FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

06/03
18 December 2002

DRAFT ASSESSMENT REPORT

PROPOSAL P242

FOODS FOR SPECIAL MEDICAL PURPOSES

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
12 February 2003
(See "Invitation for Public Submissions" for details)

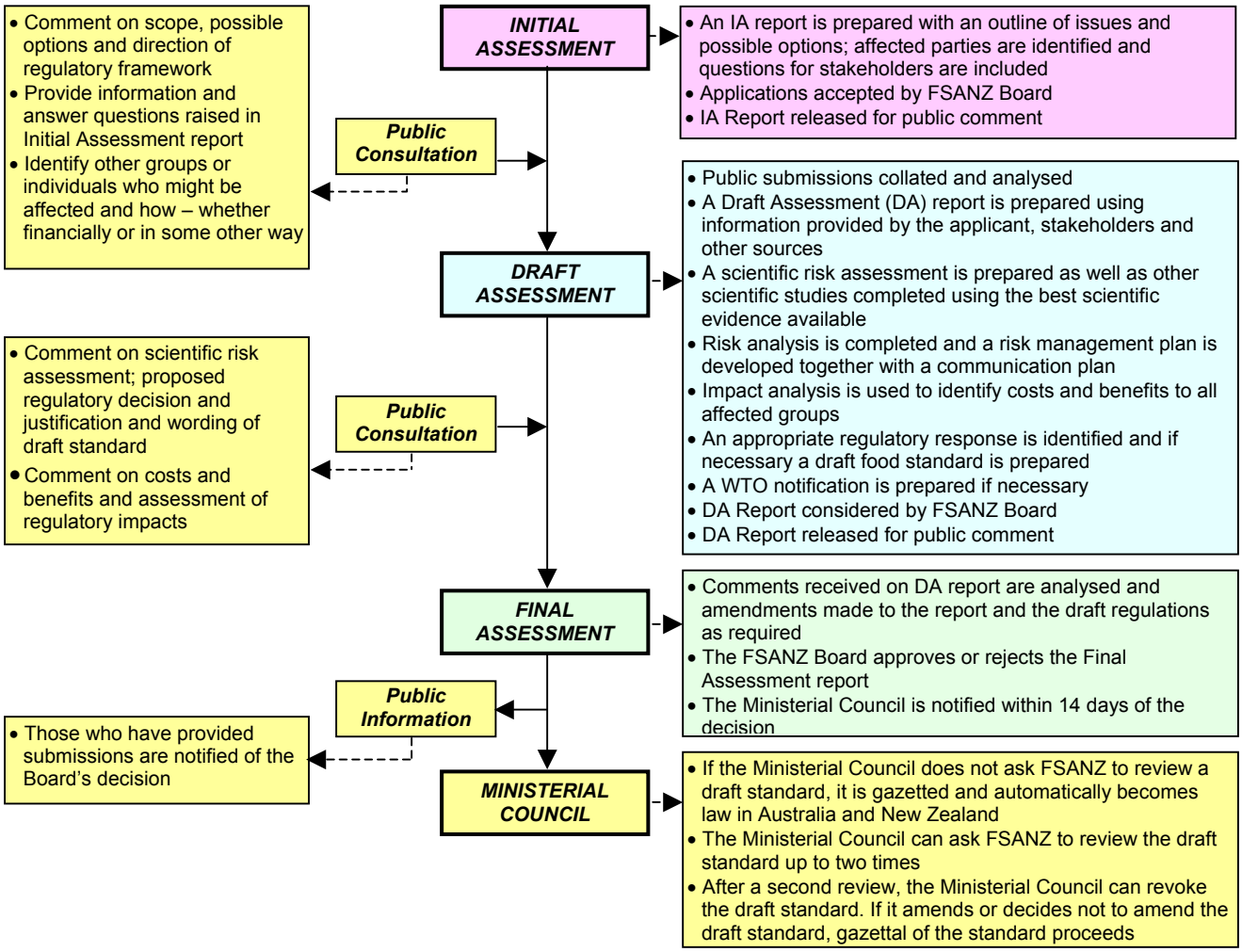
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared a Draft Assessment Report for Proposal P242 – Foods for Special Medical Purposes (FSMP); and prepared a draft variation to the *Food Standards Code.*

The Authority invites public comment on this Draft Assessment Report, the draft variation to the *Food Standards Code;* and the Regulation Impact Statement for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Final Assessment for this Proposal. Submissions should, where possible, address the objectives of the Authority as set out in Section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Food Standards 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 should be in sufficient detail to allow independent scientific assessment.

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 information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act 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.

Submissions must be made in writing and should clearly be marked with the word "Submission" and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by the Authority **by 12 February 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au .

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary and Statement of Reasons

This Draft Assessment Report reviews the issues involved in the regulation of foods for special medical purposes (FSMP), makes recommendations on a regulatory approach to FSMP and proposes the inclusion of draft Standard 2.9.5 – Foods for Special Medical Purposes (Attachment 1) in Part 2.9 of the *Food Standards Code*.

Background

FSMP are principally formulated food products, used under the supervision of medical or other health professionals, for the dietary management of individuals (including children) with either ongoing chronic medical or disability conditions or during acute phases of illness, injury 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 formulas for very low energy diets (VLED) used for weight loss.

There is minimal local manufacture of FSMP as it is estimated that 99% of products are imported, mainly from the European Union (including UK) and the United States of America. On a world scale, the Australian and New Zealand markets are comparatively small.

Regulatory Problem

The regulation of FSMP in Australia and New Zealand is unclear. The Code does not explicitly recognise FSMP and therefore unlike other foods, FSMP are not given any permissions for composition or specific labelling requirements. Because of this, the regulation of FSMP continues to be uncertain for:

- importers and local manufacturers of FSMP in complying with the Code;
- health professionals and consumers in being assured of appropriate and consistent information on the safe and effective use of FSMP; and
- government in enforcing the Code.

By nature, FSMP are products specifically formulated for use under medical or other health professional supervision, for the dietary management of individuals with particular medical conditions. These vulnerable individuals rely either fully or partially on FSMP to meet their specific nutritional requirements that cannot be satisfied by a normal diet. It is therefore essential that FSMP are both safe and effective in meeting the needs of the target population.

Objectives

The specific objectives of Proposal P242 are to:

- protect public health and safety, particularly by ensuring the safe and appropriate use of FSMP;

- develop harmonised food regulations applying to FSMP in Australia and New Zealand; and

- provide health professionals and consumers with sufficient information to make choices about the safe and effective use of FSMP.

Issues

The development of regulations for FSMP requires consideration of a number of existing regulatory principles inherent to the Code as well as issues raised through stakeholder consultation. This report discusses and makes recommendations on the:

- defining features and purpose of FSMP;
- distribution and access to FSMP including a restriction on the advertising of FSMP to the general public;
- prescribed compositional requirements, consistent where possible with international regulations;
- specific labelling requirements to allow for:
  - flexibility and consistency with international regulations where possible; and
  - the safe and effective use of FSMP including a mandatory advisory statement indicating use under medical supervision; and
- applicability of generic standards to FSMP including food additive permissions, novel foods and microbiological limits.

Options

Two options for the regulation of FSMP have been identified at Draft Assessment:

- Option 1 - maintain status quo i.e. no specific regulation of FSMP in the Code; and
- Option 2 - regulation by a discrete standard in the Code with exemptions from generic standards as appropriate.

Consultation

In October 2001, FSANZ released for public consultation an Initial Assessment for Proposal P242. In response, 26 submissions from various stakeholders were received. A summary of submitter comments is at Attachment 5. The comments and information provided in submissions has assisted with the preparation of this Draft Assessment.

Transitional Issues

In accordance with the transitional requirements for a proposal, which has reached Full (Draft) Assessment prior to the commencement of the FSANZ Act, the Full (Draft) Assessment has been reviewed. No relevant policy guidelines have been notified by the Ministerial Council, and no additional submissions were received in response to the notice given under section 14A of the FSANZ Act.

Conclusion and Recommendation

By maintaining the status quo as per Option 1, there would be minimal impact on consumers except where imported FSMP may be delayed at national borders, and a continuing negative impact on industry and government caused by the regulatory uncertainty of FSMP.

When compared to Option 1, Option 2 provides greater benefits for all affected parties. Option 2 provides continued access to and greater assurance of safe, quality products but also ensures provision of consistent information in labelling to allow for the safe and effective use of FSMP in the Australia/New Zealand context. It allows for the harmonisation of the regulations for FSMP between Australia and New Zealand, and where appropriate international regulations, providing regulatory certainty for industry and government enforcement agencies and not unduly restricting trade.

Bearing in mind that further information from industry will be gathered on the expected cost of compliance, Option 2 – regulation by a discrete standard in the Code – is at this stage considered the more superior option in meeting the regulatory objectives.

Therefore, it is recommended that the proposed amendments (Attachment 1), incorporating a draft standard for FSMP, be adopted into the Code for the following reasons.

- the inclusion of a standard for FSMP in the Code provides clear, harmonised regulations for FSMP in Australia and New Zealand;

- the explicit recognition of FSMP in the Code provides regulatory certainty for industry in complying with the Code and for government enforcement agencies;

- the regulation of FSMP provides assurance for consumers of protection of public health and safety, particularly for the target group being a vulnerable population;

- the inclusion of FSMP as 'special purpose foods' not only allows for regulatory consideration of the primary objective of safety but also efficacy;

- the inclusion of specific regulations for the composition and labelling of FSMP assures regulatory control which is commensurate with the assessed level of risk in Australia and New Zealand; and

- there is consistency with international regulations, wherever possible, to prevent potential barriers to trade that could jeopardise the supply of FSMP products to Australia/New Zealand.

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 *Australia New Zealand Food Standards Code* (the Code). In December 2000, the Code came into effect in Australia and New Zealand. It is expected that the Australian *Food Standards Code* (Volume 1) and the New Zealand *Food Regulations 1984* (NZFR) will be repealed by the end of 2002, when the Code will become the sole set of food regulations for the two countries.

As part of the transition into this new joint food regulatory system, Food Standards Australia New Zealand (FSANZ) is required to complete the review and development of several outstanding food regulation matters. These include the review and development of harmonised Australian and New Zealand regulations covering foods for special medical purposes (FSMP), which is the subject of this Draft Assessment Report.

FSMP are principally formulated food products, used under the supervision of medical or other health professionals (eg. dietitians, nurses and pharmacists), for the dietary management of individuals (including children) with either ongoing chronic medical or disability conditions or during acute phases of illness, injury or disease states. They include 'complete nutrition' formulas (i.e. intended for use as the sole source of nutrition), 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 fall outside the definition of food in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). For this reason, TPN is not considered part of the scope of this proposal. Additionally, due to the complexity of the issues involved with the regulation of specialised infant formula products, these products are also excluded from the scope of this Proposal. FSANZ expects to consider specialised infant formula products under a separate proposal following the completion of Proposal P242.

In October 2001, FSANZ (formerly the Australia New Zealand Food Authority (ANZFA)) released an Initial Assessment Report for Proposal P242 and invited public submissions. The comments and information received through submissions has assisted to progress the Proposal to Draft Assessment. A summary of submissions is at Attachment 5.

This Draft Assessment Report reviews the issues involved in the regulation of FSMP, makes recommendations on a preferred regulatory approach to FSMP and proposes the inclusion of draft Standard 2.9.5 – Foods for Special Medical Purposes (Attachment 1) in Part 2.9 of the Code. FSANZ seeks comment on this Draft Assessment, particularly in relation to the expected impact(s) of the proposed regulatory approach, to assist in the preparation of the Final Assessment of Proposal P242.

Transitional Requirements

This proposal reached Full (Draft) Assessment stage under the operation of the *Australia New Zealand Food Authority Act 1991* (ANZFA Act), and will be finalised in accordance with the provisions of the FSANZ Act. FSANZ has therefore been required to:

1. give notice under section 14A of the FSANZ Act; and

2. review the Full (Draft) Assessment having regard to any new submissions received in response to the above notice as well as any written policy guidelines that have been notified by the Ministerial Council.

2. Background

2.1 Current Regulatory Framework

2.1.1 Australia

In Australia, FSMP are not specifically regulated, as they have no explicit recognition within the Code. Due to the prohibition on the addition of nutritive substances within the general provisions of the Code (Standard 1.1.1), most FSMP-type products fail to comply and are technically 'unlawful' at the point of sale. As a result, the lack of specific regulation for FSMP is unclear causing difficulties for the State and Territories enforcement agencies as well as the Australian Quarantine and Inspection Service (AQIS).

2.1.2 New Zealand

Under the NZFR there is no specific regulation solely for FSMP, although some products may fall under Regulation 237 - Special Purpose Foods. Upon the repeal of the NZFR, expected in late 2002, Standard 1.1A.6 – Transitional Standard for Special Purpose Foods incorporates the provisions of Regulation 237 in the Code until such time as regulations for FSMP are developed.

FSMP could also fall under the New Zealand Dietary Supplement Regulations (NZDSR); a set of regulations that 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. 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). FSANZ is currently reviewing the regulation of food-type dietary supplements through Proposal P235, which is at Draft Assessment.

