10 October 2001
05/02

INITIAL ASSESSMENT REPORT
(NEW PROPOSAL - S.21 OF THE ANZFA ACT)

PROPOSAL P242

FOODS FOR SPECIAL MEDICAL PURPOSES

EXECUTIVE SUMMARY

This Initial Assessment Report seeks public comment on issues pertaining to the regulation of foods for special medical purposes (FSMP) within Australia and New Zealand; the purpose being to resolve the status of these foods within the *Australia New Zealand Food Standards Code* (Volume 2).

At present FSMP are not specifically regulated, as there is no prescribed standard within either the Australian *Food Standards Code* (Volume 1), Volume 2, or the New Zealand *Food Regulations 1984* (NZFR).

FSMP principally are formulated food products used under medical supervision for the dietary management of individuals (including children) with either ongoing chronic medical conditions or during acute phases of illness or disease states. They include 'complete nutrition' formulas either consumed orally or through an enteral route (e.g. naso-gastric tube), as well as specialised dietary supplement formulas or foods, and very low energy diet (VLED) formulas used for weight loss.

Within the context of regulatory harmonisation between Australia and New Zealand and transition into Volume 2, Proposal P242 allows for the formal abandonment of Proposal P49 that has previously considered the development of a standard for FSMP in Australia.

This initial assessment proposes several regulatory options and discusses the relative impacts of these options. Other issues pertinent to the regulation of FSMP are discussed including underlying regulatory principles, scope and definition of FSMP, distribution and access of FSMP, and compositional and labelling requirements for FSMP.

Public comment and submissions are sought on all of these issues to assist in the development of a suitable regulatory framework for FSMP. Following receipt of submissions, a Draft Assessment Report will be prepared and circulated for further public consideration.

CONTENTS

1. INTRODUCTION

On 1 July 1996, an Agreement between Australia and New Zealand (The Treaty) came into force that established a joint Australian New Zealand Food Standards System, which served to underpin the development of the joint *Australia New Zealand Food Standards Code* (Volume 2). Under this Agreement, during the transition period to the joint system, products sold in New Zealand and Australia could comply with either the *New Zealand Food Regulations 1984* (NZFR), (if manufactured or imported into New Zealand) or Volume 1 (existing Australian *Food Standards Code*) until such time as Volume 2 had been developed and became the sole set of regulations for the two countries.

In December 2000, Volume 2 came into effect in Australia and New Zealand. It is expected that most of the existing Australian and New Zealand Food Regulations (other than Volume 2) will be repealed at the end of 2002.

During the current transition period, ANZFA is required to complete the development and review of several outstanding food regulation matters. These include the development of joint regulations covering foods for special medical purposes (FSMP) (Proposal P242), which is the subject of this Initial Assessment Report.

During 1992, the then National Food Authority initiated Proposal P49 - Foods for Special Medical Purposes that was progressed to Full Assessment but subsequently stalled in 1995. Proposal P242 allows for the formal abandonment of Proposal P49 and renewed consideration of the regulation of FSMP in the context of regulatory harmonisation between Australia and New Zealand, and transition to Volume 2. The statement of reasons for abandonment of Proposal P49 is at Attachment 1.

FSMP principally are formulated food products used under medical supervision for the dietary management of individuals (including children) with either ongoing chronic medical conditions or during acute phases of illness or disease states. They include 'complete nutrition' formulas either consumed orally or through an enteral route (e.g. naso-gastric tube), as well as specialised dietary supplement formulas or foods, and very low energy diet (VLED) formulas used for weight loss. Total parenteral nutrition (TPN) products are formulated to be administered intravenously and therefore most likely fall outside the definition of food in the *ANZFA Act (1991).* For this reason, TPN is not considered part of the scope of this proposal.

In consideration of this proposal, ANZFA is seeking comment, particularly in relation to the series of questions throughout this report, from all interested parties. Submissions should clearly identify relevant issues or impact(s) and provide rationale and/or supporting documentation where possible, and clearly indicate the representation of the submitter.

2. PROBLEM / ISSUE

By nature, FSMP are products formulated to meet the specific nutritional requirements of individuals with particular medical conditions. Volume 2 does not contain specific provisions for FSMP and therefore unlike other foods, FSMP are not given any positive permissions for composition, labelling or other requirements. Because of this, an ambiguous situation exists for manufacturers in complying with the Food Standards Code, for consumers in receiving consistent information and for government enforcement agencies.

3. BACKGROUND

3.1 Current Regulatory Framework

3.1.1 Australia

In Australia, FSMP are not specifically regulated, as there is no prescribed standard within either Volume 1 or Volume 2. Some supplementary-type products may meet the current requirements of Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods in Volume 2.

Due to the current prohibition on the addition of nutritive substances within the general provisions of Volume 2 (Standard 1.1.1), most FSMP-type products fail to comply and are essentially 'unlawful' at the point of sale. As a result, the lack of specific regulation for FSMP is ambiguous causing difficulties for the State and Territories enforcement agencies as well as the Australian Quarantine and Inspection Service (AQIS).

3.1.1.1 Therapeutic Goods

In Australia the Therapeutic Goods Administration (TGA) is responsible for the regulation of therapeutic goods, primarily under the *Therapeutic Goods Act 1989.* Consequently, any product must either be listed or registered on the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. Therapeutic goods are defined under the *Therapeutic Goods Act 1989* (Attachment 2).

In the absence of a prescribed standard within the *Food Standards Code*, FSMP potentially fall in the regulatory interface of therapeutic goods and food. Furthermore, the level of formulation of FSMP and their unique role of nourishing individuals receiving medical therapy for particular health conditions can cloud their distinction as foods rather than therapeutic goods.

3.1.2 New Zealand

Under the NZFR there is no specific regulation solely for FSMP. However, some products may be covered under Regulation 237 Special Purpose Foods (Attachment 3).

It is possible some FSMP currently on the New Zealand market could be defined as medical nutritional products. Under the provisions of Regulation 20A in the NZFR, vitamins and minerals (in the forms listed in Schedule 13A) are permitted to be added to medical nutritional products (there are no upper limits for addition specified in this case). Other more specialised products may not fall under these regulations.

3.1.2.1 New Zealand Dietary Supplement Regulations 1985

The *New Zealand Dietary Supplement Regulations* (NZDSR) were made under the *New Zealand 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/therapeutic goods.

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.*

These "dietary supplements" in Australia could be regarded as foods or medicines/therapeutic goods depending on the nature and presentation of the product. It is possible that some FSMP, due to the addition of further ingredients, do not comply with Regulation 237 in the NZFR, but may comply with the NZDSR (in relation to composition).

3.1.2.2 New Zealand Medicines Regulations 1984

FSMP are not considered medicines in New Zealand, as the products are not used for a therapeutic purpose. They are used to help to improve or maintain the nutritional condition of the patient, and are not used to treat or cure any disease state.

3.2 International Regulation

3.2.1 Codex Alimentarius

The Codex Alimentarius Commission 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 standards exist for 'the labelling of and claims for foods for special medical purposes (FSMP) (CODEX STAN 180-1991), and for 'formula foods for use in very low energy diets for weight reduction' (CODEX STAN 203-1995).

The Codex Standard defines foods for special medical purposes as:

> *a category of foods for special dietary uses which are specially processed or formulated for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.*

Both the labelling of FSMP and 'formula foods used in very low energy diets' must be in accordance with the 'Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses' (CODEX STAN 146-1985).

Food for Special Dietary Uses is 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.*

3.2.2 European Commission

Food regulation in Europe occurs through Directives made by the European Union Council (EUC) and takes place in the context of establishing a uniform market place whilst ensuring the safety of food products.

