical substances), such reference values do not exist. This poses a critical question to the effect of – how should such criteria be set, if content claims are to be underpinned by surety of presence of 'meaningful' amounts?

The criteria underpinning nutrition content claims are currently under review as Proposal P234, for which further information is available from the ANZFA website (www.anzfa.gov.au or www.anzfa.govt.nz).

Health claims
Health claims are currently prohibited in relation to foods in Australia and New Zealand (refer Standard 1.1.3, Volume 2). Further detail on the relevant New Zealand legislation is at Attachment 5.

Should such claims be permitted in the future, rigorous substantiation should ensure that efficacy is taken into account insofar as it relates to the claims being made. In these cases, it would establish parameters for the concentration(s) of the nutritive substance(s) in the food and for the scientific validation of the claim against these parameters. It could be anticipated that such parameters will be more difficult to determine for less traditional bioactive substances.

Contextual statement
If health claims on foods were to 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*, (as it is the total diet that confers the overall impact on health) would such a statement also be appropriate for FTDS? Or, should FTDS not be so identified? Such a stance would be on the basis that FTDS are seen as being 'complementary' to the normal diet, rather than an integral (or substitutional, as is the case for some special purpose foods) part of it.

Alternatively it could be considered, on the basis that health claims are intended to support foods that constitute part of a normal diet, that FTDS should be prohibited from carrying health claims at all.

Codex Alimentarius

Codex generally prohibits claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition (i.e. health-type claims) unless they are either in accordance with the provisions of Codex standards or guidelines for foods under jurisdiction of the Committee on Foods for Special Dietary Uses and follow the principles set forth in these guidelines or they are permitted under the laws of the country in which the food is distributed.

It is noted that the Codex Committee on Food Labelling (CCFL) is currently reviewing the matter of health claims and considering allowing health claims within certain parameters. However, the considerations are only at Step 3 of the process and it is therefore too early to predict likely outcomes.

Further to the above, and relevant to both health and nutrition claims, the US tabled a document at the 27th meeting of the CCFL raising issues around misleading food labels. This is of concern to Codex because of the potential for adverse effects on both consumers and trade. The US has recently redrafted the original Conference Room Document in preparation for further consideration at the 30th CCFL meeting in May of this year. The following excerpt is the Conclusion from this paper[8].

> Misleading communications often involve statements, symbols, or images that are literally true but lead consumers to make false inferences. The interpretation of misleading claims may be affected by factors such as culture, knowledge and education, and label characteristics. Thus, a label that is misleading to one group or culture may not be misleading to another. Labels can be misleading in different ways: because a material fact has been omitted, because confusing language or symbols are used, because consumers make incorrect inferences to an attribute which is the subject of a claim or other communication, because consumers make incorrect inferences to unmentioned attributes, and because an endorser is improperly used. The psychological mechanisms that explain how consumers are misled by each of these types of misleading communications have been studied extensively in the literature. Misleading representations on the food label can be prevented in different ways—for example, by requiring additional information, by establishing standards, or by prohibiting representations that are judged inherently misleading.

Applicability to FTDS

Labelling in general, and claims in particular, are of considerable relevance to FTDS as, in many cases, they are a significant factor in determining the appropriate regulatory regime, the intent of, and intended market for the product. Furthermore, as this proposal progresses, consideration will need to be given to risk-management options for any identified 'risks' associated with FTDS. Labelling is recognised as an important 'tool' in risk-management. This particular aspect will be discussed further at the next stage of the review (i.e. the development of draft regulatory measures) however, it is timely within this report to consider the direct implications of labelling on FTDS, and to seek submitters' views on possible approaches to effective labelling.

The issue around misleading claims is of particular concern in respect of FTDS as the risks arising from inappropriate use may be considerable. With this in mind, ANZFA will keep a watching brief on the current activities by CCFL in respect of misleading food labels.

[8] CX/FL 02/12 Discussion Paper on Misleading Food Labels.
URL (26 March 2002) http://www.codexalimentarius.net/ccfl30/fl02_01e.htm

Initial assessment
It is most likely that labelling will be an important risk-management tool for FTDS insofar as it can provide information for consumers to guide appropriate use of the associated product. As such, it will be considered further at the next stage of development of this proposal (i.e. the Draft Assessment) wherein, consideration will be given to the risk management options to be associated with any proposed regulatory measures.

QUESTIONS ON LABELLING:

- What labelling statements are considered important for consumers to enable informed choice with respect to FTDS?
- How should underpinning criteria be set for content claims for added nutritive substances where there are no nationally accepted reference values?
- Is the labelling of products with general advisory statements that warn against consumption by vulnerable groups an appropriate risk management strategy for FTDS (eg not recommended for children/pregnant women/etc) ? Should other strategies also be adopted? If so, what other strategies are needed and why?
- Are there other substances, specific to FTDS, for which advisory or warning statements may be required (eg allergens, caffeine)? If so, what are the substances, and why are such statements necessary?
- The nutrition information requirements are set out in Standard 1.2.8 of Volume 2 and are discussed in Attachment 5 to this report. Should FTDS be exempt from the nutrition information requirements of Standard 1.2.8 in Volume 2? If so, why, and what alternative nutritional/content information would be appropriate?
- If health claims are permitted in the future, should this permission extend to FTDS?
- If so, is the contextual statement referring to the *context of the total diet* appropriate?
- Should FTDS regulated as foods be required to carry either a 'prescribed name' (eg *food-type dietary supplement*) or an advisory statement to the effect that *this is a supplementary food*?
- Are instructions regarding 'dosage' (i.e. amount and frequency) appropriate for FTDS?
- Are there are any other general labelling issues that should be considered for FTDS?

2.5 The regulatory problem

The issues described in this chapter raise three potential problems. Common to all problems is a question of the effectiveness of the current regulatory arrangements – comprising Volume 2 of the *Food Standards Code*, the NZDSR, and regulations governing therapeutic products in New Zealand and Australia.

First, is the problem that the current regulatory structure may not be sufficiently clear to adequately address the full range of FTDS products. This product range, with food characteristics and enhanced nutrition, functional, health or therapeutic properties, has grown rapidly in recent years and is expected to continue to grow in future years. Lack of clarity of the regulatory structure presents a risk of inadequate protection of public health and safety.

Second, lack of clarity of the current regulations implies a range of information to consumers that is inconsistent and confusing, and may be insufficient for them to make informed choices.

Third, the current regulations combine with the TTMRA to impact inequitably on industry. In particular, they prevent Australian industry from manufacturing FTDS products for the Australian domestic and export markets. Currently these products are available to Australian consumers, supplied by imports from New Zealand under the TTMRA.

3. REGULATORY OBJECTIVES

This Initial Assessment Report has been prepared to encourage and facilitate public comment on those issues that need to be considered, in order to create a regulatory framework for FTDS that meets ANZFA's objectives when considering the development of food standards. These objectives are outlined in the preliminary information at the beginning of this document (refer page 2). In respect of this Proposal (P235), particular emphasis is placed on public health and safety, provision of information to consumers to enable informed choice, prevention of misleading conduct, the need for risk-based analysis and fair trading of foods between Australia and New Zealand.

3.1 Objectives for a joint regulatory arrangement for *Food-type* Dietary Supplements (FTDS)

The objective for a joint regulatory arrangement for FTDS are to clarify the current regulatory structure – comprising the joint Food Standards Code, NZDSR, and the regulations governing therapeutic products in New Zealand and Australia – such that:

1. the consumption of FTDS products does not entail any risk to public health or safety;
2. the information relating to FTDS products facilitates consumers in making informed choices; and
3. its impact does not discriminate against any sector of industry.

4 REGULATORY OPTIONS

Possible options for the regulation of FTDS are discussed below and outlined schematically in Figure 4. Options 2 and 3 are based on the premises that:

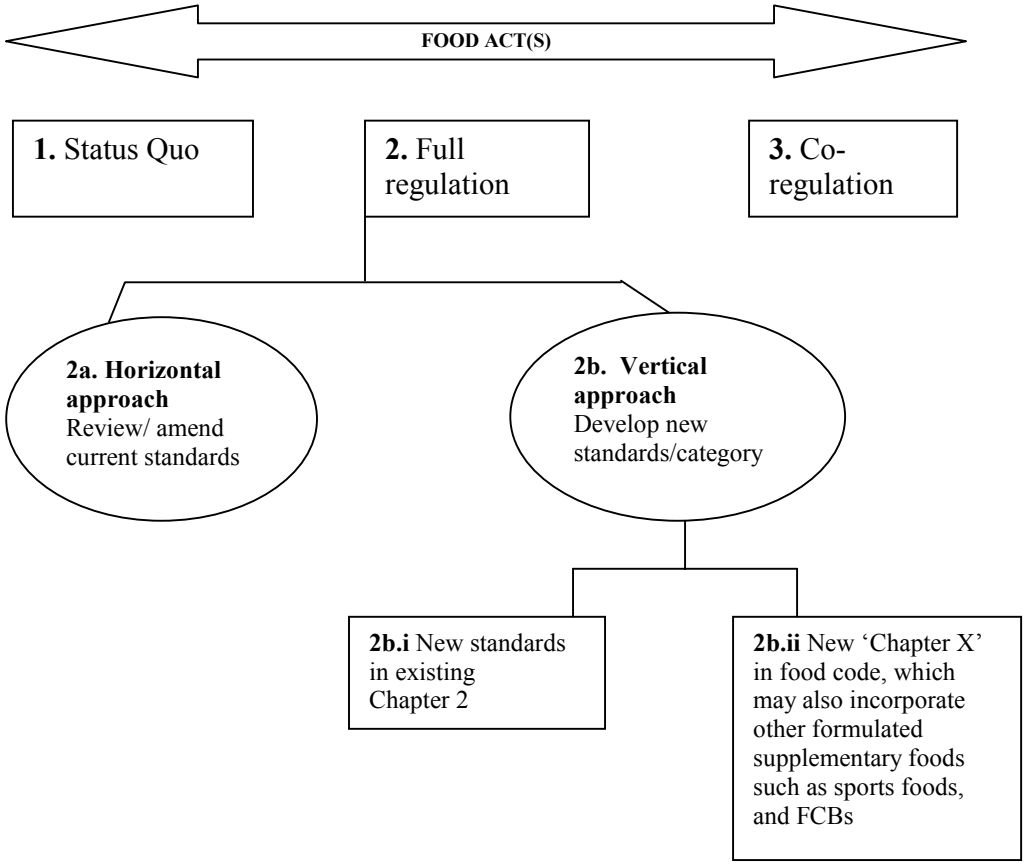
a) the *New Zealand Food Regulations 1984* will be repealed at the end of the transition period (end 2002); and
b) the New Zealand *Dietary Supplement Regulations 1985* will be revoked or amended in due course such that product presented as 'foods' could no longer be manufactured or marketed under these regulations.

Option 1 is based on premise a) only.

It is the view of ANZFA that most interest will reside in options 2 and 3. Both or either of these may require further consideration. In the interests of exploring these options as fully as possible prior to the development of any draft regulatory measures, option 2 is further expanded into options 2a, 2b.i and 2b.ii respectively. Option 3 relies more heavily on input from the community in general and industry in particular.