2.1.3 International Regulations

Due to the global nature of the FSMP market, there are number of international regulations that are of significance to the Australia / New Zealand regulatory setting. These are:

- Codex standards for 'The Labelling of and Claims for Foods for Special Medical Purposes' (CODEX STAN 180-1991), and for 'Formula Foods for use in Very Low Energy Diets for Weight Reduction' (CODEX STAN 203-1995);

- European Commission Directives on 'Dietary Foods for Special Medical Purposes' (Directive 1999/21/EC) and 'Foods Intended for Use in Energy-Restricted Diets for Weight Loss' (Directive 96/8/EC);

- United States of America 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) in 1993 clarifying the NLEA; and

- Canadian *Food and Drug Regulations 1954*, Division 24 – Foods for Special Dietary Use, specifically regulations on 'Formulated Liquid Diets' (B.24 100 – 103) and 'Foods Represented for Use in Very Low Energy Diets' (B.24 300 – 306).

2.1.4 Therapeutic Goods

In Australia, the Therapeutic Goods Administration (TGA) is responsible for the regulation of therapeutic goods under the *Therapeutic Goods Act 1989*. When first introduced, this legislation placed a number of products in the position of being classified as either a food or a therapeutic good. Products designed to nourish people with medical conditions were considered as foods. However, the absence of any explicit recognition of FSMP within the Code creates a situation where FSMP potentially fall in the regulatory interface of therapeutic goods and food.

Similarly in New Zealand, FSMP are not considered as medicines, because they are not used for a therapeutic purpose i.e. they help to improve or maintain the nutritional condition of a person, rather than being used to treat or cure any disease state. Although again 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 as therapeutic goods.

Australia and New Zealand are considering the establishment of a bi-national organisation to regulate therapeutic goods. If harmonised legislation for therapeutics is developed, it is likely that, in the absence of explicit recognition of FSMP in the Code, the current ambiguity between FSMP and therapeutic goods will remain.

2.2 Current Market and Distribution

There are four multi-national companies that almost exclusively supply the total Australian and New Zealand market of FSMP-type products. There is minimal local manufacture as the industry estimates that 99% of FSMP are imported. Products are mainly manufactured in either the European Union (including UK) or the United States of America. The market is estimated at approximately $A40 million per annum for Australia and between NZ$5 million and NZ$8 million per annum for New Zealand, which collectively on a world market scale is comparatively small.

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 formulated high energy / high protein supplements being consumed in much higher volumes than highly specialised foods for rare disease states that may only be supplied to a very small number of people.

2.2.1 Australia

The majority of FSMP (90%) are provided through healthcare settings (e.g. public and private hospitals, nursing homes), under the supervision of health professionals such as dietitians, nurses or medical staff. The supply of FSMP to healthcare facilities most often occurs through either statewide or regional health service tendering procedures. Generally, tenders outline requirements for the supply of specific FSMP including composition and price.

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. 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. FSMP are currently not available through supermarkets or convenience stores. 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.

2.2.2 New Zealand

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 in pharmacies and similar to Australia, FSMP are currently not available through supermarkets or convenience stores.

The majority of foods for special dietary use 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 products via a prescription and this is one of the main reasons why over the counter sales are very low.

2.3 Previous Considerations of Foods for Special Medical Purposes

In June 1995 a Full Assessment Report for Proposal P49 – Formula Food 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 Proposal P242 therefore, has allowed for the formal abandonment of P49 and renewed consideration of FSMP in the context of the joint Australia/New Zealand food regulatory system.

3. Regulatory Problem

The regulation of FSMP in both Australia and New Zealand is unclear. The Code does not explicitly recognise FSMP and therefore unlike other foods, FSMP are not given any permissions for composition or specific labelling requirements. Because of this, the regulation of FSMP continues to be uncertain for:

- importers and local manufacturers of FSMP in complying with the Code;
- health professionals and consumers in being assured of appropriate and consistent information on the safe and effective use of FSMP; and
- Government in enforcing the Code.

This regulatory uncertainty, owing to the lack of specific regulations for FSMP, creates difficulties for enforcement agencies at the border and occasionally causes delays in the importation of FSMP.

By nature, FSMP are products specifically formulated for use under medical or other health professional supervision, for the dietary management of individuals with particular medical conditions. These vulnerable individuals rely either fully or partially on FSMP to meet their specific nutritional requirements that cannot be satisfied by a normal diet. It is therefore essential that FSMP are both safe and effective in meeting the needs of the target population. There are also potential risks to both the target and non-target population if these products are consumed inappropriately. However, as FSMP are generally consumed under the direct supervision of a health professional, and are unlikely to be accessed or consumed by the general population, these risks are presumed to be small.

4. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in Section 10 of the FSANZ Act. 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, FSANZ 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;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The specific objectives of Proposal P242 are to:

- protect public health and safety, particularly by ensuring the safe and appropriate use of FSMP;
- develop harmonised food regulations applying to FSMP in Australia and New Zealand; and
- provide health professionals and consumers with sufficient information to make choices about the safe and effective use of FSMP.

5. Issues

The development of regulations for FSMP requires consideration of a number of existing regulatory principles inherent to the Code as well as issues raised through stakeholder consultation.

5.1 General Purpose versus Special Purpose Foods

The purpose of foods, as standardised by the Code, is considered as either 'general purpose' or 'special purpose', and the regulatory control varies according to the purpose.

FSANZ has defined special purpose foods 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[1] but until now stopped short of the Codex definition, which continues *...and/or specific diseases and disorders and which are presented as such*. The definition is firmly grounded within a traditional nutrition paradigm that has as its basis, dietary adequacy to support physiological need and maintenance of health.

Special purpose 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 (solid food) diet. The regulation of special purpose foods allows for formulations that ensure an appropriate and adequate nutrient content and in general, the greater the contribution of a food to overall dietary intake, the greater the need to provide appropriate regulatory measures to mitigate the risk to the target group(s) from inappropriate consumption. Therefore, the regulation of special purpose foods is usually by discrete standards that include exemptions from, or overriding provisions for, generic standards as appropriate.

Part 2.9 - Special Purpose Foods of the Code contains standards for infant formula products (Standard 2.9.1), foods for infants (Standard 2.9.2), formulated meal replacements and supplementary foods (Standard 2.9.3), and formulated supplementary sports foods (Standard 2.9.4), with the latter currently under review (Proposal P236).

As FSMP target a vulnerable section of the population that have particular nutritional requirements because of medical conditions or disability, it is appropriate that the definition of special purpose foods, as currently applied to the Code, be broadened to include FSMP. Therefore, a revised definition for special purpose foods, as per the Codex definition of Foods for Special Dietary Uses, has been adopted as follows:

[1] Section 2.1 Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses, CODEX STAN 146-1985

foods that are specially processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological need and/or specific diseases and disorders and which are presented as such.

FSANZ proposes to include this definition as part of a commentary to Part 2.9 in the Code. The purpose of this commentary is to explicitly acknowledge the underpinning regulatory principles for special purpose foods that consider not only the primary objective of safety but also effectiveness. Efficacy is an important principle for special purpose foods as they relied upon in meeting the particular nutritional requirements of the intended at-risk target group(s).

5.1.1 Conclusion

The definition of special purpose foods, as currently applied to the Code, be broadened to incorporate FSMP and a discrete standard for FSMP be included in *Part 2.9 Special Purpose Foods* of the Code.

5.2 Definition of FSMP

No definition for FSMP currently exists within the Code. Based on international Codex standards, 'foods for special dietary uses' have a sub-classification of 'foods for special medical purposes'[2] 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 Codex definition for foods for special medical purposes is:

a category of foods for special dietary uses which are specially processed or formulated and presented 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.

The global nature of the FSMP market is an important factor in defining FSMP for the Australia/New Zealand context as any major deviation away from the Codex definition could potentially jeopardise trade of FSMP to the local market, which could put at risk the nutritional health of individuals with particular medical conditions.

The Codex definition is an internationally recognised definition that covers the scope and intended use of FSMP and is the basis for other international food regulations eg. EC Directive, and thus provides consistency with these regulations. The Codex definition could be readily adapted into Australia/New Zealand regulations for FSMP. Furthermore, the majority of submitters commenting on the definition of FSMP supported adopting the Codex definition.

[2] Codex Standard for the Labelling of and claims for Foods for Special Medical Purposes, (CODEX STAN 180-1991)

5.2.1 Conclusion

The Codex definition for FSMP be adopted and incorporated into the Code as a means of providing consistency with international regulations.

5.3 Distribution and Access

There are currently no prohibitions on where FSMP can be sold in either Australia or New Zealand. Individuals requiring FSMP in both Australia and New Zealand access products through healthcare institutions, or purchase them either from pharmacies or directly from suppliers. In New Zealand the vast majority of FSMP are obtained via prescription, whereas in Australia consumers can obtain most FSMP without prescription, although this generally occurs under some level of health professional supervision.

To date, there appears little evidence to suggest that there are problems and an increased risk to public health and safety from the current unrestricted access to FSMP.
Given the nature and relative costs of FSMP, there appears little incentive for non-target groups to consume these products, although there are potential risks in the unsupervised and inappropriate use of formulas for very low energy diets (VLED).

Where there may be significant public health and safety concerns, the FSANZ Act has the power to restrict access to certain types of foods. Although, given the apparently successful operation of the current system, there is no need to invoke the power of the FSANZ Act and change the current access arrangements for FSMP. However, as a means of deterring inappropriate use of FSMP, the mandatory advisory labelling of products as for 'use under medical supervision' (see Section 5.5) is considered an appropriate risk management strategy.

5.3.1 Conclusion

It is not considered necessary to invoke the FSANZ Act to change the current access arrangements for FSMP. The mandatory advisory labelling of products as for 'use under medical supervision' is considered a suitable risk management strategy to deter inappropriate use.

5.3.2 Advertising of FSMP

The general principles to the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180 – 1991) state that the advertising of FSMP to the general public should be prohibited. Internationally, FSANZ is aware of regulations that restrict the advertising of FSMP including VLED to the general public[3].

In the context of Australia and New Zealand, FSANZ is unaware of any evidence that the FSMP industry is unethically advertising products to the general public. Currently most FSMP companies target advertising to health professionals through professional journals and newsletters. This is appropriate, as health professionals require access to information on FSMP to make clinical decisions, whereas consumers should be informed and guided on the use of FSMP by a health professional.

[3] Canadian *Food and Drug Regulations 1954*, B.24 300

There are, however, significant public health and safety risks associated with the unsupervised and inappropriate use of FSMP by consumers, particularly for VLED given the increasing rates of morbid obesity and high rates of self-treatment.

There was also support from submitters, including industry and health professionals, for a prohibition on the direct promotion of FSMP to consumers. The FSANZ Act allows for restrictions on the publications that may contain advertisements for particular foods. Therefore, FSANZ intends to restrict the advertising of FSMP to the general public by permitting the promotion of FSMP only through health professional publications.

5.3.3 Conclusion

To restrict the advertising and promotion of FSMP to the general public by permitting the advertisement of FSMP only in health professional publications.

Submitters to Proposal P242 are encouraged to comment on the following questions:

- Does the term 'health professional publications' suitably reflect the range of publications that should be permitted to contain advertisements for FSMP?
- If not, is there another term that better reflects the type of publications that should contain advertising on FSMP?

5.4 Composition of FSMP

FSANZ has made an assessment of the regulatory requirements for the composition of FSMP as at Attachment 2. This assessment proposes the adoption of a general principle to guide the formulation of FSMP in addition to a prescribed set of compositional requirements specific to the different types of FSMP. Nutritionally complete FSMP are classified into two separate subcategories: non-VLED and VLED. Submitters are encouraged to comment on the proposed compositional requirements for FSMP by responding to questions in Attachment 2.

A summary of the recommendations on the proposed compositional requirements for FSMP is provided below.

5.4.1 General Compositional Requirements

- Adaptation of the Codex general principle for FSMP[4] to guide the formulation of FSMP. This principle requires the formulation of FSMP to be based on sound medical and nutritional principles and that their use be demonstrated, by scientific evidence, to be safe and effective in meeting the nutritional requirements of the persons for whom they are intended.
- Harmonisation wherever possible with the compositional requirements for FSMP according to European Union directives.

[4] Section 3 Codex Standard for the Labelling of and claims for Foods for Special Medical Purposes, (CODEX STAN 180-1991)

- Permission for the addition of vitamins, minerals, trace elements, amino acids, nucleotides and other nutritive substances such as carnitine, taurine, inositol and choline.

- Adaptation of the permitted forms of nutritive substances as per the EC Directive 2001/15/EC (PARNUTS) (see Table 1 of the Appendix to Attachment 2).

5.4.2 Compositional Requirements Specific to the Different Types of FSMP:

- For nutritionally incomplete FSMP:

  - no prescribed macronutrient requirements;
  - no prescribed minimum micronutrient requirements; and
  - prescribed maximum vitamins, minerals and trace elements requirements as stated in Table 2 of the Appendix to this Attachment.

- For nutritionally complete non-VLED FSMP:

  - no prescribed macronutrient levels;
  - prescribed maximum and minimum vitamins, minerals and trace elements requirements as stated in Table 2 of the Appendix to this Attachment; and
  - permission to deviate from the minimum requirements for sodium and potassium consistent with the intended purpose of the FSMP.

- For VLED (in a recommended daily quantity):

  - a prescribed energy, protein and carbohydrate content; and
  - prescribed maximum and minimum levels of vitamins, minerals and trace elements (Table 3 of the Appendix to Attachment 2).

5.5 Labelling of FSMP

An assessment of the regulatory requirements for the labelling of FSMP is at Attachment 3. The proposed labelling for FSMP allows for flexibility and consistency with international regulations where possible. Due to the current methods of distribution, the use of supporting product literature as a means of providing information required by generic labelling standards is not considered a suitable alternative to labelling. Therefore it is proposed that generic labelling information be required on the label of a food for special medical purpose. Submitters are encouraged to comment on this issue by responding to questions included in Attachment 3. A summary of recommendations for the labelling of FSMP is provided below.