In the declaration of Directive 89/398/EEC *foodstuffs intended for particular nutritional purposes* (PARNUTS), the EUC committed to the adoption of a list of food groups for which specific directives would be developed. Directives have since been developed for dietary foods for special medical purposes (DFSMP) (Directive 1999/21/EC) and foods intended for use in energy-restricted diets for weight loss (Directive 96/8/EC).

The definition for DFSMP as defined under Directive 1999/21/EC is only slightly different to that of Codex as illustrated by the bolded text below.

Dietary foods for special medical purposes (DFSMP) are:

> *A category of foods for **particular nutritional uses** specially processed or formulated and intended for the dietary management of patients and **to** be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired **or disturbed** capacity to take, digest, absorb, metabolise **or excrete** ordinary foodstuffs or certain nutrients contained therein **or metabolites**, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by **other foods for particular nutritional uses**, or by a combination of the two.*

Directive 1999/21/EC also provides compositional criteria as well as labelling and claim requirements for DFSMP.

Directive 96/8/EC relates to both total diet replacements and meal replacements used in weight loss. This Directive also provides composition and labelling requirements similar to those for DFSMP.

3.2.3 United States of America

The regulation of “medical food” in the United States is undertaken through two pieces of federal legislation: the Orphan Drug Amendments 1988, and the Nutrition Labeling and Education Act 1990 (NLEA); as well as a final ruling by the United States Food and Drug Administration (FDA) clarifying the NLEA.

In 1988, the amendments to the Orphan Drug Act of 1983 provided the following definition for medical foods:

a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which the distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

Prior to this, the FDA considered medical foods as 'foods for special dietary use'.

The passing of the NLEA specifically exempted medical foods from the nutrition labelling, health claim, and nutrient content claim requirements applicable to most other foods including foods for special dietary use. The FDA in 1993 published final rules that exempted medical foods from nutrition labelling requirements and incorporated the statutory definition of a medical food into the agency's regulations. (21 CFR 101.9(j)(8)). In this regulation FDA specify criteria that are intended to clarify the characteristics of medical foods (Attachment 3). The tight definition of medical foods that results from the FDA's final ruling is a deliberate attempt to prevent exploitation of the NLEA provisions.

As such in the US, medical foods are subject to less regulatory scrutiny than other foods as there are no specific requirements for label information and substantiation of claims, formulation and compositional characteristics and manufacturing quality control for medical foods. In 1997, the FDA, being aware of the potential problems caused by the lack of regulatory control over medical foods, initiated a re-evaluation of its approach to the regulation of medical foods. This process has yet to be completed.

3.2.4 Canada

The *Food and Drug Regulations 1954* includes Division 24 – Foods for Special Dietary Use (FSDU). FSDU are defined as:

that has been specially processed or formulated to meet the particular requirements of a person

a) in whom a physical or physiological condition exists as a result of a disease, disorder or injury, or

b) for whom a particular effect, including but not limited to weight loss, is likely to be obtained by a controlled intake of foods.

This legislation details compositional requirements including maximum and minimum limits on nutritive substances, labelling requirements and health claim requirements. In addition to these measures, Canada also regulates some FSDU through a pre-market approval process.

3.3 Current Market and Distribution

3.3.1 Australia

Within the Australian market, there are four multi-national companies that almost exclusively supply the total market of FSMP-type products. All products available in Australia are manufactured in either Europe (including UK) or the United States of America and are subsequently imported for sale in Australia.

The Australian FSMP market is estimated at approximately $40 million per annum. The market is growing mostly as a result of improved technology, an ageing population, earlier patient discharge from hospital and a greater recognition of the importance of nutritional support in medical therapy. Volume sales vary from product to product with general nutritional support products such as high energy / high protein supplements being consumed in much higher volumes than highly specialised foods for rare disease states that may only be consumed by a very small number of people.

FSMP, particularly the highly specialised products, can be very expensive to the consumer, a problem that is often compounded by long-term dependence on such products. The majority of FSMP are provided through healthcare settings (e.g. public and private hospitals, nursing homes), usually under the supervision of health professionals such as dietitians, nurses or medical staff. Individuals requiring these products within a home/community setting either obtain supplies through regional health services (hospitals) or are able to order directly from suppliers. Consumers can also purchase products through retail pharmacies without a medical prescription. The level of financial assistance that is offered to support the purchase of products varies considerably between each State and Territory. A very small number of specialised products, predominately for metabolic disorders, are listed on the Pharmaceutical Benefits Scheme.

The supply of FSMP to health care facilities most often occurs through either state-wide or regional health service tendering procedures. Generally tenders outline requirements for the supply of specific FSMP including composition and price.

3.3.2 New Zealand

The New Zealand market is similar to that in Australia in that there are only a small number of companies who almost exclusively supply FSMP. All products available in New Zealand are manufactured (and almost all are packaged) in either Europe (including the UK) or the United States of America.

The New Zealand FSMP market is estimated to be between NZ$5 million and NZ$8 million. The volume of the market is increasing at a higher rate than the value of the market. The reasons for market growth are similar to those reported in Australia. Despite the growth in the FSMP industry, the overall market size is comparatively small on a world scale. Some highly specialised foods for rare disease states may only be supplied to one or two individuals in the entire country.

It is estimated that 95% to 99% of the FSMP market is distributed via a prescription (authorised by a medical practitioner). The remaining section of the market is available over the counter (OTC) in pharmacies. FSMP are currently not available through supermarkets or convenience stores.

The majority of FSMP-type products in New Zealand (including low protein pastas and some gluten free foods) are currently listed on the NZ Pharmaceutical Schedule, administered by PHARMAC (the Pharmaceutical Management Agency Ltd). PHARMAC is a wholly owned subsidiary of the Health Funding Authority (HFA) and has the task of managing the pharmaceutical subsidies to ensure that all New Zealanders have access to safe, cost effective, quality medicines to meet reasonable health needs.

Due to the listing of FSMP by PHARMAC, it is more cost effective for consumers to access these products via a prescription and this is one of the main reasons why OTC sales are very low.

To receive FSMP on prescription, patients must apply for a Special Authority (SA) number (authorised by a medical specialist). The SA number remains valid for one year in most instances, and in the case of long-term conditions (such as coeliac disease) for three years. During this time, repeat prescriptions can be authorised by the patient's General Practitioner (GP). Once a SA number expires a re-application must be authorised by a medical specialist.

3.4 Previous Considerations of Foods for Special Medical Purposes

In Australia, the introduction of the *Therapeutic Goods Act 1989* placed a number of products in the position of being classified as either a food or a therapeutic good. Products designed to nourish people having medical conditions were considered foods as they provided nourishment to individuals. Volume 1 did not however have the provisions to appropriately regulate these food products. Subsequently, in 1992 the then National Food Authority (NFA) adopted a recommendation from the Working Party on Therapeutics Goods and Food of the then Commonwealth Department of Health, Housing and Community Services, that a standard for foods for special medical purposes (FSMP) be developed, based on the draft standard of Codex, for inclusion in Volume 1.

The proposal (P49) included specialised infant formula, enteral feeding formula, special medical supplements and very low energy diets (VLED) for weight reduction. Following initial public consultation, the magnitude of the task to develop a standard for all four classes of foods became evident. Consequently, only VLEDs were progressed within the context of P49 and the remaining three classes of food were held over for future consideration under separate proposals.

In June 1995 the Full Assessment Report for P49 containing a draft standard for formula foods for very low energy diets (FFVLED) was released for public comment. A draft code of practice that sought to restrict the sale and advertising of FFVLED was also issued for public comment in October 1995. Soon afterwards P49 stalled when the Australian Competition and Consumer Commission advised ANZFA that there would be difficulties in implementing a code of practice that sought to restrict the sale and advertising of a food.