ANZFA invites comment on the above, and requests that any expressed preferences for option 3 be supported by as much detail as possible in respect of potential management mechanisms.

Figure 4. **Schematic representation of possible regulatory options for food-type dietary supplements.**



Option 1 – Status Quo

Status Quo – No specific standard(s) in Volume 2 to apply in Australia and New Zealand; relevant provisions of NZDSR still apply in New Zealand and TTMRA still applies between Australia and New Zealand.

Description
This regulatory system enables FTDS to be manufactured in or imported into New Zealand (under the NZDSR) and subsequently exported into Australia for sale (under TTMRA). Australian manufacturers and importers are not able to domestically produce or directly import FTDS into Australia other than from New Zealand.

Initial assessment
This option represents the current situation and as such, is not seen to be satisfactory from a regulatory perspective. This situation lends itself to trans-Tasman inequity in respect of ability to manufacture a variety of foods, considerable consumer and public health confusion due to inconsistencies in provisions for like products, and lack of harmonisation between Australia and New Zealand. As such, this option does meet the section 10 objectives identified in the preliminary information (refer page 2).

Option 2 – Full Regulation

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

Description
Under this option the relevant provisions within Volume 2 would be reviewed and amended as appropriate to provide permissions to manufacture FTDS under harmonised food regulation in Australia and New Zealand. This would provide identical, fully regulated provisions in Australia and New Zealand for the labelling and composition of FTDS.

A variety of approaches could be considered within this option. As a preliminary step the sub-options of 2a and 2b have been identified in Figure 4 above.

ANZFA also invites comment from submitters on other possibilities.

Fundamental to these considerations is an initial question as to whether the underpinning principles (and thereby, parameters imposed) of the current standards are valid and should be maintained in relation to the general food supply. These principles and the substances to which they apply have been discussed in more detail above in Section 2. For most of the standards, i.e. those governing labelling requirements, and safety issues such as levels of toxicants and additives, it is most likely that the underpinning principles would remain valid and be appropriately applied to FTDS. However, for Standard 1.3.2 – Vitamins and Minerals and Standard 1.4.4 – Prohibited and Restricted Plants and Fungi the appropriateness of the underpinning principles may be questioned.

If a horizontal approach is to be adopted i.e. that FTDS be accommodated by the generally applicable horizontal standards, the underpinning principles for Standard 1.3.2- Vitamins and Minerals (which represent a conservative approach to vitamin and mineral additions to general purpose foods, as based on Codex Guidelines) would need to be expanded considerably, and there would be no regulatory differentiation between FTDS and the general food supply (i.e. option 2a).

If however, it is viewed that the permissions and any associated risk management strategies (eg specific labelling requirements) for FTDS should maintain separateness from the general food supply, then option 2b would be the preferred approach.

Section 2 – 'Regulatory Framework' provides further detail on the actual standards and likely implications that would need to be considered within the context of options 2a and 2b.

Option 2a is a 'horizontal' approach that is based on the premise that the policy bases of particular standards (such as Standard 1.3.2 and/or Standard 1.4.4) are reviewed and amended/expanded. This approach would have the effect of allowing for the manufacture of many of the FTDS not currently addressed by Volume 2, and opening up the food supply generally to more liberal permissions.

Option 2b is a 'vertical' approach that serves to separate FTDS as discrete products that would be subject to targeted risk-assessment, most likely resulting in specific compositional permissions and labelling requirements.

Within option 2b, further consideration needs to be given to the placement of such 'vertical ' standards. Should there be commodity-specific standards that sit among the general foods or are they better placed as a discrete category (i.e. new Chapter) within the *Food Standards Code*? This also includes consideration as to whether FTDS are special purpose foods, in which case, any relevant standard(s) would be appropriately positioned in Part 2.9. Part of the rationale behind the option for a discrete category is that there are other standards that also address foods that are 'formulated' and supplementary' and therefore, may logically fit alongside FTDS in particular, Formulated Supplementary Sports Foods (FSSF) and FCBs (Formulated Caffeinated Beverages).

Two sub-options are thereby presented:

- **Option 2b.i** - a new vertical (i.e. commodity specific) standard be developed; or

- **Option 2b.ii** - a new 'chapter' in Volume 2 identifies FTDS as a conceptually discrete class of products that have in common a purported intent, potentially characterised by certain compositional characteristics and/or facets of presentation including form, labelling statements etc. It is most likely that these would all be formulated foods (as opposed to naturally occurring) and be of a 'supplemental' nature i.e. intended to supplement a normal mixed diet, rather than address dietary inadequacy. This would represent something like a 'formulated supplementary food' category. If so, such a chapter may include currently standardised products such as FSSF and FCBs.

Initial assessment
The option of full regulation is the one most likely to satisfy ANZFA's key objectives, particularly in relation to protection of public health and safety, provision for informed choice and harmonisation of trans-Tasman food regulation. As this option represents a more prescriptive approach than options 1 and 3, it could only be adopted if taken to be the minimum level of effective regulation (i.e. to meet the section 10 objectives).

Option 3 – Co-Regulation

As for Option 2 except that full regulation in Volume 2 is replaced by co-regulation with partial provisions in Volume 2 and (an) industry Code(s) of Practice, and cessation of provision for production or importation of FTDS under the NZDSR.

Description
Under this option, Volume 2 would be amended to provide for some permissions whilst other aspects would be managed through a voluntary code of practice (or possibly more than one code eg one or more in each country). Enforcement responsibilities regarding the code(s) of practice would be through multi-sectoral (including government) management in New Zealand and Australia.

Initial assessment
A number of horizontal and vertical permissions in Volume 2 already apply to some FTDS for example, there is a vertical standard applying to FCBs, and horizontal standards applying to some aspects of labelling (eg warning and advisory statements), and composition (eg prohibited and restricted plants and fungi). This means that in practice, consideration would need to be given to appropriate remaining aspects for management through a code of practice.

Some such aspects may address certain compositional matters (eg fortification beyond current permissions), and certain labelling aspects (eg nutrition claims). However, this latter area is currently also being reviewed (refer Proposal P234 via www.anzfa.gov.au or www.anzfa.govt.nz) and whether such claims remain within the province of a code of practice remains to be seen. It should also be noted that the powers under the *ANZFA Act* are limited in relation to enforceability and applicable sanctions on codes of practice.

5 IMPACT ANALYSIS

The assessment of any regulatory options needs to take into account the likely effects on the community. In order to do this the key sub-groups are identified and a systematic approach to the relative costs and benefits applied. Given below are the sub-groups that ANZFA has identified as being those most likely to be affected in differing ways by the above regulatory options.

5.1 Affected Parties

1. Those sectors of the **food industry** including New Zealand and Australian manufacturers, exporters to Australia and New Zealand including multi-national manufacturers, and New Zealand and Australian importers and exporters wishing to manufacture and/or market the foods (or related products eg ingredients, packaging) that are the subject of the proposal. Furthermore, there may be different implications for medium to small businesses, as opposed to larger multi-national companies.

2. **Consumers and the community** including specific sub-groups in the population (eg the elderly and children and public health practitioners) who will either benefit as a result of a new range of products becoming available or be subject to higher costs and/or other negative impacts; and

3. **Government** – of New Zealand, the States and Territories and the Commonwealth of Australia. In particular enforcement agencies, departments/agencies of health and trade.

5.2 Impact Analysis

In order to determine the most cost-effective and least prescriptive regulatory option for the on-going management of FTDS, it is necessary to consider the potential impact of each of the regulatory options described above, as reflected in the attributable costs and benefits to various stakeholder groups.

It should be noted that any impacts will also depend largely on the outcomes of the New Zealand MOH's deliberations as to how best to regulate products currently regulated under the NZDSR that would be regarded in Australia as foods, and how any regulatory measures developed by ANZFA and adopted by the Australia New Zealand Food Standards Council will be implemented in New Zealand.

Consumers and the community
Consumers of FTDS are primarily concerned with product safety and the provision of accurate and adequate information for informed choice when purchasing products. The development of standards specifically for FTDS will ensure safety and enable provisions for specific and appropriate labelling.

It will be important that any standards within Volume 2 (which would then be applicable to New Zealand) are implemented in an environment where sale of foods under the NZDSR is no longer possible otherwise, considerable confusion may arise due to different compositional and labelling requirements for similar products - depending on which country, and under which regulations the products have been manufactured.

It is anticipated that any changes to the regulatory management of FTDS will also impact on health professionals as consumption of FTDS may have an impact on overall nutrient and botanical intake and may in turn affect health outcomes.

Industry
There are a variety of potential impacts from the regulatory options. These are based around costs, product development and innovation opportunities, and equity of trade between Australia, New Zealand and the wider international market. For example, Australia is currently disadvantaged with respect to exporting to markets such as south-east Asia, because of the inability to establish a domestic market base.

Estimated value of the market
According to information received from industry members in New Zealand, the total domestic dietary supplement market in New Zealand was valued (as of 2001) at $NZ 285 million (retail sales) of which approximately $NZ 140 million was considered attributable to FTDS (predominantly represented by beverages). The growth over the next 12 months was anticipated to be in the vicinity of 15%, and 10% over the longer term of 5 yrs. The FTDS export market to Australia was estimated at $NZ 200 million with anticipated growth rates corresponding to the general market above.

The development of any new provisions enabling direct manufacture or importation of FTDS into Australia will undoubtedly have the effect of decreasing revenue and opportunities for New Zealand industry whilst providing new opportunities and benefits to Australian manufacturers/importers. The recent introduction of Standard 2.6.4 (Formulated Caffeinated Beverages) now caters for an estimated 60% of the FTDS market discussed above. The non-beverage FTDS market, although not large by comparison, may not be clearly reflected in the above data.

Government
The major impacts on government agencies relate to issues around harmonisation and consistency in food regulations, and implications for enforcement.

5.2.1 Data Collection

In the interest of assessing the impact of each of the above options (or any others that may be raised) ANZFA needs to determine how each of the stakeholder groups may be affected and what the likely costs and benefits will be. As part of this process ANZFA seeks input from stakeholders with regard to current information, quantitative where possible, that identifies the relevant costs and benefits.

The type of information sought includes the segment(s) of industry concerned – such as:

- the value of production per annum, value of regional production and value of export/import;

- if possible the impact of the application on that sector i.e. affect 5% of production or market share or 100%; and

- the costs and benefits of each option, as it impacts on each group of affected parties where the sum of impacts on each group gives the overall net-benefit of each option to the people of Australia and New Zealand.

The information should include direct and indirect effects, and tangible and intangible factors ensuring the time periods suit the problem and that the analysis contrasts short-term with long-term impacts.

QUESTIONS ON REGULATORY OPTIONS:

- What do you see as the potential costs and/or benefits of these options?
- For example, you may like to consider:
  - the costs and/or benefits for consumers in relation to accurate and meaningful information, the potential for consumers being mislead as to the purpose or function of a product;
  - the costs and/or benefits in relation to public health outcomes or health practices;
  - the costs and/or benefits for government in relation to administration, enforcement, public health and safety, harmonisation (or lack of) between New Zealand and Australia;
  - the costs and/or benefits for industry including compliance, reporting, innovation, equitable marketing opportunities and trade (fair trading); and
  - any effects on international trade, import/exports.