5.5.1 Application of Generic Labelling Requirements.

- The majority of the generic labelling requirements in the Code to apply to FSMP including country of origin (Standard 1.1A.3), application of labelling (Standard 1.2.1), food identification and local supplier details (Standard 1.2.2), mandatory warning and advisory statements and declarations (Standard 1.2.3), ingredient labelling (Standard 1.2.4), date marking (Standard 1.2.5), directions for use and storage (Standard 1.2.6), and legibility requirements (Standard 1.2.9).

- The requirements of Standard 1.2.8 - Nutrition Information Requirements to not apply to FSMP except for:

  - definitions; and
  - claims for lactose and gluten.

- Exemption from the provisions of Standard 1.2.10 – Percentage Labelling of Characterising Ingredients.

5.5.2 Specific Labelling Requirements for all FSMP

- Inclusion of a mandatory advisory statement that FSMP are to be used only under medical supervision, preceded by words to the effect of "Importance Notice".

- Permission for the labelling of a statement on the condition, disease or disorder for which the FSMP has been specially formulated.

- For nutrition information requirements:

  - the declaration of a nutrition information statement that may be in the form of a table with: the energy content, protein, fat, carbohydrate, vitamin, mineral and other nutritive substance quantity expressed per 100 g or 100 mL as prepared; and
  - the number of servings per package and serving size.

5.5.3 Additional Labelling Specific to FSMP other than VLED

- The labels of FSMP other than VLED to contain a statement:

  - that the product poses a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the product is intended;
  - that the product is not for parenteral use;
  - that the product is or is not intended as the sole source of nutrition;
  - concerning the adequate precautions, known side effects, contraindications, and product-drug interactions;
  - specifying the nutrient(s) which have been modified relative to normal requirements; and
  - information, where appropriate, on the specific age group(s) for which a product is intended.

5.5.4 Additional Labelling Specific to VLED

- The labels of VLED to include:

  - the prescribed statement "for the dietary management of obesity";
  - reference to the importance of maintaining an adequate daily fluid intake;
  - a statement that the product may be unsuitable for use by pregnant, nursing and lactating women or by infants, children, adolescents and elderly; and
  - a statement on the recommended daily quantity of the product to be consumed, with the quantity to be established by the manufacturer of the VLED.

5.6 Application of Generic Standards

In addition to the generic standards in Chapter 1 of the Code that relate to compositional and labelling requirements (see Sections 5.4 and 5.5), there are a number of other generic standards that are relevant in the development of regulations applying to FSMP. These include certain standards from the following sections of the Code:

- Part 1.3 Substances Added to Foods;
- Part 1.5 Foods Requiring Pre-Market Clearance; and
- Part 1.6 Microbiological and Processing Requirements.

5.6.1 Food Additives and Processing Aids

A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more technological functions specified in Schedule 5 of Standard 1.3.1 - Food Additives of the Code. A food additive may only be added to food where expressly permitted in Standard 1.3.1 and in order to achieve an identified technological function according to Good Manufacturing Practice.

Information provided by a representative body of the FSMP industry, the Australia New Zealand Enteral Nutrition Manufacturers Association (ANZENMA), indicated that permission for all food additives listed in Schedule 2, Standard 1.3.1 would be required for use in FSMP with the exception of the following functional groups: flavour enhancers, foaming agents, glazing agents, humectants, preservatives, propellants and raising agents.

The additives currently listed in Schedule 2 may generally be added to processed foods to perform a technological function provided that the proportion of the additive does not exceed the maximum level necessary to achieve one or more technological functions under conditions of Good Manufacturing Practice (GMP).

Therefore, consistent with the Code and the objectives of the reviewed food additive permissions contained therein, it is proposed that permission for all Schedule 2 additives be provided for FSMP. It is understood that some of the functional groups of additives listed in Schedule 2 were not requested by industry, however they would not have a reason or a permission to be added to FSMP if they did not serve a technological function in that food. It is considered that the use of all requested additives are technologically justified in Schedule 2 of Standard 1.3.1 for FSMP manufacturing.

ANZENMA also requested for consideration in Proposal P242 permissions for colours and colour fixatives listed in Schedule 3 and 4 for use in FSMP. The colours and colour fixatives listed in these Schedules are generally permitted in processed foods to GMP. Therefore, consistent with the Code and the objectives of the reviewed food additive permissions contained therein, permission for all Schedule 3 and 4 additives be provided for FSMP.

ANZENMA further requested for consideration in Proposal P242 permission for the preservatives – methylparaben, sorbic acid and its salts, benzoic acid and its salts and tertiary butylhydroquinone for use in FSMP.

These additives currently require permissions outside of GMP in Schedule 1 of Standard 1.3.1, and an assessment of the maximum permitted levels that should be applied to these additives is needed before any permission can be provided. The assessment would require examining the expected dietary exposure to the additive, a toxicological assessment to determine safety and an assessment of information to be provided by industry on the intended levels of use of the additives in the food products to achieve the preservative function. FSANZ intends to work with the FSMP industry to conduct this assessment as part of the Final Assessment for P242.

Under Standard 1.3.3 – Processing Aids, a substance is prohibited for use as a processing aid unless the provisions in this standard give explicit permission to do so. ANZENMA has not commented on the provisions for processing aids in the Code, and it is anticipated that the FSMP industry will not have any technological need for the use of processing aids outside of the current permissions.

Conclusion

The food additives permissions listed in Schedules 2, 3 and 4 of Standard 1.3.1 and the permissions for processing aids in Standard 1.3.3 are considered applicable to FSMP. The request by the FSMP industry for the inclusion of additional food additive provisions in Schedule 1 of Standard 1.3.1 requires further assessment before such permissions can be given. This assessment will be conducted during the Final Assessment stage for P242.

5.6.2 Foods Requiring Pre-market Clearance

Part 1.5 of the Code contains standards for foods requiring pre-market clearance, namely:

- Standard 1.5.1 – Novel Foods;
- Standard 1.5.2 – Foods Products Using Gene Technology; and
- Standard 1.5.3 – Irradiation of Food

These Standards require foods and ingredients that are either novel or produced using gene or irradiation technologies to be approved as safe for consumption prior to sale. They also contain, where prescribed, certain labelling requirements.

There are no apparent reasons why FSMP should be exempted from the requirements of these standards, particularly given the formulated nature of the products involved and their targeted use by vulnerable individuals. FSMP, like all other foods, should meet the requirements of these standards. Therefore, FSMP are expected to comply with the requirements of the Code in respect of novelty and the use of gene and irradiation technologies.

Conclusion

FSMP be required to comply with the standards requiring pre-market clearance for novel foods, foods produced using gene technology and irradiated foods.

5.6.3 Microbiological Standards

FSMP may be the sole source of nutrition for "at risk" individuals and therefore it is critical that these products are of a high microbiological quality.

FSMP include ready-to-use liquid products and powdered formulas. Ready-to use liquid products are commercially sterile and if handled and prepared hygienically, pose no particular microbiological concern. Powdered products pose a higher microbiological risk than commercially sterile liquid products, as powdered products cannot be produced to be commercially sterile. However, a high microbiological quality should be achieved through adherence to good manufacturing and hygienic practices at the manufacturing facility. Microbiological testing should provide an additional check on the production systems in place. Guidance on the handling of these products after opening and subsequent use (such as storage instructions and keeping time) should be provided.

A full microbiological evaluation for FSMP is provided at Attachment 4.

Recommendation

The control over the microbiological quality and safety of FSMP products is achieved primarily through strict adherence to good manufacturing and hygienic practices by industry.

6. Regulatory Options

The five regulatory options as originally identified at Initial Assessment have been refined. The option of providing no specific standard(s) for FSMP in the Code (Option 2 at Initial Assessment) but applying generic standards i.e. as is the situation for general purpose foods, was considered not viable due to the specialised purpose and unique properties of FSMP that distinguishes them from general purpose foods. Similarly, following consideration of submitter's comments and the difficulties associated with establishing appropriate infrastructure supports, the other proposed options involving co-regulation (Option 3 at Initial Assessment) and pre-market notification (Option 5 at Initial Assessment) were also assessed as impractical, and not considered further.

Therefore, two options are now proposed at Draft Assessment. They are:

6.1 Option 1 – Maintain status quo

Maintenance of the status quo i.e. no specific regulation of FSMP in the Code and therefore no overt recognition of FSMP under food law in either Australia or New Zealand.

6.2 Option 2 – Regulation by a discrete standard in the Code

Under this option, a discrete standard for FSMP would be included in Part 2.9 - Special Purpose Foods of the Code together with exemptions from generic standards as appropriate. The standard would contain the specific provisions for the composition and labelling of FSMP, with a level of prescription commensurate with the assessed level of risk.

7. Impact Analysis

7.1 Affected Parties

The parties affected by this proposal are: **consumers** with medical conditions including very vulnerable groups such as the disabled, frail aged and chronically ill; Australian and New Zealand **importers and manufacturers** of FSMP; and the **governments** of New Zealand, the States and Territories and the Commonwealth of Australia.

7.2 Cost-Benefit Assessment of Regulatory Options

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

7.2.1 Option 1 - Maintain Status Quo

Under this option there would be no change to the current regulatory situation for FSMP.

It is likely that **consumers** will be unaware of any impact of this option, as it is expected that consumers will continue to access the current range of products, some of which are only consumed by a small number of individuals with very special dietary requirements. They may however experience possible interruptions to supply, exposing consumers to higher risk, due to products being withheld at the border as a result of the regulatory uncertainty for enforcement: although, this is known not to occur often.

As the vast majority of products are imported from either the European Union or the United States of America, under this option the regulatory requirements of the exporting market overseas will continue to provide adequate public health and safety protection for the Australian and New Zealand population. However, some **consumers** may perceive the lack of specific domestic regulations as poor assurance of the protection of health and safety for consumers, who are mostly vulnerable population groups.

No change to the current regulatory situation will allow **industry** to continue local manufacture, albeit minimal, and importation of currently available products as well as new FSMP products. Nevertheless, the lack of specific regulations for FSMP means that there is no guidance for **industry** in complying with the Code, and there is greater likelihood that the supply of FSMP products will be interrupted by enforcement activities, creating greater expense for **industry**.

By maintaining the status quo it is likely that the **government** health care system will benefit by the continued access to FSMP products. The uncertainty caused by the lack of specific recognition of FSMP in the Code will remain however, and this will continue to cause difficulties for **government** enforcement agencies, potentially resulting in the greater use of resources.

7.2.2 Option 2 - Regulation by a discrete standard in the Code.

Option 2 allows for the harmonisation of regulations between Australia and New Zealand as well as, where appropriate, harmonisation with international regulations, thereby providing greater clarity in the regulatory environment.

This option provides **consumers** with continued access to and greater assurance of safe, quality products but also ensures provision of consistent product information, labelling and use of claims to allow for the safe and effective use of FSMP in the Australia/New Zealand context. There is a risk however that too stringent or prescriptive regulation, in comparison to overseas regulations, may potentially inhibit trade and prevent **consumers** with medical conditions from accessing products that benefit their dietary management.

For **industry**, there is likely to be significantly less confusion under Option 2, as clear regulations would provide certainty of compliance including for new innovative products.

Moreover the clarity of regulations may make enforcement easier for **governments**, thereby using fewer resources, and is likely to minimise delays with the importation of FSMP resulting in less expense to **industry**.

Depending on the degree of deviation from existing international regulations, there may be increased costs to **industry** associated with necessary reformulation or labelling changes. Industry has claimed that the cost in complying with detailed labelling requirements would result in an additional $A 2.5-3.0 million per year. This cost would be incurred if individual product units had to be relabelled following importation into Australia / New Zealand. In addition, reformulating a product brand to meet specific compositional requirements would cost approximately $A 55 000 (due to production trials). For brands produced in low volumes (stated as 5000 units) the cost per unit could be greater. In some cases this may mean that products would be withdrawn from the local market, as reformulation and relabelling would be seen by **industry** as unprofitable. Furthermore, any costs resulting from manufacturer/importer compliance to new regulatory measures would be passed onto the community/**consumers** through higher costs associated with health care system (e.g. hospitals, PHARMAC).

FSANZ has not yet examined in detail the costs as claimed by industry. The costs seem high but could be at the high end of a reasonable range. Therefore FSANZ intends to consult further with **industry** to clarify the anticipated costs associated with Option 2.

It is expected however that the regulations developed under option 2 will draw heavily on internationally recognised regulations, such as Codex, thereby reducing the likelihood of imposing prohibitive compliance costs and jeopardising trade for **industry**, and maintaining community/**consumer** access to reasonably priced products.

Submitters to Proposal P242 are encouraged to comment on the following questions:

- What are the expected costs/benefits to stakeholders of the proposed regulatory measures under Option 2 i.e. draft Standard 2.9.5 and application of generic standards as proposed in this Draft Assessment Report?

- In particular, what are the expected costs to industry of the proposed regulatory measures under Option 2?

Please provide quantitative data (including details of calculations), where possible, to support your response.

8. Consultation

8.1 Public Consultation

In October 2001, FSANZ released for public consultation an Initial Assessment Report for Proposal P242. In response, 26 submissions from various stakeholder groups were received. A summary of submitter comments is at Attachment 5. The comments and information provided in submissions has assisted with the preparation of this Draft Assessment Report.