The initiation of this proposal (P242) allows for the abandonment of P49 and renews consideration of FSMP in the context of transition to Volume 2. The statement of reasons for abandonment of P49 is at Attachment 1.

4. OBJECTIVES

4.1 Objectives of Development of Joint Regulation for Foods for Special Medical Purposes.

This is the first phase in the development of joint Australia New Zealand regulation for FSMP. 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 workable regulatory framework for FSMP that meets ANZFA's objectives.

The development and variation of any food standard(s) in or intended for Volume 2 is predicated on fulfilling ANZFA's.10 objectives, which are (in descending priority order):

(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 addition, ANZFA must also have regard to the following:

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

The development of food standard(s) are also carried out in accordance with the competition policy principles which have been adopted by the Council of Australian Governments (COAG) and the draft Code of Good Regulatory Practice (New Zealand). These principles require the review of all business regulation to remove unnecessary obstacles to competition and an assessment of proposed regulation on all affected sectors of the community, and can be encapsulated in the phrase 'minimum effective regulation'.

The specific objectives of Proposal P242 are to:

1. Protect public health and safety in relation to the consumption of FSMP, particularly by ensuring safe levels of consumption and targeting of appropriate groups.
2. Develop consistent food regulations applying to FSMP between Australia and New Zealand.
3. Provide information to health professionals and consumers to enable them to make informed choices about the consumption of FSMP and to prevent misleading conduct.

5. OPTIONS FOR REGULATION

It should be noted that the options being proposed are in the context of inclusion in Volume 2 only and it is anticipated that a transition period will be provided prior to the implementation of any regulatory control.

To date, five options have been identified for the regulation of FSMP. The options are:

Option 1 – Status Quo

Status quo - no specific regulation for FSMP in Volume 2.

Under this option there would not be any overt recognition of FSMP under food law in either Australia or New Zealand. This means that FSMP would be unlawful foods since they would not comply with the general provisions of Volume 2, e.g. the addition of nutritive substances, such as vitamins, is prohibited unless explicitly permitted.

Option 2 – Recognition in Volume 2 with minimal regulatory control
No specific standard(s) for FSMP in Volume 2; recognition of FSMP by provision of definition, application of generic standards and provisions and, where relevant, exemption from generic prohibitions.

This option allows for the lawful recognition of FSMP within Volume 2 through the provision of a definition to suitably distinguish FSMP from other foods and applying minimal restrictions by, *inter alia*, exempting FSMP from generic horizontal provisions as relevant.

Option 3 – Co-regulation
Recognition of FSMP in Volume 2 either as in Option 2 or Option 4, and complemented by an industry code of practice.

This situation incorporates regulation by either Option 2 or Option 4 with some aspects of the generic provisions in Volume 2 e.g. labelling and advertising, being administered by a voluntary industry code of practice. The requirements of the code of practice would be collaboratively prepared by ANZFA with the assistance of industry. Enforcement of such a code of practice would be the responsibility of industry.

Option 4 – Full regulation
Inclusion of a prescribed standard for FSMP within Volume 2.

Under this option a prescribed standard for FSMP would be included in Volume 2 together with possible amendments to some generic standards. This would create specific provision for the labelling and composition of FSMP available in Australia and New Zealand and provide clarity for regulation enforcement. The application of the existing Codex Standard(s) would be particularly considered in relation to this option.

Option 5 – Regulation by means of pre-market notification
Regulation in Volume 2 and the requirement for pre-market notification.

This option would regulate FSMP in Volume 2 in addition to the requirement for pre-market notification and approval. Alternatively the requirement for pre-market notification could be followed by a pre-determined time period for disallowance by ANZFA.

5.1 Affected Parties

The parties affected by this proposal are: **consumers** particularly those with medical conditions and very vulnerable groups such as the disabled, frail aged and chronically ill; **health professionals** involved in medical therapy, rehabilitation and disability therapy, and nutritional support; the **governments** of New Zealand, the States and Territories and the Commonwealth of Australia; and the **medical food industry** supplying products to the Australian and New Zealand market.

6. POTENTIAL IMPACT OF REGULATORY OPTIONS

In order to determine the most cost-effective and least prescriptive regulatory option for FSMP, ANZFA is required to assess the relative costs and benefits of each option as it impacts on the identified affected parties as discussed above.

Therefore, ANZFA seeks input from all affected parties and other interested groups or individuals in order to assess the relative impact of each regulatory option. In particular quantitative data/information is sought that will assist in this assessment, particularly any economic considerations.

Included in Attachment 5 are some of the potential impacts of regulation of FSMP that ANZFA has already identified. Below is a brief summary of the key concerns regarding the regulation of FSMP from each of the affected parties:

Consumer/Health Professionals
Both consumers and health professionals are concerned about maintaining the current supply and range of quality FSMP in Australia and New Zealand without any increase in the cost of products. In particular, they would not want the supply of very specialised low volume products jeopardised by the introduction of prescriptive regulation. Maintaining appropriate information on product labels and/or product literature is also considered important.

Industry
There are a variety of potential impacts from the regulatory options. Manufacturers of FSMP have identified these to include impacts on production costs, market supply of imported product, labelling and composition.

Government
The major impacts on government agencies relate to issues around harmonisation and consistency in food regulations, and implications for enforcement. In addition any increase in the costs associated with regulation would increase the financial burden on the healthcare system (e.g. public hospital tenders, PHARMAC).

QUESTIONS:

- **Which is your preferred regulatory option for FSMP and why?**
- In responding you may wish to consider the following questions:
  - What are the costs and/or benefits for health professionals/consumers in relation to accurate and meaningful information, changes to supply and costs in response to regulatory measures, potential for misleading consumers, risk to public health and safety etc?
  - What are the costs and/or benefits for industry in relation to compliance, market supply and distribution, labelling and composition, and product quality and safety etc?
  - What are the costs and/or benefits for government in relation to administration and enforcement, on the health and disability care system, and risk to public health and safety etc?

- **How would the costs and / or benefits change under the other proposed regulatory options?**
- Do you agree with the identified costs and benefits as outlined in Attachment 5 of this report?

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

QUESTIONS (Cont):

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

- To what extent would the industry be prepared to be responsible for enforcement and monitoring of, for example, a code of practice?
  - What level of resourcing (funding and human resources) of enforcement and reporting arrangements could the industry sustain?
  - What level of resourcing of monitoring and reporting arrangements could the industry sustain?

7. ISSUES RELATED TO THE IMPLEMENTATION AND REVIEW OF THE DEVELOPMENT OF A STANDARD FOR FOODS FOR SPECIAL MEDICAL PURPOSES

7.1 Regulatory Considerations

The development of regulation for FSMP requires consideration of a number of existing regulatory principles inherent in Volume 2.

7.1.1 Special Purpose Foods

The purpose of foods, as standardised in both Volumes 1 and 2, are considered as either 'general purpose' or 'special purpose'.

Special purpose foods are defined as those *"… foods that are specially processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological need"*. This definition is based on the Codex definition of Foods for Special Dietary Uses.

Special purpose foods differ from general foods because they are designed to deliver nutrition to at-risk groups whose dietary requirements cannot be satisfied by a normal (solid food) diet. Therefore, special purpose food standards allow for the addition of nutrients to foods to ensure an appropriate and adequate nutrient content.

Part 2.9 Special Purpose Foods of Volume 2 contains standards for foods for infants (Standard 2.9.2), formulated meal replacements and supplementary foods (Standard 2.9.3), formulated supplementary sports food (Standard 2.9.4) and infant formula products with the latter two currently under review.

It is anticipated that the regulation of FSMP would be underpinned by the principles applying to special purpose foods. Therefore, a standard has been foreshadowed for inclusion in *Part 2.9 Special Purpose Foods* of Volume 2.