Please provide quantitative data, where possible, to support your response.

- Which is your preferred regulatory option for regulating food-type dietary supplements and why ?

In relation to industry as a whole, if a regulatory system other than full regulation was proposed:

- To what extent would the industry members be prepared to come together and be involved in enforcement and monitoring of, for example, a code of practice?
  - What level of resources (funding and human resources) for managing compliance could the industry sustain?
  - What level of resources for monitoring and reporting arrangements could the industry sustain?

6 CONSULTATION

ANZFA is committed to actively engaging stakeholders in the review and development of food standards. Towards this end, the following consultation processes have been/will be undertaken.

6.1 External Advisory Groups

In June 2001, ANZFA held external advisory group (EAG) meetings in Wellington and Sydney to discuss issues relating to the specifics of the regulatory requirements for FTDS. Representatives from consumer bodies, public health, government and industry attended. Most delegates indicated their interest in participating in future meetings of the EAG as P235 is progressed. The purpose of EAG will be to provide advice to ANZFA on issues of relevance to stakeholders raised by the review of FTDS in Australia and New Zealand. This will include consideration of:

- regulatory principles underpinning development of future standards;
- implications for public health and safety;
- issues of interest and concern to consumers;
- impacts on manufacturers, distributors, importers and retailers;
- implications for enforcement; and
- issues relating to harmonisation between New Zealand and Australia.

6.2 Invitation for Public Submissions

This report has raised a number of questions throughout. These are intended to guide comment but should by no means be seen to pre-empt or restrict any views. The questions as posed relate to specific topics and can be found in boxes in the relevant sections – as identified below.

- Underlying principles – refer Section 2.4.1 – 2.4.2

- Regulation of components of FTDS - refer sections 2.4.1, 2.4.4 – 2.4.6

- Labelling of FTDS– refer Section 2.4.7 and Attachment 5

- Regulatory options - refer Section 4

ANZFA would like to thank readers for their consideration of the questions raised in this paper, and emphasises that submitters' comments will be taken into account in the development of any regulatory measures arising from this review. Furthermore, please note that comments on relevant subject matter not identified by this report are also welcome**.**

Please provide reasoning for your answers and supporting data where possible.

If considered necessary, general stakeholder forums and/or targeted consultations will be conducted in both Australia and New Zealand before the preparation of the next stage of P235, i.e. the proposed draft food regulatory measures (released for public consideration in the P235 Draft Assessment Report).

6.3 International and World Trade Organization

Australia and New Zealand are members of the World Trade Organization (WTO) and are bound as parties to WTO agreements. In Australia, an agreement developed by Coalition of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory.

Under the Treaty between the Governments of Australia and New Zealand on joint Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

7 CONCLUSION

This Report discusses regulatory considerations and related issues in respect of FTDS. ANZFA seeks comment on these matters from all sectors of the community including consumers, health professionals, industry and governments. Submissions to this Initial Assessment will be used to further develop P235, including the preparation of draft regulatory measures, which will be circulated for public consideration within the context of the Draft Assessment Report for P235.

ATTACHMENTS

Attachment 1	Definitions for dietary supplements; nutraceuticals; functional foods
Attachment 2	New Zealand *Dietary Supplement Regulations 1985*
Attachment 3	Outline of regulatory framework for foods and medicines – Australia and New Zealand
Attachment 4	International approaches to regulation of functional/dietary supplement type foods
Attachment 5	A comparison of labelling requirements – Australia and New Zealand
Attachment 6	Glossary of acronyms

ATTACHMENT 1

DEFINITIONS FOR DIETARY SUPPLEMENTS, NUTRACEUTICALS, FUNCTIONAL FOODS AND PHARMACO FOODS FROM DIFFERENT SOURCES.

1. The following definitions of dietary supplements, nutraceuticals and functional foods were acquired from J. Williams (2001) in her report for the dietetic practicum required for the completion of the Post Graduate Diploma in Dietetics, University of Otago.

Definition of Functional Food	Source **(citation)**
'Functional foods are those foods which provide specific nutritional, dietary, or metabolic benefits, and also potentially play a role in disease prevention, the mitigation of disease, the control of disease, over and above the traditional nutritional sustenance provided by the wide range of foods'.	Goodman Fielder Ltd. **(Citation not identified)**
'Functional foods are similar in appearance to conventional foods and are intended to be consumed as part of a usual diet, but have been modified to subserve physiological roles beyond the provision of simple nutrient requirements'.	National Food Authority/ Australia New Zealand Food Authority **(Preston et al., 1996)**
'Any food that has had a positive impact on an individuals health, physical performance or state of mind in addition to its nutritive values'.	Goldburg 1994 **(Heasman and Mellentin, 2001)**
'A food is said to be functional if it contains a food component (whether nutrient or not) which affect one or more targeted functions in the body in a positive way that is relevant to either the state of well-being and health or the reduction of the risk of a disease'.	Bellisle et al. 1998 **(Heasman and Mellentin, 2001)**
'A food can be said to be functional if contains a component (which may or may not be a nutrient) that affects one or a limited number of functions in the body in a targeted way so as to have positive effects on health' or 'if it has a physiologic or psychologic effect beyond the traditional nutrient effect'.	Roberfroid **(Roberfroid, 2000)** Clydesdale **(Clydesdale, 1997)**
'A food can be regarded as functional if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body beyond adequate nutritional effects in a way which is relevant either to the state of well-being and health or the reduction of the risk of a disease.'	European Consensus Document **(Diplock et al., 1999)**
'Any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients the food contains'.	The United States Institute of Medicine, National Academy of Sciences **(ADA Position paper, 1999)**
'Any modified food or food ingredient that may provide a health	Food and Nutrition Board,

benefit beyond the traditional nutrients the food contains'.	National Academy of Sciences **(Milner, 2000)**
'Functional foods are ones in which concentrations of one or more ingredients have been manipulated to enhance their contributions to a healthful diet'.	The International Food Information Council **(ADA Position paper, 1999)**
'Foods that provide health benefits beyond basic nutrition'.	The Japanese Ministry of Health and Welfare **(Pascal G, 1996)**
'Food to which some ingredients to help get into shape are added; from which allergens are removed; [for which] the result of such addition or removal is scientifically evaluated; and to which the Ministry of Health and Welfare has given permission to indicate the nature of effectiveness to the health'.	The International Life Science Institute of North America **(ADA Position paper, 1999)**
'Functional foods can be defined as those providing health benefits beyond basic nutrition and include whole, fortified, enriched or enhanced foods which have a potentially beneficial effect on health when consumed as part of a varied diet on a regular basis at effective levels'.	**Hasler, 2000**

Definition of Dietary Supplement	Source
'Any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly, or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the dietary intake of those substances normally derived from food'.	**The New Zealand Dietary Supplement Regulations (1985**)
'A product other than tobacco intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) a herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).'	The Food, Drug and Cosmetic Act (FFDCA) **(Marriott, 2000)**
'A product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. A dietary supplement: is intended for ingestion in pill, capsule, tablet, or liquid form, is not represented for use as a conventional food or as a sole item of a meal or diet, is labelled as a 'dietary supplement, includes products such as an approved new drug, antibiotic, or licensed biologic that was marketed as a dietary supplement before approval certification or licence'.	**The Dietary Supplement Health and Education Act (1994)**
'Any substance that is consumed in addition to the regular diet; that is in addition to meals, snacks, and beverages and follows the methods of delivery clauses outlined in the Act. This definition divides supplements into three categories: nutrient supplement ingredients, botanical (plant derived) supplemented ingredients, and other dietary substances.'	The United States National Institute of Health Office of Dietary Supplements **(Marriott, 2000)**

Definition of Nutraceutical	Source
'Naturally derived bioactive compounds that are found in foods, dietary supplements and herbal products, and have health promoting, disease preventing, or medicinal properties'.	Nutraceuticals Institute **(Heasman and Mellentin, 2001)**
'The bioactive ingredient that can deliver a health benefit and which can be used in a capsule, pill, powder or foods or beverages'.	The Functional Food Revolution **(Heasman and Mellentin, 2001)**
'Any substance that may be considered a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease.'	The United States National Institute of Health Office of Dietary Supplements and The Foundation for Innovation in Medicine **(Heasman and Mellentin, 2001)**
'Any substance that may be considered a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease.'	**DeFelice, 1993**

2. The report of the [New Zealand] Royal Commission on Genetic Modification (2001) identified three categories of products: dietary supplements, functional foods and pharmaco foods. These were differentiated as:

Dietary supplements are products containing extracts, concentrates or synthetic versions of food substances;

Functional foods are products with enhanced nutritional value and include foods that have been genetically modified to enhance their nutritional value, including nutraceuticals.

Pharmaco foods are a category of products that are developed to be delivery devices for the provision of specific medicines (or vaccines) for human consumption. Historically medicines have been delivered by several different means, including pills, capsules, liquids and injections. An example of a potential product is the fruit that incorporates a Hepatitis B vaccine. The differentiation of these products from foods (particularly food-type dietary supplements) needs to be considered, however the responsibility of their regulation will most probably reside with therapeutic agencies.

3. Two more recent definitions from international sources include:

Nutraceutical – *bioactive [chemical] compounds that have health benefits* **(Lachance, 2002)**; and

Functional foods – *those foods that contain increased levels of nutrients and other beneficial ingredients for specific health effects beyond those to be gained from the nutrient normally contained* **(URL just-food.com, 2002)**.

REFERENCES (to Attachment 1 only)

Clydesdale FM. A proposal for the establishment of scientific criteria for health claims for functional foods. Nutrition Reviews 1997;55(12):413-22

De Felice SL. A comparison of the US, European, and Japanese nutraceutical health and medical claim rules. Regul Affairs 1993; 163-8.

Dietary Supplement Health and Education Act of 1994. http://vm.cfsan.fda.gov/~dms/dietsupp.html

Diplock AT, Aggott PJ, Ashwell M, et al. Scientific concepts of functional foods in Europe: consensus document. Br J Nutr 1999;81(S):1-27.

Hasler CM. The changing face of functional foods. J Am College Nutr 2000;19(S):499-506.

Head RJ, Record IR, King RA. Functional foods: approaches to definition and substantiation. Nutr Rev 1996;54(11):17-20.

Heasman MP, Mellentin J. The Functional Foods Revolution: Healthy People Healthy Profits? London. Earthscan. 2001.

Lachance, P.A. (2002) Food Technology 56 (1) cited in the Functional Foodnet (FFNET) January 30 2002. URL (March 2002): www.ift.org/publications/docshop/ft_shop/01-02/01_02_pdfs/01-02-nutraceuticals.pdf

Marriott BM. Functional foods: an ecologic perspective. Am J Clin Nutr 2000;71(S):1782-34.

Milner JA. Functional foods: the US perspective. Am J Clin Nutr 2000;71(S):1654-9.

Pascal G. Functional foods: the future: how to regulate these foods. Nutr Rev 1996;54(11):199-201.

Position of the American Dietetic Association: Functional foods. J Am Diet Assoc 1999;99(10):1278-85.

Preston C, Lawrence M. Regulatory and legal aspects of functional foods: the Australian perspective. Nutr Rev 1996;54(11):156-61.