Below is a brief summary of submitter comments and views on 3 key issues in the regulation of FSMP.

8.1.1 Regulatory Options

There was a wide range of variation in opinion on this issue, with all options proposed at Initial Assessment, except Option 1 – maintenance of status quo - receiving some degree of support. Industry was more in favour of minimal regulations (e.g. Option 2), while consumers / government submitters favoured more detailed, comprehensive regulations (e.g. Options 4 and 5). Therefore, there was no consensus on a preferred option, with differences appearing between and within the various stakeholder groups.

8.1.2 Composition

Industry was strongly opposed to the regulation of the composition of FSMP as they maintain that FSMP already meet international regulations and that manufacturing to a specific composition is unviable and would result in product removals from the local market. There was support for setting compositional requirements from consumers/government submitters on the basis of adequate protection of public health and safety.

8.1.3 Labelling

Industry supported including very few labelling provisions and for flexibility to meet international labelling requirements. Health professional, consumer and government submitters were in favour of applying the majority of generic requirements in the Code to FSMP. The ability of FSMP to make reference to disease states was given widespread support from all submitters commenting on this issue.

8.2 External Advisory Group

Following the next public consultation period, FSANZ anticipates establishing an External Advisory Group (EAG) with representation from key stakeholder groups. The EAG will consider and provide advice on the issues raised in response to this Draft Assessment Report, particularly in regards to the preferred regulatory option and proposed draft standard for FSMP, and thereby assist in the preparation of the Final Assessment for Proposal P242. Consequently, FSANZ would welcome as part of submissions to this Draft Assessment expressions of interest from stakeholder groups in participating in an EAG.

8.3 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, FSANZ 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). Therefore, FSANZ intends notifying the WTO of this Proposal particularly in regard to potential technical barriers to trade (TBT) matters.

9. Transitional Issues

In accordance with the transitional requirements for a proposal, which has reached Full (Draft) Assessment prior to the commencement of the FSANZ Act, the Full (Draft) Assessment has been reviewed. No relevant policy guidelines have been notified by the Ministerial Council and no additional submissions were received in response to the notice given under section 14A of the FSANZ Act.

10. Conclusion and Recommendation

By maintaining the status quo as per Option 1, there would be minimal impact on consumers except where imported FSMP may be delayed at national borders, and a continuing negative impact on industry and government caused by the regulatory uncertainty of FSMP.

When compared to Option 1, Option 2 provides greater benefits for all affected parties. Option 2 provides continued access to and greater assurance of safe, quality products but also ensures provision of consistent information in labelling to allow for the safe and effective use of FSMP in the Australia/New Zealand context. It allows for the harmonisation of the regulations for FSMP between Australia and New Zealand, and where appropriate international regulations, providing regulatory certainty for industry and government enforcement agencies and not unduly restricting trade.

Bearing in mind that further information from industry will be gathered on the expected cost of compliance, Option 2 – regulation by a discrete standard in the Code – is at this stage considered the more superior option in meeting the regulatory objectives. Therefore, it is recommended that the proposed amendments (Attachment 1), incorporating a draft standard for FSMP, be adopted into the Code for the following reasons.

- the inclusion of a standard for FSMP in the Code provides clear, harmonised regulations for FSMP in Australia and New Zealand;

- the explicit recognition of FSMP in the Code provides regulatory certainty for industry in complying with the Code and for government enforcement agencies;

- the regulation of FSMP provides assurance for consumers of protection of public health and safety, particularly for the target group being a vulnerable population;

- the inclusion of FSMP as 'special purpose foods' not only allows for regulatory consideration of the primary objective of safety but also efficacy;

- the inclusion of specific regulations for the composition and labelling of FSMP assures regulatory control which is commensurate with the assessed level of risk in Australia and New Zealand; and

- there is consistency with international regulations, wherever possible, to prevent potential barriers to trade that could jeopardise the supply of FSMP products to Australia/New Zealand.

11. Implementation and Review

Following the consultation period for this document, and further targeted consultation with stakeholders, particularly Industry, a Final Assessment Report for this Proposal will be prepared for consideration by the FSANZ Board. Following approval by the FSANZ Board, notification will be made to the Ministerial Council and it is anticipated that the proposed draft standard would come into effect shortly thereafter upon gazettal, subject to any request from the Ministerial Council for a review.

FSANZ expects that a transition period of two years would apply to allow manufacturers and importers of FSMP sufficient time to comply with the proposed new regulations for FSMP.

Monitoring and review of the impact of this regulatory change is likely to occur, in due course, as part of the general evaluation program that FSANZ has in place to evaluate the effectiveness of new standards.

12. Attachments

1. Draft Variation to the *Australia New Zealand Food Standards Code*
2. Assessment of Compositional Requirements for FSMP
3. Assessment of Labelling Requirements for FSMP
4. Microbiological Evaluation Report
5. Summary of Submissions

ATTACHMENT 1

Draft Variations to the *Food Standards Code*

To commence: on gazettal

[1] ***Volume 2 of the Food Standards Code*** *is varied by omitting* PART 2.9 *of the* Table of Contents*, substituting –*

PART 2.9 Special Purpose Foods

Standard 2.9.1	Infant Formula Products
Standard 2.9.2	Foods for Infants
Standard 2.9.3	Formulated Meal Replacements and Formulated Supplementary Foods
Standard 2.9.4	Formulated Supplementary Sports Foods
Standard 2.9.5	Foods for Special Medical Purposes

[2] ***Standard 1.1.1*** *of Volume 2 of the Food Standards Code is varied by omitting from the definition of* warning statement -

(e) subclauses 3(3) and 3(4) of Standard 2.9.4.

substituting –

(e) subclauses 3(3) and 3(4) of Standard 2.9.4; and
(f) clause 9 of Standard 2.9.5.

[3] ***Standard 1.1A.6*** *of Volume 2 of the Food Standards Code is varied by omitting subclause 2(3), substituting –*

(3) This Standard ceases to have effect two years from the commencement of Standard 2.9.5.

[4] ***Standard 1.2.8*** *of Volume 2 of the Food Standards Code is varied by omitting paragraph 3(n), substituting –*

(n) food standardised in Standard 2.9.5; or
(o) jam setting compound.

[5] ***Standard 1.2.10*** *of Volume 2 of the Food Standards Code is varied by omitting paragraph 2(4)(i), substituting –*

(i) food standardised in Standard 2.9.5; or
(j) alcoholic beverages standardised in Part 2.7 of this Code.

[6] ***Standard 1.3.1*** *of Volume 2 of the Food Standards Code is varied by –*

[6.1] *omitting* Item **13 FOODS INTENDED FOR PARTICULAR DIETARY USES**, *substituting –*

13 SPECIAL PURPOSE FOODS

[6.2] *inserting in Schedule 1 after Item 13.4.2 –*

13.5 Foods for special medical purposes*

[7] ***Volume 2 of the Food Standards Code*** *is varied by inserting after* PART 2.8 –

COMMENTARY TO PART 2.9

The Standards in Part 2.9 recognise special purpose foods in the food supply, which differ from general foods because they provide nutrition to at-risk groups whose dietary requirements cannot always be satisfied by a normal (solid food) diet.

Special Purpose Foods are foods that have been specially processed or formulated to satisfy particular dietary requirements, which exist because of a particular physical or physiological need, and / or specific diseases and disorders. In this case, 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 occasion use of special purpose foods.

Special purpose foods may be permitted to contain added nutritive substances (as defined under Standard 1.1.1) that are not permitted for addition to general foods.

The compositional provisions in this Standard for special purpose foods are complemented by additional labelling requirements to advise on the safe and appropriate use of such foods including, where necessary, labelling requirements for use under health professional supervision and advice where relevant against inappropriate consumption and use.

[8] ***Volume 2 of the Food Standards Code*** *is varied by inserting after* Standard 2.9.4 –

STANDARD 2.9.5

FOODS FOR SPECIAL MEDICAL PURPOSES

Purpose

This Standard provides for the compositional (including nutritional) and labelling requirements of foods specially formulated for the dietary management of individuals with certain medical conditions, disabilities, or disease states. Foods regulated in this Standard are characterised by the need for medical supervision in their use. This Standard does not apply to Infant Formula Products as they are regulated by Standard 2.9.1, nor does it apply to Formulated Meal Replacements and Formulated Supplementary Foods as they are regulated by Standard 2.9.3.

The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. The use of these foods should have been demonstrated, by scientific evidence, to be safe and effective in meeting the particular nutritional requirements of the person for whom the food is intended.

Standard 1.1.1 defines 'nutritive substances' and 'average quantity' for the purposes of this Code. General labelling requirements are contained in Part 1.2. Standard 1.3.4 contains specifications for permitted nutritive substances and particular fatty acids. Standard 1.5.1 contains provisions relating to the sale of novel foods and novel food ingredients.

Table of Provisions

1 Interpretation
Division 1 – Composition
2 General restrictions on composition
3 Permitted nutritive substances
4 Additional compositional requirements for VLED
Division 2 – Advertising and Labelling
5 Prohibition on advertising
6 Date marking
7 Application of Standard 1.2.8 and declaration of nutrition information
8 Mandatory warning statement
9 Mandatory advisory statements
10 Additional labelling requirements
Schedule 1 Nutritive substances and their permitted forms
Schedule 2 Minimum and maximum vitamin and mineral amounts for non – VLED nutritionally complete foods for special medical purposes
Schedule 3 Minimum and maximum vitamin and mineral amounts for VLED
Schedule 4 Prescribed method of analysis for protein

Clauses

1 Interpretation

(1) In this Standard -

foods for special medical purposes means a category of special-purpose foods specifically processed or formulated and presented for the dietary management of persons for use solely under medical supervision. Foods for special medical purposes are those intended for –

(a) the exclusive or partial feeding of persons with limited or impaired capacity to take, digest, absorb or metabolise ordinary food or certain nutrients in the food; or

(b) persons who have other special medically-determined nutrient requirements whose dietary management cannot be achieved solely by modification of the normal diet or by using other special-purpose foods whether or not combined with the normal diet.

nutritionally complete means a formulation which may constitute the sole source of nutrition for the persons for whom the formulation is intended when it is used in accordance with the manufacturer's directions.

formulas for very low energy diets (VLED) means nutritionally complete formulas presented for use in energy restricted diets for the dietary management of obesity.

protein means protein which has a protein digestibility – corrected amino acid score of 1 when determined by the method prescribed in Schedule 4.

(2) Foods for special medical purposes do not include infant formula products or formulated meal replacements and formulated supplementary foods standardised in this Code.

Division 1 - Composition

2 General restrictions on composition

A vitamin, mineral or other nutritive substance must not be added to foods for special medical purposes unless expressly permitted in this Standard.

3 Permitted nutritive substances

(1) Any nutritive substance listed in column 1 of Schedule 1 to this Standard may be added to foods for special medical purposes provided the nutritive substance is in one or more of the corresponding forms listed in column 2 of Schedule 1.

(2) Subject to subclause (3), nutritionally complete foods for special medical purposes, other than formulas for very low energy diets, may contain vitamins and minerals only in the corresponding amount range specified in Schedule 2 to this Standard.

(3) The composition of nutritionally complete foods for special medical purposes, other than formulas for very low energy diets, may vary in the minimum amount of sodium and potassium specified in Schedule 2 to satisfy particular medical conditions.

(4) Foods for special medical purposes, other than those that are nutritionally complete, may contain vitamins and minerals only in an amount no more than that specified in column 3 of Schedule 2 of this Standard.

(5) Formulas for very low energy diets may contain vitamins and minerals only in the corresponding daily amount range specified in Schedule 3 to this Standard.

(6) L-amino acids listed in Schedule 1 may be added to formulas for very low energy diets only in an amount necessary to improve protein quality.

4 Additional compositional requirements for VLED

(1) Formulas for very low energy diets must contain no less than 1880kJ and no more than 3350kJ in a recommended daily quantity of the food.

(2) Formulas for very low energy diets must contain, in a recommended daily quantity of the food, no less than –

(a) 3g linoleic acid and 0.5g alpha-linolenic acid, and have a ratio of linoleic acid to alpha-linolenic acid of between 5 and 15; and
(b) 50g carbohydrate; and
(c) 50g protein.

Division 2 – Advertising and Labelling

5 Prohibition on advertising

(1) Subject to subclause (2), foods for special medical purposes must not be advertised.

(2) Foods for special medical purposes may be advertised in health professional publications.

6 Date marking

Paragraph 2(1)(c) of Standard 1.2.5 does not apply to foods for special medical purposes.

7 Application of Standard 1.2.8 and declaration of nutrition information

(1) Subject to subclause (2), Standard 1.2.8, other than clauses 1, 2, 15 and 16, does not apply to foods for special medical purposes.

(2) Clauses 15 and 16 of Standard 1.2.8 apply to foods for special medical purposes as prepared for consumption according to directions.

(3) The label on a package of foods for special medical purposes must include, in the form of a table or otherwise, the following information –

(a) the average energy content expressed per 100g or 100mL; and
(b) the average quantity of protein, fat and carbohydrate in the food, expressed per 100g or 100mL; and
(c) the average quantity of vitamins and minerals in the food expressed per 100g or 100mL; and
(d) the average quantity of other nutritive substances where added to the food, expressed per 100g or 100mL; and
(e) the number of servings per package and serving size.

(4) In the case of foods for special medical purposes in a powdered or concentrated form, the information required in paragraphs 7(3)(a), (b), (c) and (d) must be expressed per 100g or 100mL of the product as prepared for consumption according to directions.