7.1.2 Safety and Efficacy

Standards within the *Food Standards Code* must be based on safety as a primary underpinning principle from the ANZFA Section 10 objectives (Refer Section 4).

Efficacy to achieve a desired benefit, on the other hand, is not explicitly considered in regulating general purpose foods, rather it is implicit in the nutritional contribution of specific foods to a varied and nutritious food supply. FSMP however, are relied upon to provide specific nutritional support and as such, efficacy becomes an important policy principle for these foods.

Based on Codex general principles applying to the FSMP Standard, "*the formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.*"

7.1.3 Other Regulatory Principles

Other significant regulatory principles that have been previously developed and require considerations in the development of a standard for FSMP are those that underpin the following standards:

- general prohibitions (Standard 1.1.1);
- generic labelling (including health claims) provisions (Part 1.2);
- the addition of vitamins and minerals (Standard 1.3.2), botanicals (Standard 1.4.4), additives (Standard 1.3.1) and other substances;
- microbiological limits (Standard 1.6.1);
- novel foods (Standard 1.5.1), food produced using gene technology (Standard 1.5.2), food irradiation (Standard 1.5.3) ; and
- other relevant standards, such as formulated meal replacements and supplementary foods (Standard 2.9.3).

QUESTIONS:

- Should FSMP be regulated as special purpose foods and why?
- Should FSMP be required to conform to the existing Standards as listed above? Please explain.

7.2 Definition of Foods for Special Medical Purposes

No definition for FSMP exists within both Volume 1 and Volume 2 or in the NZFR. The way in which FSMP are defined will have particular significance to the scope of any regulatory measure.

Both Volume 1 (Standard R1) and the NZFR (Regulation 237) make provisions for foods for special dietary uses. Under these standards the composition of foods for special dietary uses must differ significantly from comparable foods.

Within Volume 2 however, no such equivalent standard exists. Foods required as part of a special diet that differ only through the modification of an ingredient or its physical form (e.g. low protein pasta or thickened fruit juice beverages) do not fall directly under a specified standard. Also, the composition of gluten free and lactose free foods are regulated only through criteria for such claims. Therefore, these foods may or may not be considered FSMP.

Based on international Codex standards (See Section 3.2.1) 'foods for special dietary uses' have a sub-classification of 'foods for special medical purposes' that are distinguished by a definition incorporating 'use under medical supervision' and where dietary management cannot be met by modification of a normal diet or other foods for special dietary uses.

The way in which other international regulatory authorities have defined and scoped FSMP has been detailed in Section 3.2 (including Attachment 3) of this paper.

QUESTIONS:

- What do you consider are the necessary components of a definition for FSMP?
- Is the Codex definition for FSMP appropriate in the Australian and New Zealand context?
- What types of products should be encompassed by a definition of FSMP?
- Should "use under medical supervision" be a defining feature of FSMP? If so, why?
- Does the term "Food for Special Medical Purposes" appropriately and accurately reflect the meaning and intent of the proposed regulatory standard? If not, then what would be a more suitable term for this standard?

7.3 Composition of Foods for Special Medical Purposes

7.3.1 Level of Compositional Regulation

Compositional considerations for FSMP relate primarily to safety. The regulatory control of the nutrient composition of special purpose foods varies according to the purpose of such foods and the level of risk involved. In general the greater the contribution of a food to overall dietary intake and the greater the number of nutrients involved in delivering a standardised composition, the more regulatory control is exercised over nutrient and occasionally ingredient composition, corresponding with the assessed level of risk. For example compositional control over infant formula, being a sole source of nutrition for a very vulnerable group, is much more prescribed than for other special purpose foods.

However, applying this cautionary approach is likely to be difficult given that almost the entire FSMP market is sourced from overseas and thus the majority of products are manufactured in accordance with other countries' regulations. Therefore, this cautionary approach may need to take into account the additional level of risk management provided by medical supervision to ensure that regulation does not serve as a trade barrier, and reduce the supply of FSMP to the Australian and New Zealand markets.

Of concern to industry, health professionals and consumers alike is the need for effective control over the quality of FSMP, particularly in light of the vulnerability of the target

populations consuming these products, the continued growth of the FSMP market, and the possible emergence of new suppliers.

7.3.2 Nutritive Substances

Australian and New Zealand food regulations treat nutritive substances in the same way as food additives in that they require explicit permission to be added to foods. Volume 2 defines a 'nutritive substance' to mean:

> "*a substance not normally consumed as a food 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 includes vitamins, minerals, amino acids, electrolytes and nucleotides*".

Depending on how nutritional purpose is interpreted, this term could cover an extensive array of biological substances.

Volume 2 provides permissions for the addition of vitamins and minerals at specific levels in general purpose foods as outlined in Standard 1.3.2. Permissions for special purpose foods are outlined in the specific standards within Part 2.9 of Volume 2. The minimum range and levels of nutrients is generally set in accordance with the purpose of the special purpose food and the risk to the target group from consumption of an otherwise nutritionally inferior product. Such risks are graduated according to the extent of the food's nutritional contribution.

Upper levels of micronutrients are controlled through either upper maximum permitted levels, or through maximum permitted claims and are also determined in accordance with the purpose of the special purpose foods and relative to the risk to the target group from consumption of the product.

Consistent with their intended use, special purpose foods may also be permitted to contain some added vitamins and trace elements that are not permitted to be added to general foods. These include biotin, pantothenic acid, vitamin K, selenium, molybdenum and chromium.

There are a number of other substances currently present in FSMP that are added for a specific nutritional purpose including inositol, fish oils, and individual amino acids such as carnitine and taurine. Given technological and medical developments it is expected that other nutritive substances will be relevant for future consideration in relation to FSMP.

In addition, the formulation of FSMP to meet the 'complete nutrition' needs of vulnerable individuals also occurs in response to medical discoveries and technological advances. This creates a challenge for the compositional regulation of FSMP in not only defining 'nutritionally complete' but also in applying regulatory controls that maintain quality and safety as well as allow for valuable innovation.

QUESTIONS:

- Are there any health and safety risks to consumers associated with the composition of FSMP? Please explain.
- Relative to the risk, should FSMP have compositional regulation?
- If so, then:
  - What nutritive requirements apply to FSMP and in what framework (e.g. standards for all FSMP, product specific standards, or other alternatives) should this regulation exist?
  - Should the definition of nutritive substances be clarified to extend beyond a potentially narrow definition of *nutritional purpose* for the purpose of permitting added substances to FSMP? If so how should that purpose be defined?
  - Should more nutritive (and other) substances be permitted additions for FSMP? If so, what criteria should be considered (e.g. safety)?
  - How should 'nutritionally complete' be defined in the context of FSMP?

- If not, then what alternatives can be utilised to ensure nutritive quality and safety levels are maintained for FSMP?

7.4 Distribution and Access

Individuals requiring FSMP in both Australia and New Zealand can currently access products through healthcare institutions, or purchase them either over the counter at pharmacies or directly from suppliers. In New Zealand the majority of FSMP are obtained via prescription whereas in Australia, consumers can obtain FSMP without prescription and it is generally assumed that some level of health professional supervision is occurring. There are currently no prohibitions on where FSMP can be sold although most are available through the health care system rather than general retailers.

To date ANZFA has no evidence of any significant risk to either target or non-target populations from the current unrestricted access arrangements for FSMP. Where there may be public health and safety concerns, the *ANZFA Act* (1991) has the capacity to restrict access to certain types of foods.

QUESTIONS:

- Does a public health and safety risk exist in the unrestricted access to FSMP?
- Are there any situations in which you believe ANZFA should restrict the sale of FSMP?
  - If so, then where should FSMP be available and in what manner should they be accessed? Should product labelling reflect any restriction on access,
  - e.g. "Pharmacy only product"?
  - If not, then what measures (if any) should be placed on the sale of FSMP?