Roberfroid MB. Concepts and strategy of functional food science: the European perspective. Am J Clin Nutr 2000;71(S):1660-4.

The Dietary Supplements Regulations 1985. Wellington, New Zealand. 1985.

URL (March 2002): http://just-food.com/news_detail.asp?art=48051&dm=yes

ATTACHMENT 2

1985/208

NEW ZEALAND DIETARY SUPPLEMENTS REGULATIONS (1985)

DAVID BEATTIE, Governor-General

ORDER IN COUNCIL

At the Government Buildings at Wellington this 19th day
of August 1985

Present:

THE HON. G.W.R PALMER PRESIDING IN COUNCIL

PURSUANT to Section 42 of the Food Act 1981, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

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ANALYSIS

REGULATIONS

1. **Title and commencement**- (1) These regulations may be cited as the Dietary Supplements Regulations 1985.

(2) This regulation, regulation 2, and regulations 4 to 11 of these regulations shall come into force on the 1st day of September 1987.

(3) Except as provided in subclause (2) of this regulation, these regulations shall come into force on the 1st day of September 1985.

2. **Interpretation**-(1) In these regulations, unless the context otherwise requires,-

'Batch' means a quantity of dietary supplement produced under essentially the same conditions during a particular period, and usually from a particular 'line' or other identifiable processing unit:

'Common name', in relation to a dietary supplement, means the name by which the dietary supplement is generally known, being a noun defined in a dictionary of the English language of authority and repute in New Zealand to mean that kind of dietary supplement; and also means any expression containing such a noun: 'Container' means any box, packet, or other receptacle in which 1 or more packages of dietary supplements are, or are to be , enclosed:

'Dietary supplement' means any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food:

'Foodstuff' means-

(a) Any food for which a standard is prescribed in any of the provisions of Part II of the Food Regulations 1984, except regulations 47, 51, 52, 54, 55, 73, 76, 196, to 200, and 202 to 204, whether or not the food is permitted by the relevant standard to contain a food additive:

(b) Any other food that does not contain a food additive other than an incidental constituent:

'Incidental constituent' means any extraneous substance, toxic substance, or pesticide that is contained or present in or on any food; but does not include any preservative, antioxidant, colouring substance, artificial sweetener, flavouring substance, food conditioner, anticaking agent, gaseous packing agent, propellant, or vitamin, or any mineral:

'Ingredient' means any substance, including a food additive (other than an incidental constituent), that is-

(a) Used in the manufacture or preparation of a dietary supplement; and

(b) Present, whether in a modified form or not, in the final product:

'Principal display panel' means the part of a label that is most likely to be displayed, presented, shown, or examined, under ordinary or customary conditions of display for retail sale; and, if such likelihood is equal in respect of 2 or more panels, means every such panel:

'Printed' includes written, typewritten, engraved, lithographed, or otherwise traced or copied.

(2) In these regulations, the symbols specified in the first column of the table to this subclause shall have the meanings specified in relation to those symbols in the second column of the table.

TABLE TO SUBCLAUSE (2)

Symbol	Meaning
g	grams
mcg	micrograms
mg	milligrams
mm	millimetres
ppm	parts per million

(3) In these regulations, unless the context otherwise requires, all references to proportions (whether percentages, parts per million, or otherwise) shall be references to proportions by weight in a dietary supplement as sold.
(4) Nothing in these regulations shall prohibit the use of any symbol the style of which conforms with a specimen in the table to subclause (2) of this regulation, or with the conventional usage of metric measurements.

PART 1
GENERAL REQUIREMENTS

3. **Maximum daily doses**-(1) Every dietary supplement described as or containing minerals or vitamins specified in the first column of the table to this subclause shall be so manufactured that each daily dose (for an adult) does not contain more than the maximum specified in the second column of the table.

TABLE TO SUBCLAUSE (1)

Dietary Supplement	Maximum Daily Dose (For Adult)
Minerals:	
Copper	5 mg
Iron	24 mg
Selenium	150 mcg
Zinc	15 mg
Vitamins:	
Vitamin A or retinol	3000 mcg
Niacin (and salts) or nicotinic acid (and salts)	100 mg
Vitamin B12 or cyanocobalamin or hydroxocobalamin	50 mcg
Vitamin D	25 mcg
Folic acid	300 mcg

(2) Every dietary supplement described as or containing any mineral, other than a mineral specified in regulation 19 (1) of these regulations, shall be so manufactured that each daily dose (for and adult) does not contain more than the maximum specified in the current edition of *Recommended Dietary Allowances*, published by the Food and Nutrition Board of the National Academy of Science and National Research Council, Washington D.C., U.S.A.

4. **Dietary supplements not to be sold unless properly labelled**-No person shall sell any package or container containing any dietary supplement, or any dietary supplement contained in a package or container, if the package or container-

(a) Does not bear a label containing all the particulars required by these regulations to be contained on a label relating to such package or container; or
(b) Bears a label containing anything that is prohibited by these regulations from appearing on a label relating to such package or container; or
(c) Bears a label containing any particulars that are not in the position, manner, and style required by these regulations in respect of a label relating to such package or container.

5. **General requirements for labelling of dietary supplements**-
(1) Every package and container containing a dietary supplement shall, unless otherwise provided in these regulations, bear a label that includes the following:
(a) The common name of the dietary supplement, or a description (other than the brand name of the dietary supplement) sufficient to indicate the true nature of the dietary supplement, or a description of the dietary supplement including the common names of its principal ingredients:
(b) A statement of the net weight or Volume or number of the contents of the package or container, whichever measure is appropriate for retail sale of the dietary supplement concerned:
(c) The trading name and business address of the manufacturer or seller or packer of the dietary supplement, or of the owner of the rights of manufacture, or of the principal or the agent of any of them:
(d) A consumer information panel that complies with regulation 9 of these regulations:
(e) The words 'DIETARY SUPPLEMENT':
(f) A batch number:
(g) A date mark, being an expression in one of the following forms:
i) Use by (followed by a date); or
ii) Not to be consumed after (followed by a date); or
iii) Words of similar meaning (followed by a date);- the relevant date in any case being no later than 5 years after the date of manufacture:
(h) A statement of the recommended daily dosage (for an adult) both as to quantity and frequency, which shall not exceed the maximum daily dose permitted by regulation 3 of these regulations, and, if the dietary supplement is suitable for children, the recommended daily dose for children:
(i) A warning in any case where a danger exists if an overdose is taken:
(j) The method of preparation before use (where necessary).
(2) Notwithstanding paragraphs (f) and (g) of subclause (1) of this regulation, no container containing a dietary supplement need be labelled with the batch number or with a date mark.
(3) Notwithstanding subclause (1) of this regulation, where dietary supplements are packed in blister or strip packaging, the packaging shall be labelled with-
(a) The common name; and
(b) A batch number.

(4) For the purposes of subclause (1)(c) of this regulation,-
(a) A postal address, not being a telegraphic or code address or an address at a Post Office, shall be given:
(b) The name and address of a person who is not ordinarily resident in New Zealand shall not be sufficient unless the dietary supplement is wholly manufactured and packed outside New Zealand:

(c) In the case where that trading name is of a body corporate (whether registered inside or outside New Zealand), either the name of the town in which the body corporate has its registered office or the full postal address of the premises where the dietary supplement is actually manufactured or packed by the body corporate shall be given as the address.

(5) Where a package or container of a dietary supplement is enclosed or wrapped in a transparent covering and the particulars with which that package or container is required to be labelled are clearly visible through that covering, that covering shall be exempt from the labelling requirements under these regulations.

(6) No person who has in that person's possession any package or container of a dietary supplement intended for sale by retail shall-

(a) Remove any label required by these regulations to be on the package or container;

(b) Alter, erase, obliterate, or obscure any word or statement borne on such a label in accordance with any of the requirements of these regulations.

6. **Form and manner of labelling**-(1) Every word or statement that is required by these regulations to be borne on a label shall-
   (a) Be conspicuously printed and, for each statement separately required, be in uniform colour contrasting strongly with a uniform background; and
   (b) Be clearly, legibly, and durably marked either on the material of the package or container or on material firmly and securely attached to the package or container; and
   (c) Be presented with continuity.

(2) The lettering of every word or statement required by these regulations shall be clear, distinct, and legible with no decoration, embellishment, or distortion that could interfere with the legibility of the words.

7. **Size of letters**- (1) The lettering of every word or statement required by these regulations to appear on labels shall be-
   (a) All capital letters; or
   (b) All lower case letters; or
   (c) Lower case letters with an initial capital letter.

(2) In every case to which paragraph (a) or paragraph (b) of subclause (1) of this regulation applies, the height of the lettering shall be uniform in every word or statement that is separately required.

(3) In every case to which paragraph © of subclause (1) of this regulation applies, the height of the lower case lettering shall be uniform in every word or statement that is separately required.

(4) Except as otherwise provided in these regulations, the lettering of any word or statement required by these regulations to appear on labels shall be not less than 1.5 mm in height, except where the package or container to be labelled is so small as to prevent the use of letters of that height, in which case letters of not less than 0.75 mm in height may be used.

(5) The height of the lettering for the common name or description that is required by these regulations to appear in the principal display panel of a label shall be not less than one-third of the height of the largest lettering appearing in that panel, and-

(a) Not less than one-twentieth of the height of the label, in the case of a label that is no longer than twice the width of the label; and

(b) Not less than one-thirtieth of the height of the label, in any other case.

(6) For the purposes of subclause (5) of this regulation, the height of a label is the distance between the top and bottom of all printed or pictorial information on the label.

8. **Principal display panel**-(1) The particulars that are required by paragraph (a) and paragraph (b) and paragraph (e) of regulation 5 (1) of these regulations to appear on a label shall appear in the principal display panel.

(2) Every word or statement that is required by these regulations to appear in the principal display panel of a label shall be in the lines that are generally parallel to the base on which the package or container rests as it is designed to be displayed.

(3) In the case of a cylindrical package or container, the width of the principal display panel on the cylindrical surface shall not exceed one-third of the circumference of the package or container.

9. **Consumer information panel**- (1) The following information, when required by these regulations to be on the label, shall be grouped together in one portion of the label (that portion being called the consumer information panel):

(a) The statement of ingredients, which shall show-

(i) The quantities or proportions of the claimed active ingredients in the package or container or in each dosage unit, or, where the dietary supplement is divided into a number of units, the quantity or proportion of the claimed active ingredients in each unit; and

(ii) The inactive ingredients in the package or container, which shall be described either by their specific names or by their class names, being any of the following permitted class names:

Antioxidants
Artificial sweeteners:
Colouring or colour:
Encapsulating or flavour:
Minerals:
Preservatives:
Tabletting aids:
Vitamins:

(b) The storage instructions (where appropriate).

(2) The consumer information panel may be any part of the label, but shall-

(a) Be conspicuously placed in relation to other information included on the label; and

(b) Be clearly differentiated from all other promotional material or illustrations.

10. **Misleading statements**- (1) No printed, pictorial, or other descriptive matter appearing on or attached to or supplied or displayed with any dietary supplement shall include any comment on, reference to, or explanation of any word, statement, or label required by these regulations to be borne on any dietary supplement if that comment, reference, or explanation either directly or by implication contradicts, qualifies, or modifies that word or statement or the contents of that label.