8 Mandatory warning statement

The label on a package of food listed in column 1 of the Table to this clause must include the warning statement listed in column 2 of the Table.

Table to clause 8

Column 1	Column 2
Formulas for very low energy diets	For the dietary management of obesity

9 Mandatory advisory statements

The label on a package of food listed in column 1 of the Table to this clause must include the corresponding advisory statements listed in column 2 of the Table.

Table to clause 9

Column 1	Column 2
Foods for special medical purposes	Statement to the effect – Important notice: Foods for special medical purposes are to be used only under medical supervision
Formulas for very low energy diets	Statements to the effect that - 1. the product may not be suitable for pregnant, nursing or lactating women or by infants, children, adolescents or the elderly; and 2. it is important to maintain an adequate daily fluid intake while using the product.
Foods regulated in this Standard, other than formulas for very low energy diets	Statements to the effect that - 1. the product poses a health hazard when consumed by persons who do not have a disease, disorder or medical condition for which the product is intended; and 2. the product is not for parenteral use; and 3. the product is intended/not intended (as the case may be) as the sole source of nutrition.

10 Additional labelling requirements

(1) The label on a package of foods for special medical purposes, other than formulas for very low energy diets must include a statement –

(a) advising of any necessary precautions, side-effects, contraindications and potential interactions with drugs, in consuming the food; and

(b) advising where the product has been formulated for a specific age group.

(2) The label on a package of formula for very low energy diets must include a statement of the recommended daily consumption amount.

(3) Where foods for special medical purposes have been specifically formulated for a condition, disease or disorder, the label on the package of the food must include a statement indicating the condition, disease or disorder, and any nutritional modifications for which the food has been specifically formulated.

Editorial note:

The majority of Standard 1.2.8 does not apply to foods for special medical purposes – however – see clause 7 of this Standard.

The requirement to declare the characterising ingredients of food in Standard 1.2.10 does not apply to foods for special medical purposes.

SCHEDULE 1

NUTRITIVE SUBSTANCES AND THEIR PERMITTED FORMS

Column 1	Column 2
Nutritive Substance	**Permitted Forms**
Vitamins	
Vitamin A	Retinol Forms
	Vitamin A (retinol)
	Vitamin A acetate (retinyl acetate)
	Vitamin A palmitate (retinyl palmitate)
	Carotenoid Forms
	beta-carotene
Thiamin	Thiamin hydrochloride
	Thiamin mononitrate
Riboflavin	Riboflavin
	Riboflavin 5'-phosphate sodium
Niacin	Niacinamide (nicotinamide)
	Nicotinic acid
Vitamin B_6	Pyridoxine 5'-phosphate
	Pyridoxine dipalmitate
	Pyridoxine hydrochloride
Folate	Pteroylmonoglutamic acid
Vitamin B_{12}	Cyanocobalamin
	Hydroxocobalamin
Biotin	d-biotin
Pantothenic Acid	d-pantothenate calcium
	Dexpanthenol
	d-pantothenate sodium
Vitamin C	L-ascorbic acid
	Ascorbyl palmitate
	Calcium L-ascorbate
	Potassium L-ascorbate
	Sodium L-ascorbate
Vitamin D	Vitamin D2 (ergocalciferol)
	Vitamin D3 (cholecalciferol)
Vitamin E	d-alpha-tocopherol
	dl-alpha-tocopherol
	d-alpha-tocopheryl acetate
	dl-alpha-tocopheryl acetate
	d-alpha-tocopheryl acid succinate
Vitamin K	Phylloquinone
Minerals	
Calcium	Calcium carbonate
	Calcium chloride
	Calcium citrate
	Calcium gluconate
	Calcium glycerophosphate
	Calcium lactate
	Calcium hydroxide
	Calcium oxide
	Calcium phosphate, monobasic
	Calcium phosphate, dibasic
	Calcium phosphate, tribasic

Chromium	Chromium chloride
	Chromium sulphate
Copper	Copper lysine complex
	Cupric carbonate
	Cupric citrate
	Cupric gluconate
	Cupric sulphate
Fluoride	Potassium fluoride
	Sodium fluoride
Iron	Ferric ammonium citrate
	Ferric sodium diphosphate
	Ferric pyrophosphate
	Ferric saccharate
	Ferrous carbonate
	Ferrous citrate
	Ferrous gluconate
	Ferrous fumarate
	Ferrous lactate
	Ferrous sulphate
	Iron, reduced (ferrum reductum)
Iodine	Potassium iodide
	Potassium iodate
	Sodium iodide
	Sodium iodate
Magnesium	Magnesium acetate
	Magnesium carbonate
	Magnesium chloride
	Magnesium citrate
	Magnesium gluconate
	Magnesium glycerophosphate
	Magnesium lactate
	Magnesium phosphate, dibasic
	Magnesium phosphate, tribasic
	Magnesium hydroxide
	Magnesium oxide
	Magnesium sulphate
Manganese	Manganese carbonate
	Manganese chloride
	Manganese citrate
	Manganese gluconate
	Manganese glycerophosphate
	Manganese sulphate
Molybdenum	Ammonium molybdate
	Sodium molybdate
Phosphorus	Calcium glycerophosphate
	Calcium phosphate, monobasic
	Calcium phosphate, dibasic
	Calcium phosphate, tribasic
	Magnesium phosphate, dibasic
	Magnesium phosphate, tribasic
	Potassium glycerophosphate
	Potassium phosphate, monobasic
	Potassium phosphate, dibasic
	Potassium phosphate, tribasic
	Sodium phosphate, monobasic
	Sodium phosphate, dibasic

	Sodium phosphate, tribasic
Potassium	Potassium bicarbonate
	Potassium carbonate
	Potassium chloride
	Potassium citrate
	Potassium gluconate
	Potassium glycerophosphate
	Potassium hydroxide
	Potassium lactate
	Potassium phosphate, monobasic
	Potassium phosphate, dibasic
	Potassium phosphate, tribasic
Sodium	Sodium bicarbonate
	Sodium carbonate
	Sodium chloride
	Sodium citrate
	Sodium gluconate
	Sodium lactate
	Sodium hydroxide
	Sodium phosphate, monobasic
	Sodium phosphate, dibasic
	Sodium phosphate, tribasic
Selenium	Sodium hydrogen selenite
	Sodium selenate
	Sodium selenite
Zinc	Zinc acetate
	Zinc carbonate
	Zinc chloride
	Zinc citrate
	Zinc gluconate
	Zinc lactate
	Zinc oxide
	Zinc sulphate
Other Nutritive Substances	
Amino Acids	Cystine
	Glycine
	L-alanine
	L-arginine
	L-aspartic acid
	L-citrulline
	L-cysteine
	L-histidine
	L-glutamic acid
	L-glutamine
	L-isoleucine
	L-leucine
	L-lysine
	L-lysine acetate
	L-methionine
	L-ornithine
	L-phenylalanine
	L-proline
	L-threonine
	L-tryptophan
	L-tyrosine
	L-valine

Carnitine	L-carnitine
	L-carnitine hydrochloride
Choline	Choline
	Choline bitartrate
	Choline chloride
	Choline citrate
Inositol	Inositol
Nucleotides	Adenosine 5'-monophosphate
	Adenosine 5'-monophosphate sodium salt
	Cytidine 5'-monophosphate
	Cytidine 5'-monophosphate sodium salt
	Guanosine 5'-monophosphate
	Guanosine 5'-monophosphate sodium salt
	Inosine 5'-monophosphate
	Inosine 5'-monophosphate sodium salt
	Uridine 5'-monophosphate
	Uridine 5'-monophosphate sodium salt
Taurine	Taurine

SCHEDULE 2

MINIMUM AND MAXIMUM VITAMIN AND MINERAL AMOUNTS FOR NON-VLED NUTRITIONALLY COMPLETE FOODS FOR SPECIAL MEDICAL PURPOSES

Column 1	Column 2	Column 3
Nutrient (unit)	**Minimum Amount / 100kJ**	**Maximum Amount / 100kJ**
Vitamin A (μg)	8.4 retinol equivalents	34 retinol equivalents
Thiamin (mg)	0.015	0.12
Riboflavin (mg)	0.02	0.12
Niacin (mg)	0.22 niacin equivalents	0.4 niacin equivalents
Vitamin B_6 (mg)	0.02	1.15
Folate (μg)	2.5	11.5
Vitamin B_{12} (μg)	0.017	0.17
Vitamin C (mg)	0.54	23
Vitamin D (μg)	0.12	0.57
Vitamin E (mg)	0.5 alpha-tocopherol equivalents per g of polyunsaturated fatty acids expressed as linoleic acid, but in no case less than 0.1mg alpha-tocopherol equivalents per 100kJ	11 alpha-tocopherol equivalents
Biotin (μg)	0.18	1.8
Pantothenic Acid (mg)	0.035	0.35
Vitamin K (μg)	0.85	5
Calcium (mg)	8.4	28.7
Magnesium (mg)	1.8	4
Iron (mg)	0.12	0.5
Phosphorus (mg)	7.2	46
Zinc (mg)	0.12	0.46
Manganese (mg)	0.012	0.126
Copper (μg)	15	114
Iodine (μg)	1.55	12.64
Chromium (μg)	0.3	3.6
Molybdenum (μg)	0.72	23
Selenium (μg)	0.6	4.6
Sodium (mg)	7.2	42
Potassium (mg)	19	70
Chloride (mg)	7.2	42.
Fluoride (mg)	No minimum set	0.11

SCHEDULE 3

MINIMUM AND MAXIMUM VITAMIN AND MINERAL AMOUNTS FOR VLED

Nutrient (unit)	Minimum Daily Amount	Maximum Daily Amount
Vitamin A (μg)	700 retinol equivalents	3000 retinol equivalents
Thiamin (mg)	1.10	No maximum set
Riboflavin (mg)	1.6	No maximum set
Niacin (mg)	18 niacin equivalents	35 niacin equivalents
Vitamin B_6 (mg)	1.5	100
Folate (μg)	200	1000
Vitamin B_{12} (μg)	1.4	No maximum set
Vitamin C (mg)	45	2000
Vitamin D (μg)	5.0	50
Vitamin E (mg)	10 alpha-tocopherol equivalents	1000 alpha-tocopherol equivalents
Biotin (μg)	15	No maximum set
Pantothenic Acid (mg)	3	No maximum set
Calcium (mg)	700	2500
Magnesium (mg)	150	350
Iron (mg)	16	45
Phosphorus (mg)	550	4000
Zinc (mg)	9.5	40.0
Manganese (mg)	1.0	11
Copper (mg)	1.1	10
Iodine (μg)	130	1100
Selenium (μg)	55	400
Molybdenum (μg)	No minimum set	2000
Sodium (mg)	575	No maximum set
Potassium (mg)	3100	No maximum set

SCHEDULE 4

PRESCRIBED METHOD OF ANALYSIS FOR PROTEIN

The protein digestibility-corrected amino acid score is to be determined by the method set out in section 8 of the *FAO (Food and Agriculture Organization) Food and Nutrition Paper No. 51 (1991) Protein quality evaluation,* Report of Joint FAO/WHO Expert consultation, FAO, Rome.

The data for determining the protein digestibility-corrected amino acid score may be derived from one or more of the following:

(i) the manufacturers analysis of the food; and
(ii) calculation from the actual quantity and proportion of amino acids in the ingredients used; and
(iii) calculation from generally accepted amino acid data.

Tables 8 and 11 of the *FAO (Food and Agriculture Organization) Food and Nutrition Paper No. 51 (1991) Protein quality evaluation,* Report of Joint FAO/WHO Expert consultation, FAO, Rome, may be used as a reference for selecting an appropriate true protein digestibility factor.

A true protein digestibility factor of 1 can be assigned to L-form amino acids in the calculation of the protein digestibility-corrected amino acid score.

ATTACHMENT 2

Proposal P242 - Foods For Special Medical Purposes (FSMP) Compositional Assessment

Foods for Special Medical Purposes (FSMP) are one of the most heavily formulated and modified categories of food available. These products need to be manufactured so that the composition, safety and efficacy are sufficient to meet the dietary needs of a consumer whose health is compromised.

The formulation of FSMP can vary significantly depending upon their intended use and can be classified into two main categories: those that may be used as the sole source of nutrition (nutritionally complete), and those that are only intended to supplement or partially replace the diet (nutritionally incomplete). The use of "may" in nutritionally complete refers to situations where small peripheral sources of nutrition may be included in the diet, e.g. additional fluids containing a small amount of minerals.

International Regulation of FSMP Composition

The compositional requirements of international regulations for FSMP vary in their range of provisions and degree of prescriptiveness.

Detailed compositional regulations for FSMP – excluding formulas for very low energy diets (VLED) – are provided in European and Canadian regulations [1,2]. European FSMP legislation distinguishes between three categories of products:

a) nutritionally complete that have a standard nutrient formulation and constitute the sole source of nourishment;
b) nutritionally complete that have a nutrient adapted formulation and constitute the sole source of nourishment; and
c) nutritionally incomplete that have either a standard formulation or nutrient adapted formulation and are not suitable for use as the sole source of nourishment.

All three categories must comply with compositional requirements for vitamins, minerals and trace elements expressed per 100 kJ; although the b) and c) categories can deviate from these requirements on a nutrient-by-nutrient basis where there is scientific evidence to support such deviation. Canadian regulations are similar to European legislation, differing only in that separate detailed compositional requirements are provided for supplementary FSMP (a class of nutritionally incomplete FSMP) in addition to compositional requirements for nutritionally complete formulas. Canadian regulations also allow for deviations from prescribed requirements where necessary to meet specific needs.