7.5 Labelling of Foods for Special Medical Purposes

7.5.1 Current Labelling Practices

The majority of FSMP on the New Zealand and Australian market are packaged and labelled in Europe or USA (depending on the source of the product). As previously discussed, the quantity of FSMP consumed in Australia and New Zealand are small compared to other global markets. Most manufacturers consider it is not cost effective to create separate labels for the local market. This is an important issue in the regulation of FSMP, as ANZFA is required to meets its Section 10 objectives (refer Section 4) whilst not imposing inappropriate regulatory constraints that may force some suppliers out of the market. This in turn may restrict or inhibit consumer access to products, which in this case, may be vital to their health.

In both Australia and New Zealand, a large proportion of FSMP are recommended by, or prescribed by a qualified health professional. Most suppliers of FSMP produce and distribute product information to health professionals. In general, such product information is more useful than the actual label in conveying relevant product information because it is often customised to local conditions. This accompanying product information is however, not routinely provided to all health professionals and is not usually distributed to consumers. In these circumstances, the label offers the most information about a product. Therefore, the adequacy of current overseas product labelling will need to be considered in the regulation of FSMP.

The provisions for labelling in Volume 2 also apply to the advertisement of foods. Most FSMP companies target advertising to health professionals through professional newsletters and journals, and occasionally to consumers through non-government support organisations.

7.5.2 Generic Labelling Requirements

In Volume 2 there are a number of generic or 'horizontal' labelling requirements for packaged foods including;

- the product's country of origin (Currently applies to foods produced in Australia. ANZFA is reviewing country of origin labelling (Proposal P237) in the context of transition to Volume 2);
- application of labelling and other information requirements (Standard 1.2.1) and labelling legibility (Standard 1.2.9);
- food identification including the food name, lot and batch number and local manufacturer/supplier contact details (Standard 1.2.2);
- date marking (Standard 1.2.5) and directions for use or storage (Standard 1.2.6);
- mandatory warning and advisory statements and declarations (Standard 1.2.3)
- ingredient listing (Standard 1.2.4) and percentage of characterising ingredients (Standard 1.2.10); and
- nutrition information (Standard 1.2.8).

Currently most FSMP labels include product identification, full ingredient listing, nutrition information panels, date marking, and lot and batch numbers. Due to the difficulties in re-labelling imported products for the local market, as previously discussed, most local suppliers ensure accompanying product information contains local information including supplier contact details and appropriate local reference values e.g. Australian and New Zealand Recommended Dietary Intakes (RDI).

7.5.3 Warning and Advisory Statements

Under Volume 2, all food labelling must comply with Standard 1.2.3 *Mandatory Warning and Advisory Statements and Declarations* unless specifically exempt. These statements are considered important to ensure consumers are adequately informed of any potential risks to themselves, if they consume the product. When FSMP are available over the counter this would be considered equally as important. However as FSMP are recommended for use under medical supervision, it may be argued that this responsibility falls to the person recommending the product.

Many FSMP currently voluntarily carry the advisory statement "Use under medical supervision". This statement helps to clarify the importance of using the products under the direction of a medical doctor and implies that these products are not suitable for the general population. However, this term can cause confusion as other health professionals such as dietitians, nurses and pharmacists, may be in a position to recommend the use of FSMP. The term 'Health Professional' is a possible option, although a clear definition would be required to clarify which health professionals are qualified to recommend and supervise the use of FSMP.

7.5.4 Health and related claims

Health claims are currently prohibited under Volume 2. Food labels and advertisements are not permitted to use the word 'health' in conjunction with the name of the food. In addition, unless expressly permitted, food labelling and advertisements are prohibited from:

- making a therapeutic or prophylactic claim;
- making an expression or implication that may be interpreted as advice of a medical nature; and
- mentioning a disease or physiological condition.

The recent review of health and related claims (Proposal P153) has recommended a draft standard to regulate health claims, Draft Standard 1.2.7 - *Health and related claims about food.* The draft standard maintains the current prohibition on health claims but makes provisions for exemption following rigorous scientific substantiation. Therefore, under proposed Standard 1.2.7, a health claim could be made if the evidence for the claim is convincing. In the proposed substantiation of claims ANZFA has defined "convincing" as;

> *Studies show consistent associations, with little or no evidence to the contrary. There should be a substantial number of acceptable studies, preferably including prospective designs and randomised controlled trials, conducted in different population groups, controlled for possible confounding factors. Any dose-response relationships should be supportive of a causal relationship. Associations should be biologically plausible. Laboratory evidence is usually supportive or strongly supportive.*

Specific nutrition claims, on the other hand, are permitted in the NZFR and by a voluntary code of practice in Australia. ANZFA is currently reviewing nutrient content and other related claims (Proposal P234) to determine the most appropriate and effective regulatory mechanism for managing these types of claims and the criteria that should apply.

Many FSMP are generally formulated to meet the requirements of a specific disease or physiological state. In this case, the label of the product may need to mention this specific

condition in order to clearly identify the purpose of the product. This issue will need to be considered in the regulation of FSMP, as it may be appropriate for FSMP to be specifically permitted to make reference to particular disease states, thereby over-riding the general prohibition as proposed in draft Standard 1.2.7. Conversely, from a consumer point of view claims made by manufacturers must be able to be substantiated to prevent misleading conduct.

In addition, any exemption to the general prohibition on prophylactic and therapeutic claims would need to take careful account of the Australian Therapeutic Goods Act and its New Zealand equivalent.

QUESTIONS:

- Should FSMP be exempt from the various horizontal labelling standards in Volume 2? If so, which ones and why?
- If FSMP were to be required to comply with all generic labelling requirements in Volume 2, what cost would there be to industry in terms of re-labelling of products? (Please quantify if possible)
- Should FSMP be labelled with contact details of the product supplier, in the relevant country (Australia and New Zealand)? Is the provision of these details in supporting information sufficient?
- If changes could not be made on product labels, what is the best way to ensure all necessary information is available to the end consumer? What information is considered necessary?
- Should FSMP comply with the requirements of Standard 1.2.3 – *Mandatory Warning and Advisory Statements and Declarations*? If so, why? If FSMP were only available under medical supervision, is it reasonable that the medical practitioner should consider the appropriateness of the product from supporting information, and label declarations may be not required?
- How can FSMP be labelled to support the market of specialised products for people with specific conditions, but to prevent the misuse of FSMP, or the marketing of inappropriate products?
- Should FSMP carry the warning "Use only under medical supervision"? (Please state reasons for agreeing/disagreeing). What alternative statements/means could be appropriate to inform consumers that these products are not suitable for consumption by the general public?
- Should FSMP be permitted to make reference to particular disease states? If so, why?
- Is the definition of "convincing" appropriate for the substantiation of health claims in FSMP?

8. ONSULTATION

8.1 External Stakeholders

During late July and early August 2001, ANZFA held discussions with a range of external stakeholders in Australia and New Zealand. The purpose of these informal meetings was to gather information on the current manufacture, supply and consumption of FSMP and to identify specific issues relevant for consideration in the proposed regulation of FSMP. Stakeholders included in these meetings were representatives from industry, government and

the dietetic profession. Additionally, limited contact with consumers has occurred through National Carer Association networks.

8.2 Stakeholder Forums

Stakeholder forums may be held in both Australia and New Zealand following the review of submissions from the first round of public comment and before the preparation of the next stage of the Proposal, the Draft Assessment Report.

8.3 Release for Public Consultation

The Initial Assessment Report will be released in October for a six-week consultation period. The views of the submitters will be incorporated into the development of the Draft Assessment Report. Further public comment will be sought on the Draft Assessment Report in early 2002, which will include a proposed regulatory approach.