(2) No printed, pictorial, or other descriptive matter supplied or displayed with any dietary supplement shall include any false or misleading statement, word, brand, picture, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion of the dietary supplement or of any ingredients of the dietary supplement.

11. **Therapeutic claims**- Except as permitted by the Medicines Act 1981 and any regulations made under that Act, no dietary supplement or package or container containing a dietary supplement shall be advertised or labelled with a statement relating to any of the following matters:

(a) Treating or preventing disease:
(b) Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition:
(c) Altering the shape, structure, size, or weight of the human body:
(d) Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way.

PART II
SPECIFIC REQUIREMENTS

12. **Tabletting aids**- (1) In these regulations 'tabletting aid' means a food grade substance that is added to a dietary supplement to constitute the form in which that supplement is sold; and includes an encapsulating aid.
(2)The following tabletting aids or encapsulating aids, and any other food conditioners specified in the Food Regulations 1984*, may be added to dietary supplements:
Alginic acid and its derivatives:
Beeswax:
Bone meal (sterilised); calcium phosphate:
Carbohydrate sweeteners:
Carnauba wax:
Cellulose and its derivatives:
Coating pigments:
Enteric coatings:
Gelatin:
Gelatin capsule shells:
Lactose:
Lecithin:
Light mineral oils:
Monoglycerides, diglycerides, and triglycerides from edible oils and fats:
Montan ester wax:
Pectins:
Polyethylene glycols:
Polyvinylpyrrolidone and its derivatives:
Shellac:
Silicic acid and its salts:
Talc (sterilised):
Vegetable gums:
Vegetable oils, and hydrogenated vegetable oils:
Xanthan gum:
Zein corn protein.

13. **Preservatives**- (1) In these regulations 'preservative' means any substance that, when added to a dietary supplement, has the property of arresting or impeding fermentation, putrefaction, or decomposition.
(2) Dietary supplements may contain any of the following preservatives and no others:
Benzoic acid or sodium benzoate:
Parahydroxybenzoic acid and its esters:

Sorbic acid, or its sodium, calcium, or potassium salts:
Sulphur dioxide, or sulphites calculated as sulphur dioxide.

14. **Antioxidants-** (1) In these regulations 'antioxidant' means any substance that, when added to a dietary supplement, has the property of arresting or retarding oxidative rancidity.
(2) Dietary supplements may contain any of the following antioxidants and no others:
(a) Propyl gallate, dodecyl gallate, octyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and tertiary butylhydroquinone (TBHQ), where the proportion of those antioxidants, singly or in combination, does not exceed 500 ppm:
(b) Ascorbyl palmitate, and ascorbyl stearate, where the proportion of those
(c) Natural tocopherols, synthetic tocopherols, citric acid, and sodium citrate:
(d) Isopropyl citrate mixture, monoglyceride citrate, and phosphoric acid, where the proportion of those antioxidants, whether singly or in combination, does nor exceed 100 ppm.

15. **Colouring substances**- (1)In these regulations 'colouring substance' means any substance that, when added or applied to a dietary supplement, is capable of impairing colour to that dietary supplement.
(2) Dietary supplements may contain any of the colouring substances (and, where appropriate, their aluminium lakes) specified in the table to this subclause and no others.

TABLE TO SUBCLAUSE (2)

Common Name	Index Name	Index Number
Allura Red AC	CI Food Red 17	16035
Aluminium		77000
Amaranth	CI Food Red 9	16185
Annatto extracts (bixin, norbixin)	CI Natural Orange 4	75120
Anthocyanins		40800
Beet red (betanin)		
B-carotene	CI Food Orange 5	
B-apo-8'-carotenol	CI Food Orange 6	40820
B-apo-8'-carotenoic acid, and its		40825
ethyl	CI Food Orange 7	
And methyl esters	CI Food Black 1	28440
Brilliant Black PN	CI Food Blue 2	42090
Brilliant Blue FCF	CI Food Brown 3	20285
Brown HT	CI Food Orange 8	40850
Canthaxanthin		14720
Caramel	CI Food Red 3	
Carmoisine (azorubine)	CI Natural Green 3	75810
Chlorophyll		75470
Chlorophyll copper complex		
Chlorophyllin copper complex,		
potassium and sodium salts	CI Natural Red 4	
Cochineal (carminic acid)	CI Food Red 14	45430
Erythrosine	CI Food Green 3	42053
Fast Green FCF		77480
Gold		44090
Grape skin extracts	CI Food Green 4	

Green S	CI Food Blue 1	73015
Indigotine (indigo carmine)	CI Pigment Red 101&102	77491
Iron oxides and hydrated iron oxides	CI Pigment Yellow 42&43	77495
	CI Pigment Black 11	77499
		16255
Paprika (paprika oleoresin)		
(capsanthin and capsorubin)	CI Food Red 7	
Ponceau 4R		75100
Riboflavin (lactoflavin)		
Riboflavin-5-phosphate	CI Natural Yellow 6 & 19	
Saffron (crocin, crocetin)		77820
Silver	CI Food Yellow 3	15985
Sunset Yellow FCF	CI Food Yellow 4	19140
Tartrazine		77891
Titanium dioxide	CI Natural Yellow 3	75300
Turmeric (curcumin)	CI Natural Yellow 27	75135
Xanthophylls		

NOTE: The index numbers specified in the third column of this table are the numbers allotted in the current edition of the Colour Index published jointly by the Society of Dyers and Colourists of the United Kingdom and the Association of Textile Chemists and Colorists of the United States of America.

16. Artificial sweeteners- (1) In these regulations 'artificial sweetener' means any substance that when added to a dietary supplement, is capable of impairing sweetness to that dietary supplement, and that is not a saccharide, polyhydric alcohol, or honey.

(2) Dietary supplements may contain any of the following artificial sweeteners and no others:

Aspartame:

Saccharin and its sodium, and calcium and ammonium compounds:

Sodium cyclamate and calcium cyclamate.

17. **Flavouring substances**- (1) In these regulations 'flavouring substance' means any wholesome substance that, when added or applied to a dietary supplement, is capable of imparting flavours to, or enhancing flavours in, that dietary supplement.

(2) Dietary supplements may contain any flavouring substance, except the following:

Cade oil:

Coumarin:

Nitrobenzene:

Pyroligneous acid:

Safrole and isosafrole:

Sassafras oil.

18. Vitamins- (1) The dietary supplements specified in the first column of the table to this subclause, or any compound of those supplements, and no others, may be described as vitamins, and the quantity of vitamins in those dietary supplements shall be calculated in accordance with the second column of that table.

TABLE TO SUBCLAUSE (1)

Dietary supplement described as vitamins or containing vitamins	Calculated as
Vitamin A or retinol	retinol in mcg
Vitamin B1 or thiamine	thiamine in mg
Vitamin B2 or riboflavin	riboflavine in mg
Niacin or nicotinic acid	niacin equivalents in mg
Pantothenic acid	pantothenic acid in mg
Vitamin B6 or pyridoxine	pyridoxine in mg
Vitamin B12 or cyanocobalamin, or hydroxycobalamin	vitamin B12 in mcg
Vitamin C or ascorbic acid	ascorbic acid in mg
Vitamin D or calciferol	calciferol in mcg
Vitamin D or cholecalciferol	cholecalciferol in mcg
Vitamin E	vitamin E in mg
Biotin	biotin in mcg
Vitamin K	vitamin K in mcg
Vitamin K1 or phytomenadione	vitamin K1 in mcg
Vitamin K or menaphthone	vitamin K in mcg
Folic acid	folic acid in mcg

(2) If the quantity of vitamins in a dietary supplement is declared on a label, it shall be stated to an accuracy of not greater than 3 significant figures.
(3) There may be marked on any package or container containing a dietary supplement, described as or containing a vitamin, a statement indicating-

(a) The presence of vitamins; and

(b) The quantity, calculated in accordance with the table to subclause (1) of this regulation, of that vitamin in that package or container or in each dosage unit, or, where the dietary supplement is divided into a number of units, the quantity of that vitamin in each unit.

19. Minerals- (1) The following dietary supplements may be described as minerals:
Calcium:
Chlorine:
Chromium:
Copper:
Fluorine:
Iodine:
Iron:
Magnesium:
Manganese:
Molybdenum:
Phosphorus:
Potassium:
Selenium:
Sodium:
Zinc.

(2) If the quantity of minerals in a dietary supplement is declared on a label, it shall be stated in milligrams or micrograms to an accuracy of not greater than 3 significant figures.
(3) There may be marked on any package or container containing a dietary supplement described as or containing a mineral, a statement indicating-

(a) The presence of minerals; and

(b) The quantity of that mineral in that package or container or in each dosage unit, where the dietary supplement is divided into a number of units the quantity of that mineral in each unit.

20. Enzymes-The following enzymes may be added to dietary supplements:
Amylase and protease derived from *Aspergillus flavus oryzae* or *Aspergillus niger*:
Bromelin:
Ficin:
Invertase:
Papain:
Pectinase:
Pepsin:
Rennet and protein-coagulating enzymes:
Lactase:
Lipase.

PART III
OFFENCES and PENALTY

21. Offence**s and penalty**- (1)Every person who contravenes of fails to comply with any of the provisions of regulations 3, 4, 5(6), 13(2), 14(2), 15(2), 16(2), 17(2) and 18(1) of these regulations commits an offence against these regulations.
(2) Every person who commits an offence against these regulations is liable to a fine not exceeding $500, and, in the case of a continuing offence, to a further fine not exceeding $50 for every day on which the offence has continued.

P.G Millen,
Clerk of the Executive Council.

EXPLANATORY NOTE

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, in a sense, fill the gap between the Food Regulation 1984 and the Medicines Regulation 1984, in that dietary supplements are not ‘food’ or ‘medicine’ in the ordinary sense of those words. However, they are ‘food’ within the meaning of the Food Act 1981, and will be ‘related products’ within the meaning of the Medicines Act 1981 if therapeutic claims are made for them.

Part I prescribes certain general requirements relating to the manufacture, labelling, and advertising of dietary supplements, and follows broadly the equivalent provisions of Part I of the Food Regulations 1984.

Part II prescribes certain specific requirements relating to food additive standards in respect of certain classes of dietary supplements.

Issued under the authority of the Regulations Act 1936.
Date of notification in *Gazette*: 22 August 1985.
These regulations are administered in the Department of Health.

1986/378

THE DIETARY SUPPLEMENTS REGULATIONS 1985, AMENDMENT NO. 1

Paul Reeves, Governor-General

ORDER IN COUNCIL

At Wellington this 19th day of December 1986

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to Section 42 of the Food Act 1981, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

REGULATIONS

1. Title and commencement-(1) These regulations may be cited as the Dietary Supplements Regulations 1985, Amendment No. 1, and shall be read together with and deemed part of the Dietary Supplements Regulations 1985 (hereinafter referred to as the principal regulations).
(2) These regulations shall come into force on the 1st day of January 1987.