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1 European Commission Directive on dietary foods for special medical purposes (Directive 1999/21/EC).
2 Canadian *Food and Drug Regulations 1954*, Division 24 – Foods for Special Dietary Use; 'Formulated Liquid Diets' (B.24 100 – 103).

The United States [3] and Codex [4] regulations for FSMP do not provide specific compositional provisions but instead include a general principle that FSMP be formulated in a safe and efficacious manner that is consistent with their intended use. Codex, Europe and Canada also have specific regulations for VLED[5,6,7] which prescribe compositional requirements including minimum and maximum requirements for vitamins, minerals and trace elements, and minimum macronutrient levels. In all of these regulations, the compositional requirements are expressed as the total amount to be consumed over the course of a day from VLED, with additional labelling directions required for the quantity of VLED to be consumed on a daily basis.

Statutory Objectives as they Apply to the Composition of FSMP

When any variation to the *Australia New Zealand Food Standards Code* (the Code) is proposed, the primary objectives as laid down in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) must be considered. Of particular relevance to considerations on the composition of FSMP is the primary objective of "protection of public health and safety".

Public Health and Safety Risks for FSMP

The level of regulatory control over the composition of special-purpose foods varies according to the function 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 occasional ingredient composition, corresponding with the assessed level of risk.

A demonstrated safe and efficacious composition is essential as FSMP contribute to the diets of individuals who have a compromised health status. Applying detailed compositional restrictions to the entire range of FSMP would be inappropriate however, as the public health and safety risks associated with the composition of FSMP vary according to the product type. Some FSMP comprise a minor component of the diet, whereas others are used as a primary source of nutritional support. Applying an overly cautionary approach to all FSMP would also be impractical because almost the entire FSMP market is sourced from overseas, with the majority of products being manufactured in accordance with EC directives.

Therefore, in regulating the composition of FSMP it is proposed that a general principle be adopted to guide the formulation of all FSMP. Such a principle should capture the need for demonstrated safety and efficacy, and is best reflected by the part of the general principle in the Codex Standard for FSMP that relates to composition:

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3 United States of America federal legislation: the *Orphan Drug Amendments 1988*, and the *Nutrition Labeling and Education Act 1990*.

4 Codex Standard on the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991)

5 Codex Standard on Formula Foods for use in Very Low Energy Diets for Weight Reduction (CODEX STAN 203-1995)

6 EC Commission Directive on food intended for use in energy-restricted diets for weight reduction (Directive 96/8/EC)

7 Canadian *Food and Drug Regulations 1954*, Division 24 – Foods for Special Dietary Use; 'Foods Represented for Use in Very Low Energy Diets' (B.24 300 – 306)

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.

Nutritionally complete FSMP (including VLED) need to be nutritionally adequate for use as the sole source of nutrition, and have a high risk associated with their composition. Therefore, in addition to the general principle stated above, the setting of minimum levels for essential nutrients is proposed to manage the risks for these types of FSMP, and is a requirement consistent with EC directives.

As nutritionally incomplete FSMP only partially contribute to the diet, there is no health need to establish minimum compositional requirements beyond meeting the general principle. Nutritional adequacy can be obtained through the inclusion of other foods within the diet.

Maximum limits are required however for all types of FSMP due to safety reasons. The highly formulated nature of FSMP presents a risk of excessive vitamin and mineral additions, and is a risk that applies equally to all products. The provision of upper nutrient limits in addition to the general requirement for both nutritionally incomplete and nutritionally complete FSMP would therefore minimise the potential for an excessive nutrient consumption.

In considering the compositional regulation of FSMP, FSANZ has noted that medical supervision can counteract many of the health risks associated with the use of FSMP. Although medical supervision is considered a feature of FSMP, such supervision cannot, and should not be responsible for compensating risks associated with the nutritional integrity of these products.

Conclusion

Two main regulatory measures can be applied to meet the primary objective of protection of public health and safety: a general principle on composition for all FSMP, and an additional set of compositional requirements specific to the different types of FSMP to complement this principle. Minimum compositional requirements are required for the category of nutritionally complete FSMP only, while maximum requirements will be established for all FSMP. A compositional framework of this nature will provide regulatory control for the greater risks associated with certain types of FSMP, while maintaining the flexibility needed across the full range of FSMP.

The Addition of Nutritive Substances to FSMP

In achieving an efficacious formulation appropriate for their intended use, all FSMP need to contain a wide range of added nutritive substances [8]. However, Australian and New Zealand food regulations treat nutritive substances in the same way as food additives in that they require explicit permission in the Code before they can be added to foods.

[8] Standard 1.1.1 of the Code 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".*

Nearly all FSMP contain a comprehensive range of essential vitamins and minerals. Many, but not all of these products also contain many trace elements identified as essential for human requirements (manganese, selenium, chromium, and molybdenum), while a range of other substances are only found in a small selection of FSMP (e.g. choline, biotin, pantothenic acid, inositol, carnitine, taurine, and free arginine). Amino acids are also added to FSMP as a means of achieving an adequate content and quality of protein.

Many of these nutritive substances are not permitted in the generic standards of the Code, and the inclusion of a explicit permission for each particular nutritive substance and its various forms will therefore be necessary to allow for the adequate formulation of FSMP. In developing such permissions, FSANZ has referenced European legislation [9] as a source of permitted forms (see Table 1 of the Appendix to this Attachment). European legislation has been referenced, as Europe is the only major overseas region supplying FSMP to the domestic market that has undertaken a toxicological and nutritional assessment on a wide range of substances appropriate for use with FSMP. No other applicable list of permissions has been identified, including domestic or Codex publications.

In considering the addition of nutritive substances to FSMP, recognition has been given to the application of provisions for the identification and purity of added substances as provided under Standard 1.3.4.

Conclusion

To allow for the efficacious formulation of FSMP, the addition of nutritive substances will be permitted. The range of permitted nutritive substances will need to include all essential vitamins, minerals, trace elements, amino acids, nucleotides and other substances such as carnitine, taurine, inositol and choline as a means of enabling FSMP to be formulated consistently with their intended use. To ensure that this permitted range of nutritive substances is safe for consumption and compatible with the majority of imported FSMP, the permitted forms established for FSMP by EC will be adapted for inclusion in the proposed standard for FSMP (see Table 1 of the Appendix to this Attachment).

Application of the Compositional Framework to the Different Types of FSMP

Macronutrient Requirements

For nutritionally complete FSMP it is expected that the macronutrient content provided will consist of sufficient protein, fat and carbohydrate to meet daily needs. Health Professionals often select non-VLED nutritionally complete FSMP for use with patients according to a macronutrient composition capable of meeting nutritional needs. Therefore no specific provisions beyond the general principle for a safe, efficacious formulation are considered necessary for the macronutrient composition of non-VLED nutritionally complete FSMP.

[9] European Commission Directive on Substances that may be added for Specific Nutritional Purposes in Foods for Particular Nutritional Uses (2001/15/EC) (PARNUTS)

For nutritionally incomplete FSMP the establishment of requirements for macronutrients is also seen as unnecessary, as macronutrients vary in their levels across this class of FSMP or are absent altogether. Often it is this variation or absence of macronutrients that defines the purpose of nutritionally incomplete FSMP.

However, there is a greater public health and safety risk associated with the macronutrient composition of VLED than for other FSMP (including non-VLED nutritionally complete FSMP), due to the use of these products in semi-starvation regimes. Insufficient provision of protein, fat and carbohydrate in a very low energy diet can result in a substantial loss of lean body mass and may significantly alter normal metabolic processes (Pi-Sunyer, 1994). Furthermore, from a historical perspective there is also a need for effective regulation of macronutrients, as unsuitable macronutrient formulations of early forms of VLED have often produced deleterious effects (ADA, 1990; NTPTO, 1993).

Macronutrient requirements are specified in the Codex Standard for VLED. This standard provides minimum quantities for protein; carbohydrate; energy; and the essential fatty acids, linoleic acid and α-linolenic acid. Also stated is a ratio of linoleic acid to α-linolenic acid, a maximum limit on energy content, and provisions requiring a specified protein quality (FAO, 1991). In the absence of any domestic macronutrient reference values applicable to VLED, it is proposed that all of these compositional requirements be incorporated into FSMP regulations for Australia and New Zealand.

Vitamin, Mineral and Trace Element Requirements

Unlike macronutrients, the requirements for vitamins, minerals and trace elements are applicable to all types of FSMP, both VLED and non-VLED. Both of these types of FSMP have a substantial health risk associated with their micronutrient composition and require a detailed set of minimum and maximum levels. However, the average energy requirements for the consumers of each category are very different and will thus require a different expression of nutrients in the respective products. It is therefore appropriate to separate micronutrient requirements for VLED (expressed as a daily quantity) from non-VLED products (expressed per 100 kJ).

As identified above, nutritionally incomplete FSMP do not require a set of minimum compositional requirements. The application of maximum requirements for micronutrients is however seen as necessary to manage the risk of excessive nutrient intakes, and is best reflected by the maximum limits that apply to non-VLED nutritionally complete FSMP.

In establishing maximum and minimum limits that are suitable for Australian and New Zealand public health and safety requirements, domestic values should be used where possible. However, applicable domestic reference values for vitamins and minerals - the Recommended Dietary Intakes (RDI) - differ from other overseas vitamin and mineral requirements for FSMP, in that they have been designed only for the average healthy population and not for groups with a compromised health status. Furthermore, the RDI are scheduled for a review in the near future; a process that may result in a significant change to these values.

Therefore, in the interests of harmonising domestic regulations with the most comprehensive and internationally applicable compositional requirements, it is proposed that the minimum values for vitamins, minerals and trace elements established in European directives [1,6] should be used for FSMP. FSANZ is also aware that some of the multi-national manufacturers of FSMP have already modified their product ranges to reflect these European compositional requirements (Russell & Green, 2001); and as the majority of FSMP are imported from this region, the inclusion of European values in the domestic regulations should not, therefore, place an undue burden upon industry. Maximum values on the other hand, should not be derived primarily from European legislation, as the establishment of these values occurred solely on the basis of multiplying minimum values by a factor of three (European Scientific Committee for Food, 1996). Preferably, maximum limits should be developed on the basis of a sound scientific risk assessment, and are best reflected by the use of the Upper Tolerable Intake Levels (UL) produced by the United States Institute of Medicine (United States Institute of Medicine: 2000-a, 2000-b, 2000-c, 2001) [10]. UL have not been developed for all essential vitamins, minerals and trace elements that are added to FSMP; in the absence of an UL for a nutrient, European maximums will be used as an alternative.

Compositional Requirements Associated with Certain Medical Conditions

The provision of any detailed maximum and minimum limits presents a potential regulatory problem, as many FSMP require a nutrient profile that is unique to various disease conditions. A number of FSMP are characterised by an increase or decrease of nutrients beyond the limits of normal human nutrition as a means of meeting this purpose. However for non-VLED products, maximum and minimum requirements are established for vitamins and minerals only. Therefore, it is not expected that these compositional requirements will place substantial constraints on the current manufacture of FSMP, as the majority of nutrient modifications occur with macronutrients rather than micronutrients.

However, some products formulated for specific conditions/diseases may require electrolyte restrictions below the proposed minimum levels. Therefore, it is appropriate that permission be granted to allow for deviation from prescribed minimum requirements for sodium and potassium. This permission will ensure that the proposed compositional requirements do not prevent FSMP from meeting the unique nutritional needs of the target consumer.

The permission to deviate should not, however, allow modifications where no medical or scientific rationale exists; the supply of such nutrients must be consistent with public health and safety requirements.

A similar permission is not warranted for VLED, as their composition is designed for one purpose only – weight loss – and should not vary from specified requirements.

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1 European Commission Directive on dietary foods for special medical purposes (Directive 1999/21/EC).

6 EC Commission Directive on food intended for use in energy-restricted diets for weight reduction (Directive 96/8/EC)

10 The UL are expressed as daily quantities. For the purposes of determining maximum limits expressed per 100kJ the UL have been divided by 87 i.e. based on daily energy reference value of 8700kJ/day.

Submitters to the Draft Assessment for Proposal P242 are encouraged to comment on the following questions:

- Aside from sodium and potassium, will the absence of permission for FSMP to deviate from the proposed compositional requirements according to their intended purpose prevent the formulation of FSMP specific to various conditions/disease states?

  - If so, which specific requirements (listed in Tables 2 and 3 of the Appendix to this Attachment) will cause a problem and why? Also please provide details on particular product type(s) that may be affected in this manner.

Conclusion

FSMP can be classified into two separate subcategories: nutritionally complete and nutritionally incomplete. Nutritionally complete FSMP require both maximum and minimum compositional requirements for micronutrients whereas nutritionally incomplete FSMP will only need to comply with maximum limits. The category of nutritionally complete FSMP can be further divided into non-VLED and VLED with macronutrient requirements only considered necessary for VLED. Permission to deviate from these prescribed requirements will apply only to the electrolytes, sodium and potassium.

Summary of Recommendations

To manage the composition requirements of FSMP, in accordance with the assessment provided above, the following model is recommended for the compositional regulation of FSMP.