8.4 International and World Trade Organization obligations

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 the Council 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). WTO considerations will be considered in detail in the Draft Assessment Report.

9. CONCLUSION

This Initial Assessment Report discusses specific issues in relation to the regulation of FSMP and raises several questions for which ANZFA seeks public comment. Responses to this Report will be used to develop the next stage of the Proposal, including drafting an appropriate response to jointly regulate FSMP in Australia and New Zealand.

10. 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*.

11. INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a draft assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and

organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority 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 reasonably be expected to be, destroyed or diminished by disclosure.

Following its draft assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. 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 inquiry, which the Authority will hold to consider the draft standard or draft variation to a standard.

All submissions on this matter should be clearly marked "Submission – Proposal P242" and sent to one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278
or by E-mail to slo@anzfa.gov.au

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Fax (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by: **21 November 2001**.

12. ATTACHMENTS

1. Abandonment of Proposal 49 Statement of Reasons
2. Excerpts from the Therapeutic Goods Regulations
3. Excerpts from the New Zealand Food Regulations
4. United States FDA Final Ruling on Medical Foods
5. Potential Impact of Regulatory Options

ATTACHMENT 1

STATEMENT OF REASONS

PROPOSAL P49

ABANDONMENT OF FOODS FOR SPECIAL MEDICAL PURPOSES

In 1992, the then National Food Authority accepted the recommendation of the Therapeutics Goods and Food Working Party of the then Commonwealth Department of Health, Housing and Community Services, that a standard for foods for special medical purposes (FSMP) be developed, based on the draft standard of Codex.

Subsequently the Authority raised Proposal P49 - Foods for Special Medical Purposes. Four classes of products were intended to be included in the FSMP category; specialised infant formula, enteral feeding formula, special medical products and very low energy diets (VLED) for weight reduction.

Following initial public consultation on P49 in 1992, the magnitude of the task to develop a standard for all four classes of foods became evident. Consequently, only VLEDs were progressed within the context of P49 and the remaining three classes of food were held over for consideration under separate proposals.

In June 1995 the Full Assessment Report for P49 containing a draft standard for formula foods for very low energy diets (FFVLED) was released for public comment. A draft code of practice that sought to restrict the sale and advertising of FFVLEDs was also issued for public comment in October 1995. Soon afterwards, the Australian Competition and Consumer Commission (ACCC) advised ANZFA that there would be difficulties in implementing a code of practice that sought to restrict the sale and advertising of a food. As a result of the ACCC's advice, Proposal P49 stalled and no further work has occurred to progress P49.

Within the context of regulatory harmonisation between Australia and New Zealand, and transition into the joint *Australia and New Zealand Food Standards Code* (Volume 2), ANZFA has decided to renew consideration of the regulation of FSMP under a new proposal. As such, P49 will be abandoned and a new Proposal P242 will seek to develop joint regulations for FSMP for inclusion in Volume 2. This new proposal will include enteral feed formulas, specialised dietary supplement formulas or foods, and very low energy diet (VLED) formulas used for weight loss. Specialised infant formulas will be considered separately when the review of infant formula (Proposal P93) is complete.

The Initial Assessment Report for the new Proposal P242, Foods for Special Medical Purposes, will be released for public comment in October 2001.

ATTACHMENT 2

EXCERPTS FROM THERAPEUTIC GOODS REGULATION

Under the *Therapeutic Goods Act 1989* –

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

(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.

Presentation, *in relation to therapeutic goods, means the way in which goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods.*

therapeutic use *means use in conjunction with:*

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or

(b) influencing, inhibiting or modifying a physiological process in persons or animals to a disease or ailment; 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

(f) the replacement or modification of parts of the anatomy in persons or animals

Section 7 of the *Therapeutic Goods Act 1989* provides TGA with the regulatory capacity to declare that particular goods or classes of goods:

(a) are or are not therapeutic goods, or

(b) when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods.

ATTACHMENT 3

EXCERPTS FROM THE NEW ZEALAND FOOD REGULATIONS (1984)

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.

(2) The composition of special purpose foods shall differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

(3) Special purpose foods shall include the following:

(a) Foods with modified composition:

(i) Low sodium foods and salt substitutes:
(ii) Gluten-free foods:
(iii) Amino acid modified foods:
(iv) Carbohydrate modified foods:
(v) Low energy and reduced energy foods:

(b) Foods that meet the special physiological needs of infants and young children:

(i) Infant formula and follow-on formula
(ii) Supplementary foods for infants and young children:

(c) Meal replacements:

(i) Meal replacements for weight reduction diets:

(ii) Medical nutritional products:

(d) Electrolyte drinks.

(4) For the purposes of these regulations, an infant shall be a person not more than 12 months of age, and young children shall be persons from the age of 12 months up to the age of 3 years.

(5) Special purpose foods shall be prepared from wholesome foodstuffs, and may contain salt.

(6) Special purpose foods with modified composition, other than salt substitutes, shall comply with the compositional standard, including food additives, set for the normal counterpart, except for the changes necessary to comply with the particular special purpose food standard.

(7) Special purpose foods for which no standard is prescribed in this Part of these regulations may contain, where appropriate, the following food additives:

(a) Any food conditioner specified in regulation 253(2) of these regulations:

(b) Any anticaking agent specified in regulation 254(2) of these regulations:

(c)[9] Permitted flavouring substances:

(ca)[9] Spices:

(d) Any colouring substance specified in the table to regulation 250(2) of these regulations:

(e) Any propellant specified in regulation 255(2) of these regulations:

(f) Any preservative specified in the table to subclause (7) of regulation 248 of these regulations in relation to special purpose foods for which no standard is prescribed in this Part of these regulations, in a proportion not exceeding the maximum permitted by that regulation:

(g) Subject to subclause (7A) of this regulation, vitamins and minerals as permitted in the normal counterpart of the food in accordance with the provisions of regulation 20A of these regulations.

(7A) Meal replacements and electrolyte drinks may contain vitamins and minerals in accordance with the provisions of regulation 20A of these regulations

(8) The label on each package of special purpose food, other than salt substitutes, amino acid modified food, infant formula, follow-on formula, and supplementary foods for infants and young children, shall bear a statement of -

(a) The proportion of protein, fat, and carbohydrate in the food; and

(b) The energy content of the food.

(9) The particulars required by subclause (8) of this regulation shall be declared in accordance with the provisions of regulation 13A of these regulations.

(10) to (12) *{REVOKED}*[5]

(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.

(18)[9] Where a standard exists for the normal counterpart of a special purpose food with modified composition, and that standard contains a particular flavouring provision regarding the labelling of flavour in that food, then that labelling provision shall also apply to the special purpose food. If there are no specific labelling requirements, then the provisions of regulation 252F of these regulations shall apply.

239A. Amino acid modified foods

(1) Amino acid modified food shall be food in the preparation of which there has been a restriction in the use of ingredients containing 1 or more particular amino acids or a reduction of the content of 1 or more particular amino acids in any of the ingredients.

(1A)[9] Amino acid modified food may contain vitamins and minerals in accordance with the provisions of regulation 20A of these regulations.

(2) The label on each package of amino acid modified food shall bear 1 or more of the following:

(a) The words "amino acid modified food":

(b) The name of the amino acid or amino acids that have been restricted:

(c) The name of the disease, or a name describing the condition of the group of people, for which the product is intended:

(d) The words "low protein", where applicable.

(3) The label on each package of amino acid modified food shall bear, in the nutrition information statement, a statement of -

(a) The quantity of carbohydrate, protein, and fat in the food, expressed in g; and

(b) The energy content of the food, expressed in kJ; and

(c) The quantity of sodium, and of potassium, in the food, expressed in mg; and

(d) The quantity of the particular amino acid or protein present in the food, or both, as appropriate for the intended use of the food.