2. Commencement of principal regulations- (1)Regulation 1 of the principal regulations is hereby amended by revoking subclauses (2) and (3), and substituting the following subclauses:
'(2) Regulations 2 and 4 to 11 of these regulations shall come into force on the 1st day of September 1987.'
'(3) Except as provided in subclause (2) of this regulation, these regulations shall come into force on the 1st day of January 1987.'

P.G MILLEN,
Clerk of the Executive Council.

EXPLANATORY NOTE
This note is not part of the regulations, but is intended to indicate their general effect.

These regulations relate to the commencement of the principal regulations. Because of a drafting error in regulation 1(2) of those regulations, it appears that none of the provisions of the principal regulations have yet come into force.
These regulations provide that the principal regulations will come into force on 1 January 1987, except those provisions that relate to labelling. They will come into force on 1 September 1987.

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Issued under the authority of the Regulations Act 1936.
Date of notifications in *Gazette*: 22 December 1986.
These regulations are administered in the Department of Health.

ATTACHMENT 3

OUTLINE OF REGULATORY FRAMEWORK FOR FOODS AND MEDICINES/THERAPEUTIC PRODUCTS – AUSTRALIA AND NEW ZEALAND

1. Regulatory Framework - Australia

In Australia, there are broadly two categories of products that are for human consumption. Such products are either food products regulated under the State and Territory food legislation and *Imported Food Control Act 1992* (Commonwealth) which require that food sold in or imported into Australia must comply with the provisions of the *Food Standards Code.* The other category is 'therapeutic goods' (the Australian term for therapeutic products) (and includes prescription and over-the-counter medicines and complementary medicines) regulated under the *Therapeutic Goods Act 1989.* There is however, an interface between foods and therapeutic goods, specifically medicines, and at times it is not always apparent as to which side of this food - medicine interface a particular product will fall. Many FTDS are within the vicinity of this interface. Appendix 1 provides definitions for foods and medicines in Australia and New Zealand.

1.1 Foods

As noted above, foods are regulated within Australia under the *Food Standards Code*. Compliance with the *Food Standards Code* is the responsibility of the jurisdictions i.e. enacted at State and Territory level in Australia for domestic product and by the Australian Quarantine Inspection Service (AQIS) for imported goods.

1.2 Therapeutic Goods

In Australia the Therapeutic Goods Administration (TGA) has the responsibility of regulating therapeutic goods, under the *Therapeutic Goods Act 1989.* This Act requires that therapeutic goods must either be listed or registered on the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. Part of this process includes an evaluation and assessment which ensures the product's quality and safety, and in the case of registrable goods, efficacy. Compliance is the responsibility of the TGA and therefore nationally consistent.

Therapeutic goods are defined under the *Therapeutic Goods Act 1989,* and declarations under section 7 provide regulatory clarity to industry, consumers and regulatory bodies about the classification of particular categories of products (refer Appendix 1). For example, products containing fibre in a capsule, tablet or similar delivery device are regulated as therapeutic goods and fibre products such as processed bran or powder fibre products are regulated as foods, provided that no therapeutic claims are made – this implies that if a therapeutic claim is made the product will be regulated as a therapeutic good.

In Australia the term 'therapeutic goods' includes products that may be prescription medicines, over-the-counter medicines or complementary medicines. Products positioned at the food - medicine interface are more likely to be complementary medicines than prescription or over-the-counter medicines. Complementary medicines are also defined under the *Therapeutic Goods Act 1989* and include herbal medicines, homeopathic preparations, vitamins, minerals and trace elements and other nutritional supplements.

The *Therapeutic Goods Regulations 1990* provide further definitions in relation to these particular substances (refer Appendix 1).

1.3 Food -Medicine Interface

Products at the food - therapeutic products (specifically medicines) interface have typically been considered by an inter-agency (ANZFA, TGA and AQIS) advisory team on a case-by-case basis as the delineation is not always apparent. Factors considered in determining whether a particular product is a food or a therapeutic good include physical presentation, compositional ingredients, market and promotional intent, suggested directions of use and or dosage schedules, associated labelling statements and whether or not the product is likely to be consumed as a food or therapeutic good. A harmonised interface does not exist between New Zealand and Australia due to the differing regulatory frameworks.

2. Regulatory Framework - New Zealand

In New Zealand foods are regulated by either the New Zealand *Food Regulations 1984* (NZFR) or the New Zealand *Dietary Supplement Regulations 1985* (NZDSR). Meanwhile, products of a more therapeutic nature are regulated as medicines under the *Medicines Act 1981* or as dietary supplements under the NZDSR.

2.1 Food

Dietary supplements and foods (as regulated under the NZFR) come under the New Zealand *Food Act 1981* and are the responsibility of the New Zealand Ministry of Health (MOH). Dietary supplements currently include what would be regarded in Australia as food-type and therapeutic-type products.

ANZFA understands the MoH is intending that the NZDSR ultimately be repealed, and after the necessary legislative processes have taken place, Volume 2 will be the sole legislation applicable to foods. The outcomes of these deliberations will affect how, and when, any standards developed and/or amended by ANZFA and adopted by the Australia New Zealand Food Standards Council will be implemented.

2.2 Dietary Supplements

The NZDSR were made under the *Food Act 1981*, and commenced in August 1985. In contrast to Australia, these regulations created a separate regulatory category for dietary supplements in addition to those for foods and medicines. In Australia these 'dietary supplements' would be regarded as foods or therapeutic products.

The NZDSR define a dietary supplement as:

> *any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets, which are intended to supplement the intake of those substances normally derived from food.*

2.3 Medicines

Medicines in New Zealand are regulated by the *Medicines Act 1981*. This Act covers pharmaceuticals and other therapeutic-type products but does not include those products generally considered in Australia to be 'complementary medicines', which are more

commonly manufactured under the NZDSR. Medicines are the responsibility of Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, a business unit of the MOH.

2.4 New Zealand Food - Medicine Interface

In New Zealand, products at the interface between foods and medicines are regulated as either foods (including dietary supplements) under the *Food Act 1981* (in compliance with either the *Food Regulations 1984* or the NZDSR); or medicines under the *Medicines Act 1981* (in compliance with the *Medicines Regulations 1981*). Product compliance is determined by the Ministry of Health and if necessary the Categorisation Committee (The Committee). The Committee comprises advisors from the Food Section and Medsafe and meets on an as needs basis to determine whether a product complies with food or medicines legislation, and whether any appropriate action is necessary.

In deciding the appropriate legislation for products, the reviewers take into consideration the ingredient composition, presentation and form of product, purpose of the product, labelling including any therapeutic or other claims, recommendations for use and consumption and consumer expectation of the product.

In New Zealand there are currently three interface areas to be considered:

- the interface between foods and dietary supplements;
- the interface between dietary supplements and medicines; and
- the interface between foods and medicines.

3. Trans Tasman Mutual Recognition

The TTMRA came into effect on 1 May 1998 to promote closer economic relations and trade between Australia and New Zealand. Under TTMRA, a range of products, including food that can be legally sold in one country, may be lawfully imported into and sold in the other country.

Prior to the commencement of TTMRA, Standard T1 of the *Food Standards Code* specifically prevented the importation into and sale in Australia of 'dietary supplements' regulated under the *Dietary Supplements Regulations 1985* in New Zealand. Such products were required to comply with *Food Standards Code*, or the *Therapeutic Goods Act 1989.*

Following the commencement of TTMRA, products that complied with the *Dietary Supplements Regulations 1985, Food Regulations 1984, Medicines Act 1981* that are not considered to be 'therapeutic goods' within the meaning of the *Therapeutic Goods Act 1989* may be lawfully imported from New Zealand and sold in Australia. Products that come within the definition of 'therapeutic goods' in the *Therapeutic Goods Act 1989* must comply with the requirements of that Act for sale in Australia.

The TTMR Act provides specific reference to the *Therapeutic Goods Act 1989*, in that therapeutic goods for sale in Australia must comply with all the requirements of that Act, irrespective of compliance with any laws in New Zealand.

APPENDIX 1 TO ATTACHMENT 3

DEFINITIONS PERTAINING TO FOODS AND MEDICINES ACCORDING TO NEW ZEALAND AND AUSTRALIAN LEGISLATION

Australia		New Zealand	
Medicine[1]	**Food[2]**	**Medicine[3]**	**Food[4,5]**
medicine means: (a) therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal; and (b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of therapeutic device, not to be therapeutic devices. ***therapeutic goods*** means goods: (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be: (i) for therapeutic use; or (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or	***food*** means: (1)***Food*** includes: (a) any substance or thing of a kind used, capable of being used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared); and (b) any substance or thing of a kind used, capable of being used, or represented as being for use, as an ingredient or additive in a substance or thing referred to in paragraph (a); and (c) any substance used in preparing a substance or thing referred to in paragraph (a); and (d) chewing gum or an ingredient or additive in chewing gum, or any substance used in preparing chewing gum; and (e) any substance or thing declared to be a food under a declaration in force under section 3B. (It does not matter whether the substance, thing or chewing gum is in a condition fit for human consumption.)	***medicine*** means--- (1) Subject to subsection (2) of this section, in this Act, unless the context otherwise requires, the term ``medicine" means any substance or article, other than a medical device, that is manufactured, imported, sold, or supplied wholly or principally--- (a) For administering to one or more human beings for a therapeutic purpose; or (b) For use as an ingredient in the preparation of any substance or article that is to be administered to one or more human beings for a therapeutic purpose, where it is so used--- (i) In a pharmacy or a hospital; or (ii) By a practitioner; or (iii) In the course of any business that consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies; or (c) For use as a pregnancy test. (2) In this Act, unless the context otherwise requires, the term ``medicine" does not include-- (a) Substances used in dental surgery for filling dental cavities; or	***food*** means anything that is used or represented for use as food or drink for human beings; and includes--- (a) Any ingredient or nutrient or other constituent of any food or drink, whether that ingredient or nutrient or other constituent is consumed or represented for consumption by human beings by itself or when used in the preparation of or mixed with or added to any food or drink; and (b) Anything that is or is intended to be mixed with or added to any food or drink; and (c) Chewing gum, and any ingredient of chewing gum, and anything that is or is intended to be mixed with or added to chewing gum: ***dietary supplement*** means: any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as sachets, capsules, liquids, lozenges, pastilles, powders or tablets, which are intended to supplement the intake of those substances normally derived from food.