General Compositional Requirements:

- Adaptation of the Codex general principle for FSMP[5] to guide the formulation of FSMP. This principle requires the formulation of FSMP to be based on sound medical and nutritional principles and that their use be demonstrated, by scientific evidence, to be safe and effective in meeting the nutritional requirements of the persons for whom they are intended.
- Harmonisation wherever possible with the compositional requirements for FSMP according to European Union regulations.
- Permission for the addition of vitamins, minerals, trace elements, amino acids, nucleotides and other nutritive substances such as carnitine, taurine, inositol and choline.
- Adaptation of the permitted forms of nutritive substances as per the EC Directive 2001/15/EC (PARNUTS) (see Table 1 of the Appendix to this Attachment).

[5] Section 3 Codex Standard for the Labelling of and claims for Foods for Special Medical Purposes, (CODEX STAN 180-1991)

Compositional Requirements Specific to the Different Types of FSMP:

- For nutritionally incomplete FSMP:

  - no prescribed macronutrient requirements;
  - no prescribed minimum micronutrient requirements; and
  - prescribed maximum vitamins, minerals and trace elements requirements as stated in Table 2 of the Appendix to this Attachment;

- For nutritionally complete non-VLED FSMP:

  - no prescribed macronutrient levels;
  - prescribed maximum and minimum vitamins, minerals and trace elements requirements as stated in Table 2 of the Appendix to this Attachment; and
  - permission to deviate from the minimum requirements for sodium and potassium consistent with the intended purpose of the FSMP.

- For VLED (in a recommended daily quantity):

  - prescribed maximum and minimum levels of vitamins, minerals and trace elements (Table 3 of the Appendix to Attachment 2);
  - a prescribed energy content of between 1880-3350 kJ;
  - at least 3g linoleic acid and 0.5g α-linolenic acid with a ratio of linoleic acid to α-linolenic acid between 5 and 15;
  - at least 50g carbohydrate; and
  - at least 50g protein with a prescribed protein quality.

  In addition, as requirements are expressed as a total daily quantity, VLED labelling provisions will contain a requirement for the labelling of a statement on the recommended daily quantity of the product to be consumed, with the quantity to be established by the manufacturer of the VLED.

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Appendix to Attachment 2

Table 1: Permitted Nutritive Substances and Permitted Forms

Nutritive Substance	Permitted Form
Vitamins	
Vitamin A	*Retinol Forms*
	Vitamin A (retinol)
	Vitamin A acetate (retinyl acetate)
	Vitamin A palmitate (retinyl palmitate)
	Carotenoid Forms
	Beta-carotene
Thiamin	Thiamin hydrochloride
	Thiamin mononitrate
Riboflavin	Riboflavin
	Riboflavin 5'-phosphate sodium
Niacin	Niacinamide (nicotinamide)
	Nicotinic acid
Vitamin B_6	Pyridoxine 5'-phosphate
	Pyridoxine dipalmitate
	Pyridoxine hydrochloride
Folate	Pteroylmonoglutamic acid
Vitamin B_{12}	Cyanocobalamin
	Hydroxocobalamin
Biotin	d-biotin
Pantothenic acid	d-pantothenate calcium
	Dexpanthenol
	d-pantothenate sodium
Vitamin C	L-ascorbic acid
	Ascorbyl palmitate
	Calcium L-ascorbate
	Potassium L-ascorbate
	Sodium L-ascorbate
Vitamin D	Vitamin D2 (ergocalciferol)
	Vitamin D3 (cholecalciferol)
Vitamin E	d- alpha-tocopherol
	dl-alpha-tocopherol
	d-alpha-tocopheryl acetate
	dl-alpha-tocopheryl acetate
	d-alpha-tocopheryl acid succinate
Vitamin K	Phylloquinone
Minerals	
Calcium	Calcium carbonate
	Calcium chloride
	Calcium citrate
	Calcium gluconate
	Calcium glycerophosphate

	Calcium hydroxide
	Calcium lactate
	Calcium oxide
	Calcium phosphate, monobasic
	Calcium phosphate, dibasic
	Calcium phosphate, tribasic
Chromium	Chromium chloride
	Chromium sulphate
Copper	Copper lysine complex
	Cupric carbonate
	Cupric citrate
	Cupric gluconate
	Cupric sulphate
Fluoride	Potassium fluoride
	Sodium fluoride
Iron	Ferric ammonium citrate
	Ferric sodium diphosphate
	Ferric pyrophosphate
	Ferric saccharate
	Ferrous carbonate
	Ferrous citrate
	Ferrous gluconate
	Ferrous fumarate
	Ferrous lactate
	Ferrous sulphate
	Iron, reduced (ferrum reductum)
Iodine	Potassium iodide
	Potassium iodate
	Sodium iodide
	Potassium iodate
Magnesium	Magnesium acetate
	Magnesium carbonate
	Magnesium chloride
	Magnesium citrate
	Magnesium gluconate
	Magnesium glycerophosphate
	Magnesium lactate
	Magnesium phosphate, dibasic
	Magnesium phosphate, tribasic
	Magnesium hydroxide
	Magnesium oxide
	Magnesium sulphate
Manganese	Manganese carbonate
	Manganese chloride
	Manganese citrate
	Manganese gluconate
	Manganese glycerophosphate
	Manganese sulphate

Molybdenum	Ammonium molybdate
	Sodium molybdate
Phosphorus	Calcium glycerophosphate
	Calcium phosphate, monobasic
	Calcium phosphate, dibasic
	Calcium phosphate, tribasic
	Magnesium phosphate, dibasic
	Magnesium phosphate, tribasic
	Potassium glycerophosphate
	Potassium phosphate, monobasic
	Potassium phosphate, dibasic
	Potassium phosphate, tribasic
	Sodium phosphate, monobasic
	Sodium phosphate, dibasic
	Sodium phosphate, tribasic
Potassium	Potassium bicarbonate
	Potassium carbonate
	Potassium chloride
	Potassium citrate
	Potassium gluconate
	Potassium glycerophosphate
	Potassium hydroxide
	Potassium lactate
	Potassium phosphate, monobasic
	Potassium phosphate, dibasic
	Potassium phosphate, tribasic
Sodium	Sodium bicarbonate
	Sodium carbonate
	Sodium chloride
	Sodium citrate
	Sodium gluconate
	Sodium lactate
	Sodium hydroxide
	Sodium phosphate, monobasic
	Sodium phosphate, dibasic
	Sodium phosphate, tribasic
Selenium	Sodium hydrogen selenite
	Sodium selenate
	Sodium selenite
Zinc	Zinc acetate
	Zinc carbonate
	Zinc chloride
	Zinc citrate
	Zinc gluconate
	Zinc lactate
	Zinc oxide
	Zinc sulphate

Other Nutritive Substances	
Amino acids	Cystine
	Glycine
	L-alanine
	L-arginine
	L-aspartic acid
	L-citrulline
	L-cysteine
	L-histidine
	L-glutamic acid
	L-glutamine
	L-isoleucine
	L-leucine
	L-lysine
	L-lysine acetate
	L-methionine
	L-ornithine
	L-phenylalanine
	L-proline
	L-threonine
	L-tryptophan
	L-tyrosine
	L-valine
Carnitine	L-carnitine
	L-carnitine hydrochloride
Choline	Choline
	Choline chloride
	Choline bitartrate
	Choline citrate
Inositol	Inositol
Nucleotides	Adenosine 5’-monophosphate
	Adenosine 5’-monophosphate sodium salt
	Cytidine 5’-monophosphate
	Cytidine 5’-monophosphate sodium salt
	Guanosine 5’-monophosphate
	Guanosine 5’-monophosphate sodium salt
	Inosine 5’-monophosphate
	Inosine 5’-monophosphate sodium salt
	Uridine 5’-monophosphate
	Uridine 5’-monophosphate sodium salt
Taurine	Taurine

Table 2: Minimum and Maximum Vitamin, Mineral and Trace Element Requirements for non-VLED Nutritionally Complete FSMP Expressed per 100 kJ

Nutrient (unit)	Minimum Amount / 100 kJ	Maximum Amount / 100 kJ
Vitamins		
Vitamin A	8.4 μg retinol equivalents	34 μg retinol equivalents
Thiamin	0.015 mg	0.12 mg
Riboflavin	0.02 mg	0.12 mg
Niacin	0.22 mg niacin equivalents	0.4 mg niacin equivalents
Vitamin B_6	0.02 mg	1.15 mg
Folate	2.5 μg	11.5 μg
Vitamin B_{12}	0.017 μg	0.17 μg
Vitamin C	0.54 mg	23 mg
Vitamin D	0.12 μg	0.57 μg
Vitamin E	0.5 mg alpha-tocopherol equivalents per g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg alpha-tocopherol equivalents per 100 kJ.	11 mg alpha-tocopherol equivalents
Biotin	0.18 μg	1.8 μg
Pantothenate	0.035 mg	0.35 mg
Vitamin K	0.85 μg	5 μg
Minerals		
Calcium	8.4 mg	28.7 mg
Magnesium	1.8 mg	4 mg
Iron	0.12 mg	0.5 mg
Phosphorus	7.2 mg	46 mg
Zinc	0.12 mg	0.46 mg
Manganese	0.012 mg	0.126 mg
Copper	15 μg	114 μg
Iodine	1.55 μg	12.64 μg
Chromium	0.3 μg	3.6 μg
Molybdenum	0.72 μg	23 μg
Selenium	0.6 μg	4.6 μg
Sodium	7.2 mg	42 mg
Potassium	19 mg	70 mg
Chloride	7.2 mg	42 mg
Fluoride	No minimum to be set	0.11 mg

Table 3: Minimum and Maximum Vitamin, Mineral and Trace Element Requirements for VLED Expressed as a Daily Quantity

Nutrient (unit)	Minimum Daily Amount	Maximum Daily Amount
VITAMINS		
Vitamin A	700 μg retinol equivalents	3000 μg retinol equivalents
Thiamin	1.1 mg	No maximum to be set
Riboflavin	1.6 mg	No maximum to be set
Niacin	18 mg niacin equivalents	35 mg niacin equivalents
Vitamin B_6	1.5 mg	100 mg
Folate	200 μg	1000 μg
Vitamin B_{12}	1.4 μg	No maximum to be set
Vitamin C	45 mg	2000 mg
Vitamin D	5.0 μg	50 μg
Vitamin E	10 mg alpha-tocopherol equivalents	1000 mg alpha-tocopherol equivalents
Biotin	15 μg	No maximum to be set
Pantothenate	3 mg	No maximum to be set
MINERALS		
Calcium	700 mg	2500 mg
Magnesium	150 mg	350 mg
Iron	16 mg	45 mg
Phosphorus	550 mg	4000 mg
Zinc	9.5 mg	40.0 mg
Manganese	1.0 mg	11 mg
Copper	1.1 mg	10 mg
Iodine	130 μg	1100 μg
Selenium	55 μg	400 μg
Molybdenum	No minimum to be set	2000 μg
Sodium	575 mg	No maximum to be set
Potassium	3100 mg	No maximum to be set

ATTACHMENT 3

Proposal P242 - Foods For Special Medical Purposes (FSMP) Labelling Assessment

The purpose of this assessment is to consider issues relevant to the labelling of Foods for Special Medical Purposes (FSMP), particularly in regard to the underlying principles and generic labelling requirements contained in the *Australia New Zealand Food Standards Code* (the Code), and to propose labelling requirements for inclusion in FSMP regulations.

In addition, a significant proportion of submitters provided comments on issues related to the labelling of FSMP including:

- the use of supporting product literature;
- mandatory warning and advisory statements;
- use of the term 'use under medical supervision';
- labelling of domestic supplier details; and
- reference to disease states.

Application of Generic Labelling Requirements

In Part 1.2 – Labelling and Other Information Requirements of the Code, there are a number of generic or 'horizontal' labelling provisions. These are:

- 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).

The majority of FSMP (99%) in Australia and New Zealand are imported predominantly from the United States of America or Europe, and are therefore labelled according to the regulations of these regions. For the most part, certain labelling features are applied consistently across the majority of product types, and are often representative of the provisions contained in Codex labelling standards [1,2]. However, the information provided does not always comply with the above-mentioned generic provisions of the Code.

In principle the application of domestic generic labelling provisions to FSMP would be consistent with the regulation of other foods, although the realities of a domestic FSMP market reliant on international importation must be taken into account.

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1 Codex Standard on the Labelling and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

2 Codex Standard on the Labelling and Claims for Pre-packaged Foods for Special Dietary Uses (CODEX STAN 146-1985).

Furthermore, FSANZ is required to meet its Section 10 objectives: 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; whilst not imposing regulatory constraints that may force some suppliers out of the market. Therefore the application of generic requirements to the labelling of FSMP require consideration on a case-by-case basis according to the assessed risk to public health and safety, and the information needs of health professionals and consumers.

Conclusion

Neither a blanket exemption from, nor full compliance with generic provisions in the Code is a suitable option for the labelling of FSMP. In considering the application of generic labelling standards, measures to address the assessed public health and safety risks should be balanced with the capabilities of industry to label imported products accordingly, and the unique information needs of supervising health professionals and FSMP consumers.

Use of Supporting Product Literature

In general, FSMP suppliers use supporting product literature as a method of conveying product information to health professionals that is customised with relevant local information. This product information however, is not routinely provided to all health professionals and is not usually distributed to consumers; supporting literature is often provided via separate mail deliveries, advertisements, or inserts in other literature, and rarely accompanies the product itself. In these circumstances, the label provides a superior means of communicating information about a product, especially for consumers.