(4) The particulars required by subclause (3) of this regulation shall be declared per 100 g or 100 ml (as the case may require) of the food as sold, and, if the food requires dilution or preparation before consumption, per stated quantity of the food prepared according to the directions on the label.

(5) The label on each package of amino acid modified food shall bear, in the principal display panel, in 3 mm lettering, the words "Take only on medical advice".

PART IA
GENERAL STANDARD FOR VITAMINS AND MINERALS

20A. **Addition of vitamins and minerals** –

(1) No vitamin shall be added to a food unless –

(a) The vitamin or mineral is specifically permitted in any other provision of these regulations to be added in accordance with the provisions of this regulation or, in the case of a special purpose food, the addition is specifically permitted elsewhere in these regulations; and

(b) The vitamin or mineral is in a permitted form as specified in the Thirteenth Schedule to these regulations or, in the case of a special purpose food, in schedule 13A to these regulations.

Reg. 22

SCHEDULE

SCHEDULE 18A SUBSTITUTED

Reg. 20A

"SCHEDULE 18A

PERMITTED FORMS OF VITAMINS AND MINERALS FOR SPECIAL PURPOSE FOODS

Column 1	Column 2	Column 3
Special purpose food	Vitamin/mineral	Permitted forms of vitamin or mineral in special purpose food
Meal replacements	Vitamin A	*Retinol Forms* vitamin A (retinol) vitamin A acetate (retinyl acetate) vitamin A palmitate (retinyl palmitate) vitamin A propionate (retinyl propionate) *Carotenoid Forms* beta-apo-8´-carotenal beta-carotene beta-apo-8´-carotenoic acid ethyl ester
	Thiamin (Vitamin B_1)	thiamin hydrochloride thiamin mononitrate thiamin monophosphate
	Riboflavin (Vitamin B_2)	riboflavin riboflavin 5´-phosphate sodium
	Niacin	niacinamide (nicotinamide) nicotinic acid
	Folate	folic acid
	Vitamin B_6	pyridoxine hydrochloride pyridoxine-5´-phosphate
	Vitamin B_{12}	cyanocobalamin hydroxocobalamin
	Vitamin C	L-ascorbic acid ascorbyl palmitate calcium ascorbate potassium ascorbate sodium ascorbate
	Vitamin D	vitamin D_2 (ergocalciferol) vitamin D_3 (cholecalciferol)
	Vitamin E	dl-alpha-tocopherol d-alpha-tocopherol concentrate

SCHEDULE—*continued*

SCHEDULE 18A SUBSTITUTED—*continued*

"SCHEDULE 18A—*continued*

PERMITTED FORMS OF VITAMINS AND MINERALS FOR SPECIAL PURPOSE FOODS—*continued*

Column 1	Column 2	Column 3
Special purpose food	Vitamin/mineral	Permitted forms of vitamin or mineral in special purpose food
Meal replacements —*continued*		tocopherols concentrate, mixed
		d-alpha-tocopheryl acetate
		dl-alpha-tocopheryl acetate
		d-alpha-tocopheryl acid succinate
	Biotin	d-biotin
	Pantothenic acid	d-calcium pantothenate
		dexpanthenol
		d-sodium pantothenate
	Vitamin K	vitamin K_1 (phylloquinone/phytonenadione)
	Calcium	calcium carbonate
		calcium chloride
		calcium citrate
		calcium gluconate
		calcium glycerophosphate
		calcium hydroxide
		calcium lactate
		calcium oxide
		calcium phosphate, dibasic
		calcium phosphate, monobasic
		calcium phosphate, tribasic
		calcium sulphate
		calcium sodium lactate
	Chromium	chromic chloride
		high chromium yeast
	Copper	copper gluconate
		copper-lysine complex
		cupric carbonate
		cupric citrate
		cupric sulphate

SCHEDULE—*continued*

SCHEDULE 13A SUBSTITUTED—*continued*

"SCHEDULE 13A—*continued*

PERMITTED FORMS OF VITAMINS AND MINERALS FOR SPECIAL PURPOSE FOODS—*continued*

Column 1	Column 2	Column 3
Special purpose food	Vitamin/mineral	Permitted forms of vitamin or mineral in special purpose food
Meal replacements —*continued*	Iron	ferric ammonium citrate - brown
		ferric ammonium citrate - green
		ferric ammonium phosphate
		ferric citrate
		ferric hydroxide
		ferric phosphate
		ferric pyrophosphate
		ferric sulphate (iron III sulphate)
		ferrous carbonate
		ferrous citrate
		ferrous fumarate
		ferrous gluconate
		ferrous lactate
		ferrous succinate
		ferrous sulphate (dried and iron II sulphate)
		iron, reduced
	Iodine	potassium iodate
		potassium iodide
		sodium iodate
		sodium iodide
	Magnesium	magnesium carbonate
		magnesium chloride
		magnesium citrate
		magnesium gluconate
		magnesium hydroxide
		magnesium oxide
		magnesium phosphate, dibasic
		magnesium phosphate, monobasic
		magnesium phosphate, tribasic
		magnesium sulphate
	Manganese	manganese carbonate

SCHEDULE—*continued*

SCHEDULE 13A SUBSTITUTED—*continued*

"SCHEDULE 13A—*continued*

PERMITTED FORMS OF VITAMINS AND MINERALS FOR SPECIAL PURPOSE FOODS—*continued*

Column 1	Column 2	Column 3
Special purpose food	Vitamin/mineral	Permitted forms of vitamin or mineral in special purpose food
Meal replacements —*continued*		manganese chloride
		manganese citrate
		manganese sulphate
	Molybdenum	yeast, high molybdenum
		sodium molybdate
	Phosphorus	bone phosphate
		calcium glycerophosphate
		calcium phosphate, dibasic
		calcium phosphate, monobasic
		calcium phosphate, tribasic
		magnesium phosphate, dibasic
		magnesium phosphate, monobasic
		magnesium phosphate, tribasic
		phosphoric acid
		potassium glycerophosphate
		potassium phosphate, dibasic
		potassium phosphate, monobasic
		potassium phosphate, tribasic
		sodium phosphate, dibasic
		sodium phosphate, monobasic
		sodium phosphate, tribasic
	Potassium	potassium bicarbonate
		potassium carbonate
		potassium chloride

SCHEDULE—*continued*

SCHEDULE 13A SUBSTITUTED—*continued*

"SCHEDULE 13A—*continued*

PERMITTED FORMS OF VITAMINS AND MINERALS FOR SPECIAL PURPOSE FOODS—*continued*

Column 1	Column 2	Column 3
Special purpose food	Vitamin/mineral	Permitted forms of vitamin or mineral in special purpose food
Meal replacements —*continued*		potassium citrate potassium gluconate potassium glycerophosphate potassium hydroxide potassium iodide potassium lactate solution potassium phosphate, dibasic potassium phosphate, monobasic potassium phosphate, tribasic
	Selenium	high selenium yeast selenomethionine sodium selenate sodium selenite
	Sodium	sodium bicarbonate sodium carbonate sodium chloride sodium citrate sodium gluconate sodium hydroxide sodium iodide sodium lactate sodium phosphate, dibasic sodium phosphate, monobasic sodium phosphate, tribasic sodium sulphate sodium tartrate
	Zinc	zinc acetate zinc chloride zinc citrate zinc gluconate zinc lactate