Australia		New Zealand	
Medicine[1]	**Food[2]**	**Medicine[3]**	**Food[4,5]**
(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii); and includes goods declared to be therapeutic goods under an order in force under section 7, but does not include: (c) goods declared not to be therapeutic goods under an order in force under section 7; or (d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or (e) goods for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the *Australia New Zealand Food Authority Act 1991*; or (f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented. ***therapeutic use*** means use in or in connection with: (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or	(2) However, ***food*** does not include a therapeutic good within the meaning of the *Therapeutic Goods Act 1989*. (3) To avoid doubt, ***food*** may include live animals and plants. **3B Declaration of what is food** (1) After consulting the Authority, the Minister may make a written declaration that a substance or thing is food for the purposes of this Act. (2) The Minister must cause a copy of the declaration to be published in the *Gazette* and in the New Zealand Gazette. (3) A declaration takes effect on the day specified in the declaration. That day must not be a day before the declaration is published. (4) A declaration is a disallowable instrument for the purposes of section 46A of the *Acts Interpretation Act 1901*.	(b) Bandages and other surgical dressings, except medicated dressings where the medication has a curative function that is not limited to sterilising the dressing; or (c) Any radioactive material within the meaning of Section 2 (1) of the Radiation Protection Act 1965; or (d) Any animal food in which a medicine is incorporated; or (e) Any animal remedy; or (f) Any other substance or article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of substance or article that is not a medicine for the purposes of this Act. ***related product*** ---In this Part of this Act, unless the context otherwise requires, the term ``related product'' means any cosmetic or dentifrice or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose; but does not include--- (a) Any medicine: (b) Any substance or article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of substance or article that is not a related product for the purposes of this Act. ***herbal remedy*** means a medicine (not being or containing a prescription medicine, or a restricted medicine, or a pharmacy-only medicine) consisting of--	

Australia		New Zealand	
Medicine[1]	**Food**[2]	**Medicine**[3]	**Food**[4,5]
(b) influencing, inhibiting or modifying a physiological process in persons or animals; or (c) testing the susceptibility of persons or animals to a disease or ailment; or (d) influencing, controlling or preventing conception in persons; or (e) testing for pregnancy in persons; or the replacement or modification of parts of the anatomy in persons or animals.		(a) Any substance produced by subjecting a plant to drying, crushing, or any other similar process; or (b) A mixture comprising 2 or more such substances only; or (c) A mixture comprising 1 or more such substances with water or ethyl alcohol or any inert substance: ***therapeutic purpose*** ---In this Act, unless the context otherwise requires, the term ``therapeutic purpose'' means--- (a) Treating or preventing disease; or (b) Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or (c) Effecting contraception; or (d) Inducing anaesthesia; or (e) Altering the shape, structure, size, or weight of the human body; or Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way; or Cleaning, soaking, or lubricating contact lenses.	

1. Australian *Therapeutic Goods Act 1989*
2. ANZFA Act
3. New Zealand *Medicines Act 1981*
4. New Zealand *Food Act 1981*
5. New Zealand *Dietary Supplement Regulations 1985*

ATTACHMENT 4

INTERNATIONAL APPROACHES TO THE REGULATION OF FUNCTIONAL/DIETARY SUPPLEMENT TYPE FOODS

Europe

A wide range of products, known under the term food supplements, diet integrators or others, has been marketed in Community Member States for a number of years. The national rules applicable to them across the Community Member States may differ substantially. This has led to obstacles to intra-community trade that the application of the principle of mutual recognition did not succeed in overcoming. In June 1997 the Commission circulated a discussion paper on the subject and requested comments on the relevant issues. Comments received made it evident that it is necessary to adopt Community rules on these products marketed as foodstuffs.

A proposal specifically addressing supplements marketed in pre-packaged form and presented as foodstuffs has been developed and amended throughout 2000 and 2001 by the European Commission. It should be noted that although the Directive refers to products presented as foodstuffs*, these differ from the current Australian New Zealand considerations as the European approach includes products presented in dosage form i.e. forms that would most likely be considered by ANZFA and TGA to be complementary medicines.

*For the purposes of this Directive:

(a) 'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities;…

Ref: The Council of the European Union. 12394/01 Brussels, 8 November 2001
(Finalised text yet to be published)

The Directive notes that there is a wide range of nutrients and other ingredients that might be present in supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plant and herbal extracts. As a first stage it has been considered that the Directive should only cover food supplements (including tablets and capsules) containing vitamins and minerals and that rules around other bio-active ingredients should be considered at later stage. (Extracted and adapted from EUR-Lex: Commission Proposals 501PC0159 and 500PC0222, and personal communication). On 14th March 2002 the European Parliament voted in favour of the legislative text as its Common Position. The new European Union rules will harmonise the substantially divergent national rules on the sale of food supplements in the forms of tablets and capsules, and introduce a common set of safety rules for food supplements that contain vitamins and minerals.

The Directive concerns only those supplements presented as foodstuffs. Specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect used as ingredients of food supplements should be laid down at a later stage, provided that adequate and appropriate scientific data about them become available. Until such specific Community rules are adopted and without prejudice to the provisions of the Treaty, national rules concerning nutrients or other substances with nutritional or physiological effect used as ingredients of food supplements, for which no Community specific rules have been adopted, may be applicable. (Ref: The Council of the European Union. 12394/01 Brussels, 8 November 2001. Finalised text yet to be published)

United Kingdom

The United Kingdom categorises products as either foods or medicines, regulated by separate government agencies, with no specific legislation covering food-type dietary supplements. The Ministry of Agriculture, Fisheries and Food (MAFF) has authority to draft regulations for foods, with enforcement responsibilities delegated to local trading standards officers (or environmental health departments of local authorities). The Medicines Control Agency (MCA) has authority for drug regulation and enforcement.

The *Food Safety Act 1990* prohibits medicinal claims on foods indicating that the food has the property of preventing, treating, or curing a human disease. In addition there is no system of pre-market approval of claims linking a food component to the reduction in the risk of disease.

Licensed dietary supplements are regulated under the *Medicines Act 1968*. Medicines generally require pre-market approval (or licensing), although some exception exists for herbal products that do not make medicinal claims. Medicines or medicinal products have been defined as any substance or combination of substances which may be administered to humans with the view to making a diagnosis or to restoring, correcting or modifying physiological functions, and may carry medicinal claims. Dietary supplements containing vitamins, amino acids or minerals are generally subject to food safety and food labelling legislation rather than medicines control.

The Borderline Unit of the MCA issued a leaflet in 1995 entitled 'What is a Medicinal Product?' in an attempt to clarify the distinction between drugs and foods. The MCA's Borderline Section will offer advice on the status of a product in cases of doubt. In making a decision, the MCA considers each product individually and considers information such as claims made for the product, any pharmacological properties of the ingredients, whether there are any similar licensed products on the market, and how it is presented to the public through labelling, packaging, promotional literature and advertisements.

United States

Many of the FTDS in the US such as fortified drinks, powders and bars, are positioned under the *Dietary Supplement Health and Education Act 1994* (DSHEA).
The term 'dietary supplement' is defined in the DSHEA (see Attachment 1).

The regulation of dietary supplements under DSHEA is, for the most part, a post-marketing program regulated by the US Food and Drug Administration (FDA). The manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed.

DSHEA grants the FDA the authority to establish Good Manufacturing Practice (GMP) regulations governing the preparation, packaging, and holding of dietary supplements under conditions that help ensure their safety. Once a supplement is marketed, the FDA has the responsibility for showing that the product is unsafe before it can take action to restrict the product's use.

Dietary ingredients marketed prior to the enactment of the DSHEA (15 October 1994) were considered to be safe and dietary supplements containing these ingredients are permitted to be freely marketed, in the same way as foods. There are no regulations that limit a serving size or the amount of a nutrient in any form of dietary supplements. Under the DSHEA, industry is required to submit to FDA any 'new ingredient' intended for use in a dietary supplement at least 75 days prior to the expected introduction onto the market. There is no requirement that the manufacturer receive FDA approval or clearance before marketing the product after the 75-day period has expired.

Under DSHEA, manufacturers may make three types of claims for their dietary supplement products: health claims, structure/function claims, and nutrient content claims. These claims describe respectively: the link between a food substance and disease or a health-related condition; the intended benefits of using the product; or the amount of a nutrient or dietary substance in a product.

The FDA acknowledges in their ten-year plan that there is a real and growing concern about the interactions between dietary supplements and over-the-counter and prescription medicines. In addition, it is recognised that without visible FDA regulatory presence, the potential for exaggerated claims, unpredictable composition, and toxicity are of considerable concern.

Canada

In Canada, products considered [by ANZFA as] food-type dietary supplements (FTDS) are generally classified as natural health products, and are subject to the *Food and Drugs Act 1953*. Being neither foods nor drugs, natural health products have existed in an area of regulatory uncertainty, making it difficult to establish, and comply with, appropriate and consistent regulatory processes.

The Canadian regulatory agencies are currently assessing this category of products in order to develop an applicable regulatory framework. The Office of Natural Health Products has been established and through an Expert Advisory Committee and consultations with stakeholders, is working to develop and implement a tripartite regulatory framework. This Office will be a new regulatory authority, separate from the Therapeutic Products Programme and Food Directorate, reporting to the Assistant Deputy Minister, Health Protection Branch. Under the proposed scheme the Office will have the authority to approve natural health products for the Canadian market.

The Natural Health Products Directorate has recently completed its 2nd phase of the consultation process in building an appropriate regulatory framework for natural health products. The resultant Natural Health Products Regulations have now been pre-published in the Canada Gazette, Part 1 on December 22, 2001 and the accompanying Regulatory Impact Analysis Statement is available on from:
http://www.hc-sc.gc.ca/hpb/onhp/regs_cg1_cover_e.html

Representations can be made with respect to the proposed regulations within 90 days of the publication of the gazette notice.

Japan

In Japan, products considered as FTDS are generally classified and regulated by the Ministry of Health and Welfare under the Foods For Specified Health Uses (FOSHU) system.

Under Japan's *Nutrition Improvement Act 1992* the regulatory system of FOSHU was developed to delineate 'functional foods' from the pharmaceutical regulations. Specifically, products regulated under the FOSHU system include those that are consumed as foods and exclude therapeutic products in tablet, capsule or powder form. The regulatory framework established special food categories under the FOSHU system as: foods for the sick, powdered milk for pregnant or lactating women, formulated powdered milk for infants, foods for the elderly and functional foods.

The FOSHU system approves products according to distinct food categories and has specific aims relating to improving the health of particular population groups. FOSHU regulated products are typically novel products and not value added general-purpose foods. The majority of products are specifically focused on prevention of disease and maintenance of health status rather than the direct treatment of disease states.

Health agencies of the Japanese government develop and maintain the regulatory framework that covers products that are to be regulated under the FOSHU system.

ATTACHMENT 5

A COMPARISON OF LABELLING REQUIREMENTS AUSTRALIA AND NEW ZEALAND

1. General labelling requirements – Volume 2

Volume 2 contains many generic labelling requirements that apply to all foods. Those of particular relevance to food-type dietary supplements (FTDS) are:

Standard 1.2.3 – **Mandatory warning and advisory statements and declarations**. Sub-clause 2 states that the label on certain products must include an advisory statement to the effect that they are either unpasteurised, contain phenylalanine, quinine or caffeine.

Standard 1.2.8 – **Nutrition information requirements** applies to any standard in Volume 2 unless specifically exempted. This standard sets out the conditions for making nutrition claims and declaring nutrition information on food labels, including mandating a Nutrition Information Panel on most manufactured foods. Given below is an example of a Nutrition Information Panel (refer Standard 1.2.8 subclause 5(1), Volume 2 v. 58)

NUTRITION INFORMATION Servings per package: (insert number of servings) Serving size: g (or mL or other units as appropriate)		
	Quantity per Serving	Quantity per 100 g (or 100 mL)
Energy	kJ (Cal)	kJ (Cal)
Protein	g	g
Fat, total	g	g
- saturated	g	g
Carbohydrate	g	g
sugars	g	g
Sodium	mg (mmol)	mg (mmol)
(insert any other nutrient or biologically active substance to be declared)	g, mg, µg (or other units as appropriate)	g, mg, µg (or other units as appropriate)

Standard 1.2.10 – requires the declaration of the percentage of characterising ingredients/components in foods.

Standard 1.3.2 – Vitamins and Minerals regulates the claims which can be made in relation to the presence of a vitamin or mineral in those foods for which the voluntary addition of vitamins and/or minerals is permitted.

These standards, contained within Volume 2, are posted on ANZFA's website: www.anzfa.gov.au or www.anzfa.govt.nz.

Prescribed name - the requirement for prescribed names on products as per Volume 1, has been largely replaced in Volume 2 by the more flexible requirement that the name on the label clearly reflect the 'true nature of the product'.

Specific labelling requirements – some standards also have specific labelling requirements. For example, FCBs require an advised consumption limit and advice to the effect that the product is not recommended for certain (specified) subgroups; and sports foods require advice to the effect that the product should be used in conjunction with an appropriate physical training or exercise program.

Until such time as a final decision is made by the Australia New Zealand Food Standards Council with regard to the proposed health claims Standard, health claims are prohibited under Volume 2 according to Standard 1.1.3, Clause 1:

> *'(1) Save where otherwise expressly prescribed in this Code, any label on a package containing or any advertisement for food shall not include a claim for therapeutic or prophylactic action or a claim described by words of similar import.*
>
> *(2) Any label on a package containing or an advertisement for a food shall not include the word 'health' or any word or words of similar import as a part of or in conjunction with the name of the food.*
>
> *(3) Save where otherwise expressly prescribed by this Code, any label on a package containing or any advertisement for food shall not contain any word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person.*
>
> *(4) Save where otherwise expressly prescribed by this Code, the label on a package containing or any advertisement for food shall not contain the name of or a reference to any disease or physiological condition.*

2. General labelling requirements- New Zealand

<u>New Zealand *Dietary Supplement Regulations 1985* (NZDSR)</u>

The NZDSR has specific labelling requirements that relate to all dietary supplements including FTDS. In conjunction with product identification, weight/volume and usage instructions, these include the requirements to provide:

- the common name and/or description of the product;
- the words 'dietary supplement';
- a statement of recommended dosage both in terms of quantity and frequency;
- warning in case of overdose where danger exists; and
- a consumer information panel that includes the types and quantities or proportions of claimed 'active' ingredients.

The common name and/or description of a product is to provide the consumer with information that is generally understood by the community, rather than the more technical

terminology. Many of the active ingredients of FTDS are known by more than one term and may be marketed under a number of different names.

Inclusion of the term 'dietary supplement' is required to aid the enforcement officers with the identification of the product, as well as providing the consumer with a way of differentiating between a dietary supplement and the non-supplemented counterpart foods that may appear visually the same.

Recommended dosage is provided to aid the consumer in terms of appropriate and safe levels of consumption. The stated dosage should not exceed the maximum daily dose permitted by reference to specific daily permissions for certain vitamins and minerals as given in the NZDSR.

Requirements to list and quantitatively state the active ingredients are to provide information for the consumer in relation to the claimed ingredients. The specific requirements are as follows:

> **Consumer information panel**- (1) The following information, when required by these regulations to be on the label, shall be grouped together in one portion of the label (that portion being called the consumer information panel):
>
> The statement of ingredients, which shall show -
>
> The quantities or proportions of the claimed active ingredients in the package or container or in each dosage unit, or, where the dietary supplement is divided into a number of units, the quantity or proportion of the claimed active ingredients in each unit; and
> The inactive ingredients in the package or container, which shall be described either by their specific names or by their class names, being any of the following permitted class names:
>
> Antioxidants
> Artificial sweeteners:
> Colouring or colour:
> Encapsulating or flavour:
> Minerals:
> Preservatives:
> Tabletting aids:
> Vitamins:
>
> The storage instructions (where appropriate).
>
> (2)The consumer information panel may be any part of the label, but shall-
> Be conspicuously placed in relation to other information included on the label; and
> Be clearly differentiated from all other promotional material or illustrations.

Dietary supplements may not make therapeutic claims (except as permitted by the *Medicines Act 1981*, see next section) relating to any of the following:

- *(a) treating or preventing disease;*
- *(b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;*
- *(c) altering the shape, structure, size or weight of the human body;*

(d) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way.

New Zealand Food Regulations 1984 (NZFR)

The general labelling provisions for all foods would apply to any FTDS that are made to the NZFR. In terms of volume this is not a significant number of products. Furthermore, after the end of the transition period (December 2002) the NZFR are proposed to be replaced by the provisions of Volume 2.

3. Nutrition Claims

Australian State and Territory Food Legislation
The review of FTDS should be considered in the context of provisions in State and Territory legislation relating to the labelling of food. Some of these provisions are reflected in the draft *Model Food Act* 2000 which states that it is an offence punishable by a fine:

- for a person to engage in conduct that is misleading or deceptive or likely to mislead or deceive in relation to the advertising, packaging or labelling of food intended for sale or the sale of food (clause 14(1));

- for food to be advertised, packaged or labelled in a way that falsely describes the food (clause 14(2)); and

- for a person to sell food which is packaged or labelled in a way that falsely describes the food (clause 14(3)).

Trade Practices Act 1974 (Commonwealth) and *Fair Trading Acts*
Sections 52 and 53 of the *Trade Practices Act* 1974 and the State and Territory Fair Trading Acts prohibit, in general terms, conduct that is false, misleading or deceptive.

New Zealand
The Commerce Commission (NZ) enforces the *Fair Trading Act* 1986 and the *Commerce Act* 1986. The Ministry of Economic Development is responsible for the administration of the *Fair Trading Act*. The *Fair Trading Act* is modelled on the Australian *Trade Practices Act* 1974.

Sections 10, 13(a) (e) and (h) of the New Zealand *Fair Trading Act* 1986 relate to food labelling and marketing. Specifically, claims about food content, quality, and quantity, characteristics or benefits must not be misleading or deceptive. In relation to food, this includes labelling of food products, any advertising, promotional material, or verbal representation about those products.

In New Zealand, the Advertising Standards Authority Inc. adopted a Code for Advertising of Food (November 2000) to which all advertisements are subject. The Code stipulates that advertisements should comply with four broad principles to ensure advertising is conducted in a manner that is socially responsible and does not mislead or deceive the consumer.

4. Health and related claims

New Zealand
New Zealand Medicines Act, 1981

No food or dietary supplement shall be advertised or labelled as having a therapeutic purpose. A therapeutic purpose is defined as:

- treating or preventing a disease; or
- diagnosing disease or ascertaining the existence, degree or extent of physiological condition; or
- affecting contraception; or
- inducing anaesthesia; or
- altering the shape, structure, size or weight of the human body; or
- otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any way; or
- cleaning, soaking or lubricating contact lenses.

New Zealand Food Regulations 1984

R. 4. GENERAL REQUIREMENTS FOR LABELLING OF FOODS--

(8) No label on a package of a food shall bear, as part of the name of the food or in association with the name of the food, the word 'health' or any variation of that word.

R. 237. SPECIAL PURPOSE FOODS--

(1) Special purpose foods shall be foods that are specially processed or formulated to satisfy particular dietary requirements that exist because of--

(a) A particular physical or physiological condition; or
(b) A specific disease or disorder; or
(c) Both such a condition and a disease or disorder,--

and are presented as such.

(13) No label on a package of a food, except a special purpose food, shall bear the words 'special purpose food', or words of similar meaning (such as, food for a specific dietary use).

(14) Every label used in connection with a special purpose food shall state the special purpose of the food.

(15) No food shall be described, expressly or by implication, as a special purpose food unless the food complies with the requirements of these regulations.

(16) No label on a package of any special purpose food, except an amino acid modified food, shall contain the name of any disease, disorder, or physiological condition in association with the name of the food.

(17) No label on a package of any special purpose food shall include, in the principal display panel, the word ‘health’, or words of similar meaning, or any word of which ‘health’ forms a part, except as part of the trading name in the statement required by regulation 4 (1) (c) of these regulations.

ATTACHMENT 6

GLOSSARY OF ACRONYMS

AAT	Administrative Appeals Tribunal
ACCC	Australian Competition and Consumer Commission
ACS	Australian Customs Service
AFGC	Australian Food and Grocery Council
AFFA	Agriculture, Fisheries and Forestry – Australia, Department of
AIEH	Australian Institute of Environmental Health
AHMAC	Australian Health Ministers Advisory Council
ANZCERTA	Australia New Zealand Closer Economic Relations Trade Agreement
ANZFA	Australia New Zealand Food Authority
ANZFRMC	Australia New Zealand Food Regulation Ministerial Council
ANZFSC	Australia New Zealand Food Standards Council
APEC	Asia-Pacific Economic Co-operation
AQIS	Australian Quarantine and Inspection Service
ARMCANZ	Agriculture and Resource Management Council of Australia and New Zealand
ASEAN	Association of South-East Asian Nations
ATDS	Australian Total Diet Survey
ATSIC	Aboriginal and Torres Strait Islander Commission
BSE	Bovine Spongiform Encephalopathy
BSES	Bi-National Surveillance and Enforcement Strategy
CDNANZ	Communicable Diseases Network of Australia and New Zealand
CER	Closer Economic Relations
COAG	Council of Australian Governments
Codex	Codex Alimentarius Commission
CoPoNC	Code of Practice on Nutrient Claims in Food Labels and in Advertisements
DFAT	Foreign Affairs and Trade, Department of
DHAC	Health and Aged Care, Department of
DISC	Development and Implementation Sub-Committee (of FRSC)
DoFA	Finance and Administration, Department of
EAGAR	Expert Advisory Group on Antimicrobial Resistance
EC	European Commission
EFA	European Food Authority (proposed for 2002)
FAO	Food and Agriculture Organisation

FCMC	Food Code Management Committee
FRSC	Food Regulation Standing Committee
FSANZ	Food Standards Australia New Zealand
FSC	Food Standards Code
FSMP	Foods for Special Medical Purposes
FTDS	Food-Type Dietary Supplements
GATT	General Agreement on Tariffs and Trade
GM	Genetically Modified
HAC	Health and Aged Care
IGA	Inter-Governmental Agreement
JETACAR	Joint Expert Technical Advisory Committee on Antibiotic Resistance
MCDS	Ministerial Council on Drug Strategy
MRG	Maori Reference Group
MRL	Maximum Residue Limit
MSQA	Meat Safety Quality Assurance
NH&MRC	National Health and Medical Research Council
NRA	National Registration Authority
NTD	Neural Tube Defects
NZDSR	New Zealand Dietary Supplement Regulations 1985
NZFR	New Zealand Food Regulations 1984
OECD	Organisation for Economic Co-operation and Development
PES	Performance Enhancement Scheme
RAS	Rapid Alert System
RIS	Regulation Impact Statement
SFOs	Senior Food Officers
SPS	Sanitary and Phyto Sanitary
TAG	Technical Advisory Group
TBT	Technical Barriers to Trade
TGA	Therapeutic Goods Administration
TPA	Trade Practices Act
TTMRA	Trans-Tasman Mutual Recognition Arrangement
WHO	World Health Organization
WTO	World Trade Organization