SCHEDULE—*continued*

SCHEDULE 13A SUBSTITUTED—*continued*

"SCHEDULE 13A—*continued*

PERMITTED FORMS OF VITAMINS AND MINERALS FOR SPECIAL PURPOSE FOODS—*continued*

Column 1	Column 2	Column 3
Special purpose food	Vitamin/mineral	Permitted forms of vitamin or mineral in special purpose food
Meal replacements —*continued*		zinc oxide zinc sulphate
Amino acid modified foods	Vitamins and minerals as for meal replacements	Permitted forms of vitamin or mineral as for meal replacements
Electrolyte drinks	Calcium	calcium chloride
	Magnesium	magnesium sulphate
	Potassium	potassium chloride
	Sodium	sodium chloride
Infant formula and follow-on formula	Vitamin A	*Retinol forms* vitamin A (retinol) vitamin A acetate (retinyl acetate) vitamin A palmitate (retinyl palmitate) vitamin A propionate (retinyl propionate) *Carotenoid forms* beta-carotene
	Thiamin (Vitamin B_1)	thiamin hydrochloride thiamin mononitrate
	Riboflavin (Vitamin B_2)	riboflavin riboflavin 5′-phosphate sodium
	Niacin	niacinamide (nicotinamide) nicotinic acid
	Folate	folic acid
	Vitamin B_6	pyridoxine hydrochloride pyridoxine-5′-phosphate
	Vitamin B_{12}	cyanocobalamin hydroxocobalamin
	Vitamin C	L-ascorbic acid ascorbyl palmitate

ATTACHMENT 4

UNITED STATES OF AMERICA FOOD AND DRUG ADMINISTRATION
FINAL RULING ON MEDICAL FOODS

Code of Food Regulations, Title 21 – Food and Drugs
Chapter I, Part 101 – Food Labeling
Section 101.9 Nutrition labeling of food

(j) The following foods are exempt from this section or are subject to special labeling requirements:

(8) Medical foods are defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if:

- **(i)** It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
- **(ii)** It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the diet alone;
- **(iii)** It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
- **(iv)** It is intended to be used under medical supervision; and
- **(v)** It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

The final ruling is an excerpt from a larger document, the title for which is provided above. A copy of this document can be obtained from the Food and Drug Administration website at: *http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr101_01.html*

ATTACHMENT 5

POTENTIAL IMPACT OF REGULATORY OPTIONS

Option 1 – Status Quo

Status quo - no specific regulation for FSMP in Volume 2.

Under this option there would not be any overt recognition of FSMP under food law in either Australia or New Zealand. This means that FSMP would be unlawful foods since they would not comply with the general provisions of Volume 2, e.g. the addition of nutritive substances, such as vitamins, is prohibited unless explicitly permitted.

Government

Benefits

- No change to any current enforcement in Australia and New Zealand
- No increase in the cost of products purchased by the healthcare system. (E.g. PHARMAC, hospital tenders).

Costs

- Continued ambiguity for the Australian Quarantine and Inspection Service (AQIS) on the surveillance of imported FSMP.
- Potential for inconsistent enforcement by the State, Territories and New Zealand authorities regarding the sale of these products.

Consumers/Health Professionals

Benefits

- No changes to the current range of FSMP available.
- No impact on the supply of low volume specialised products.
- No change to the cost of FSMP products
- Potential for greater market competition thereby increasing range and availability of products and cheaper products.

Costs

- Inconsistencies in level of product information, labelling and use of therapeutic claims between products.
- No restrictions on the composition and quality of products available. Potential for introduction onto the Australian/New Zealand market of lower quality products.
- No regulatory controls to protect public health and safety.

Industry

Benefits

- No changes required to current labelling and product composition.
- Maintains current range of products available and allows for innovation.

Costs

- Potential for problems with the importation of products.
- Products remain ‘unlawful’ causing ambiguity for manufacturers and enforcement agencies.
- Risk of new market competitors compromising product quality and standards.

Option 2 – Recognition in Volume 2 with minimal regulatory control

No specific standard(s) for FSMP in Volume 2; recognition of FSMP by provision of definition, application of generic standards and provisions and, where relevant, exemption from generic prohibitions.

This option allows for the lawful recognition of FSMP within Volume 2 through the provision of a definition to suitably distinguish FSMP from other foods and applying minimal restrictions by, *inter alia*, exempting FSMp from generic horizontal provisions as relevant.

Government

Benefits

- Less ambiguity for enforcement agencies
- No changes to supply and costs of FSMP to the healthcare system

Costs

- Minimal regulatory control over FSMP with potential for future public health risk.

Consumer/Health Professionals

Benefits

- As for Option 1.

Costs

- Minimal regulatory control over FSMP with potential for future public health risk.

Industry

Benefits

- As for Option 1.

Costs

- Risk of new market competitors compromising product quality and standards.

Option 3 – Co-regulation

Recognition of FSMP in Volume 2 either as in Option 2 or Option 4, and complemented by an industry code of practice.

This situation incorporates regulation by either Option 2 or Option 4 with some aspects of the generic provisions in Volume 2 e.g. Labelling and advertising, being administered by a voluntary industry code of practice. The requirements of the code of practice would be collaboratively prepared by ANZFA with the assistance of industry. Enforcement of such a code of practice would be the responsibility of industry.

Government

Benefits

- The burden of full regulation would lessen.

Costs

- The combination of government agencies and industry may compromise regulatory objectives, increase the ambiguity of enforcement and ultimately lead to reduced public health and safety.

Consumer/Health Professionals

Benefits

- A consistent industry-wide approach to the provision of product information, labelling and use of therapeutic claims.

Costs

- Potential for poor compliance by industry to code of practice.
- Potential for increases in product cost caused by the administration of a Code of Practice.

Industry

Benefits

- Less prescriptive than full regulation in Option 4.
- Greater control over product characteristics, labelling and enforcement.
- Companies can elect not to comply with the Code of Practice.

Costs

- Increased costs and responsibility, management and enforcement associated with a voluntary code of practice.
- Potential for inequity in trading between companies complying with code of practice and those choosing not to.

Option 4 – Full regulation

Inclusion of a prescribed standard for FSMP within Volume 2.

Under this option a prescribed standard for FSMP would be included in Volume 2 together with possible amendments to some generic standards. This would create specific provision for the labelling and composition of FSMP available in Australia and New Zealand and provide clarity for regulation enforcement. The application of the existing Codex Standard(s) would be particularly considered in relation to this option.

Government

Benefits

- A consistent regulatory approach to FSMP creating clarity for import control and enforcement.
- Full regulatory control to manage any present and future public health and safety risks.

Costs

- Any enforcement burden and costs arising from implementation of an additional standard.
- Potential price increases and reduction in product range available for the health care system.

Consumer/Health Professionals

Benefits

- A consistent industry-wide approach to the provision of product information, labelling and use of therapeutic claims.
- Full regulatory control to manage any present and future public health and safety risks.

Costs

- Potential for reduced product range and availability.

Industry

Benefits

- Clear consistent regulations on composition, labelling and quality of products.
- Consistent approach to import control and enforcement

Costs

- Increased costs associated with compliance with regulatory requirements
- Potential for reduction in product range

Option 5 – Regulation by means of pre-market approval

Regulation in Volume 2 and the requirement for pre-market notification.

This option would regulate FSMP in Volume 2 in addition to the requirement for pre-market notification and approval. Alternatively the requirement for pre-market notification could be followed by a pre-determined time period for disallowance by ANZFA.

Government

Benefits

- Same as Option 4

Costs

- Increased costs in the implementation, management and enforcement of a pre-market clearance scheme

Consumer/Health Professionals

Benefits

- Potential for greater regulatory flexibility in approval of a wider range of products.

Costs

- Potential for reduced product range and availability

Industry

Benefits

- Potentially less prescriptive than Option 4.
- Potential for greater regulatory flexibility in approval of new products.

Costs

- Possible profit losses while awaiting approval.