Standard 1.1.1 provides the definition of a label as it applies to the Code. This definition incorporates the requirement that a label be "…attached to or used in connection with or accompanying any food or package". By this definition, supporting product literature can act as a means of providing labelling information as long as it is in direct association with the product. However, as mentioned above, this is not the usual practice for the distribution of supporting product literature, and therefore such material most likely does not meet the stated definition of a label. Furthermore, without any assurance that current distribution practices can supply supporting product literature at all times with the product, there is no guarantee that any associated public health and safety risks will be effectively managed through the provision of labelling information on supporting product literature.

Conclusion

Due to the current methods of distribution of supporting product literature, this material is not considered a label and cannot effectively deliver the risk management provided by a label. Therefore, supporting product literature is not a suitable substitute for product labelling as a means of providing the information required by generic labelling provisions in the Code.

Submitters to the Draft Assessment for Proposal P242 are encouraged to comment on the following questions:

- Do you believe that the current distribution practices for the supply of supporting product information (in lieu of labelling) guarantees that health professionals and/or consumers receive all necessary information for the appropriate use of FSMP? Please provide evidence in support of your position when answering this question.
- If you do not believe this to be the case, can current distribution practices be altered to ensure the accompaniment of supporting product literature with the distribution/sale of a FSMP? If so, how costly and difficult would such a change be?

Mandatory Advisory Statements and Declarations

Standard 1.2.3 requires all food to be labelled with mandatory warning and advisory statements and declarations unless specifically exempt. The statements covered by Standard 1.2.3 fall into three categories: warning statements, advisory statements, and declarations of certain substances. Warning statements must be presented on a label in the exact format specified, as these statements are related to high public health and safety risks. Advisory statements, on the other hand, need only be worded in a way that expresses the intent of such a statement and are used to alert consumers to a potential risk associated with the consumption of the food. Declarations of substances known to cause adverse reactions in various susceptible individuals must also be in the ingredients list of label as a means of alerting consumers to their presence in the food.

The inclusion of mandatory warning and advisory statements, and declarations in the Code is considered necessary for all foods to ensure that certain consumer groups are adequately informed of any potential risks to themselves, if they consume the product.

As FSMP require medical supervision for their use, it can be assumed that there is an inherent level of protection against the risk of a consumer inadvertently consuming a substance that is likely to cause an adverse reaction. Health professionals are often aware of health conditions that may be affected by certain substances, and can pass this information onto the consumer. Therefore, supervising health professionals require sufficient access to the information provided by mandatory warning and advisory statements and declarations. The public health and safety risks controlled through the provision of this information to health professionals are significant enough to warrant compliance with Standard 1.2.3.

In considering this generic labelling requirement, FSANZ recognises the potential for supporting product literature to contain advisory statements and declarations. However, as detailed above, the current distribution practices for supporting product literature cannot guarantee the accompaniment of this material with the sale of FSMP to either a health professional or consumer, and cannot therefore, be used as effective means of providing mandatory advisory statements and declarations in lieu of the product label.

Conclusion

The mandatory warning and advisory statements and declarations contained in Standard 1.2.3 should apply to FSMP. This information should be included on product labelling, as this information is vital for enabling health professionals to appropriately supervise the use of FSMP.

Labelling of the Term "Use Under Medical Supervision"

Many FSMP currently available in Australian and New Zealand markets voluntarily carry the advisory statement "use under medical supervision". This statement clarifies the importance of consuming FSMP under the direction of a medical doctor and implies that these products are not suitable for the general population. Therefore, a statement on medical supervision is an important piece of labelling information for the general public, and assists enforcement agencies in distinguishing FSMP from other food categories.

In regulating a labelling statement on medical supervision, there are several issues that need to be considered. The first is that all FSMP labels should carry a statement on medical supervision without exception; this is a defining feature of these products and is a measure that is supported by stakeholder submissions. The second is that any statement on medical supervision should be highly visible and separated from surrounding labelling features, a requirement detailed in the Codex standard for FSMP [1]. To facilitate this display, words to the effect of "Important Notice" should precede an advisory statement on medical supervision. This preceding notice is consistent with provisions for other special purpose food categories in the Code (e.g. Standard 2.9.1) and European FSMP regulations [3].

Lastly, the words "use under medical supervision" may cause confusion, as other health professionals such as dietitians, nurses and pharmacists also supervise the use of FSMP. However, the general public is unlikely to come into contact with FSMP outside of hospitals and pharmacies where suitable clarification on the requirement for medical supervision can be provided. Therefore, an advisory rather than a warning statement is suitable for the labelling of "use under medical supervision" where the intent rather than the wording is regulated. This measure allows flexibility, while maintaining the appropriate risk management that a statement on medical supervision is intended to achieve. Regulating an advisory statement will also prevent the situation where manufacturers have to relabel imported products as a result of minor word variations, thus removing a potential barrier to trade.

Conclusion

To adequately manage the risks associated with the inappropriate consumption of FSMP, a statement to the effect of "use under medical supervision" should be a mandatory labelling requirement provided in FSMP regulations. It is also proposed that the words to the effect of "Important Notice" precede this statement as a means of highlighting it from surrounding features on the label of a food for special medical purposes.

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1 Codex Standard on the Labelling and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

3 European Commission Directive on dietary foods for special medical purposes (Directive 1999/21/EC).

Provision of Domestic Supplier Details

A requirement exists in Standard 1.2.2 of the Code for all food labels to display the name and business address in Australia or New Zealand of the supplier. The labelling of the domestic supplier's details serves two purposes: to assist in the event of a food recall for tracing a product back to its source, and to provide consumers with contact information about the local supplier. Very few food categories are exempt from these requirements.

Most suppliers of FSMP ensure that local information (including supplier contact details) is provided on supporting product literature rather than on the product label.

To trace a product back to its origin of manufacture, sufficient information must be available to identify points of sale and the transfer of products between various distributors. For FSMP, identifying product movement and points of sale may be difficult. A recent example highlighted this problem, with difficulties encountered in April 2002 for the recall of a food for special medical purposes (Portagen) over concerns of microbiological contamination.

The provision of information on local supplier details is an important labelling feature that enables consumers to identify the source of the product and to contact the local supplier if necessary. However, with adequate medical supervision this information can be easily relayed to the consumer provided that the supervising health professional has such information.

The provision of local supplier details is considered important for both the ability to recall a product and for the adequate provision of information to the consumer of FSMP. In both situations the public health and safety risks are such that provision of this information on supporting product literature would be suitable option for meeting these requirements, were there assurances that such material always accompanied the sale of FSMP. However, as outlined above, information provided on supporting product literature does not routinely accompany the sale of FSMP.

Conclusion

The provision of local supplier details as stated in Standard 1.2.2 should be applied to FSMP, as this information is important in the recall of FSMP and for providing contact information about the local supplier.

Reference to Disease States and Health Claims

Prohibition on the Use of Health Claims

Transitional Standard 1.1A.2 - Health Claims prohibits the use of health claims on labels and associated materials, including:

- making a therapeutic or prophylactic claim, or a claim of similar import (clause 3(a));
- using the word 'health' or any words of similar import in conjunction with the name of the food (clause 3(b));
- containing any wording, statement, or claim; either expressed or implied, that may be interpreted as advice of a medical nature (clause 3(c)); or
- referencing a disease or physiological condition (clause 3(d)).

If FSMP are to be used in the correct manner, then some recognition and identification of the purpose for their use must be provided, including the disease state(s) that they have been designed for. This identification is clearly supported by existing international FSMP regulations, including those of Codex [1].

To effectively allow for FSMP to make reference to disease states, an overriding permission for use of the claims listed in Clauses 3(c) and 3(d) of Standard 1.1A.2 is required. In assessing these requirements, FSANZ has noted comments from stakeholders that any permission should not encompass claims of therapeutic properties / actions. The statements covered by the Clauses 3(a) and 3(b) of Standard 1.1A.2 are not associated with the effective use of FSMP, and the prohibition on the use of such statements should be maintained for FSMP.

Review of Health Claims

Proposal P153 was raised in April 1997 to review the prohibitions on the labelling of health claims. This proposal progressed to the stage of recommending draft Standard 1.2.7 - Health and Related Claims to the then Australia New Zealand Food Standards Council (ANZFSC). ANZFSC however, delayed a decision on P153 pending the development of a policy framework for health and nutrition claims. A policy framework is due for consideration by ANZFSC in 2003, and could potentially alter the recommendations for the regulation of health claims made by P153.

Prior to ANZFSC's decision on policy development, P153 had recommended that draft Standard 1.2.7 maintain the current prohibition on health claims with provisions for exemption following rigorous scientific substantiation and pre-market approval. P153 has indicated that exemptions would be unlikely on a body of scientific evidence that is less than convincing, where "convincing" is defined 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.*

This definition had been developed to ensure that any health claims made on food labels are based on sound scientific principles and are not misleading. Although it is not proposed that claims on FSMP undergo a pre-market approval process, such claims should be made consistent with the developments in P153 on the substantiation of claims. Therefore, any reference to a disease state should be based on a "convincing" level of evidence as defined above. Although several submitters have indicated that a stronger level of substantiation is required, no evidence for, or suggestions of alternative definitions and mechanisms were provided.

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[1] Codex Standard on the Labelling and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

Conclusion

For FSMP to effectively convey information on the illnesses and conditions that they have been designed for, a permission to make reference to disease states on labels is required within FSMP regulations. This permission will override the prohibitions contained in Clauses 3(c) and 3(d) of Standard 1.1A.2, or their equivalent when Standard 1.2.7 is incorporated into the Code. In permitting references to disease states on FSMP labels, it is the intent that manufacturers will be capable of substantiating these statements with "convincing" scientific and medical evidence.

Nutrition Information

Under Standard 1.2.8 – Nutrition Information Requirements of the Code, the provision of a nutrition information panel (NIP) is mandatory on all food packages except where certain exemptions apply. Currently, nutrition information is provided on FSMP, however this information is usually consistent with overseas regulations and does not necessarily comply with the requirements of Standard 1.2.8 e.g. format, order of nutrients, and the labelling of percentage daily intake information.

In practice, it could be argued that the provision of nutrition information is more relevant to supervising health professionals than consumers, because they rely on this information when advising on the use of FSMP. Health professionals usually have access to supporting product literature, and as long as this material supplies accurate nutrition information, then the risk of incorrect medical advice to FSMP consumers is minimised. However, detailed nutrition information, should be an essential feature on label of a food for special medical purposes even if it is referenced against overseas standards, as this information can be utilised in situations where supporting literature is not accessible.

Standard 1.2.8 also contains provisions relating to nutrition claims, including claims for: polyunsaturated, monounsaturated, and omega fatty acids; energy ("low joule"); lactose; gluten; salt and potassium. These provisions contain specific criteria that prevent nutrition claims from being misleading, or to ensure that such claims are based on a consistent product composition. However, these provisions were developed to manage the risks for nutrition claims made to the general public, and not for nutrition claims made to health professionals or the supervised consumers of FSMP. Therefore, the criteria specified for nutrition claims in Standard 1.2.8 are not considered relevant to FSMP and therefore should not apply. Only the claims on lactose and gluten content are considered applicable in the regulation of FSMP due to the potential for inconsistent claiming.

To allow for flexibility it is proposed that Standard 1.2.8 not apply to FSMP except for certain provisions such as definitions, and claims on lactose and gluten content. Alternatively, specific nutrition information requirements will apply to FSMP including the requirement for a nutrition information statement, which may be in the form of a table, detailing:

- the energy content and the average quantity of protein, fat, carbohydrate, vitamin, mineral and other nutritive substances expressed per 100 g or 100 ml as prepared, and
- the number of servings per package and serving size.

These proposed requirements for nutrition information are consistent with Codex and European standards [1,3,4,5] and will allow FSMP the flexibility to label with nutrition information appropriate to the domestic market, even if it is in a non-domestic format.

Conclusion

The provision of nutrition information is an important requirement for the labelling of FSMP. However to allow for flexibility, Standard 1.2.8 is proposed not to apply to FSMP except for provisions on definitions and lactose and gluten claims. Instead specific nutrition information requirements consistent with Codex will apply to FSMP.

Other Generic Labelling Provisions in the Code

A number of other generic labelling provisions are currently mandated in the Code; namely: lot identification, date marking, percentage labelling of characterising ingredients, directions for use or storage, and country of origin. Of those FSMP identified by FSANZ, the majority of products complied with these labelling requirements, with the only exception occurring for percentage labelling of characterising ingredients. FSANZ does not, however, consider the lack of percentage labelling to be of significant concern, as the highly formulated nature of FSMP makes this form of labelling unnecessary.

Conclusion

The generic provisions in the Code for the labelling of lot identification, directions for use or storage, or country of origin are to apply to FSMP. FSMP will, however, be exempted from the requirements on percentage labelling of characterising ingredients.

Additional Labelling Requirements for FSMP

A number of additional labelling requirements established under the Codex system of regulation (adopted by European legislation) for both VLED and non-VLED products may be applicable to FSMP in the context of Australian and New Zealand regulations. These requirements are not currently specified anywhere in the Code.

The Codex FSMP standard [1] provides the following additional labelling requirements:

- a statement that FSMP poses a health hazard when consumed by individuals who do not have the medical conditions that the product is intended for (Clause 4.4.3);
- a statement that the product is not for parenteral use (Clause 4.4.4);
- a statement that the product is / is not intended as the sole source of nutrition (Clause 4.4.5);

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1 Codex Standard on the Labelling and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

3 EC Commission Directive on dietary foods for special medical purposes (Directive 1999/21/EC).

4 Codex Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction (CODEX STAN 203-1995).

5 EC Commission Directive on food intended for use in energy-restricted diets for weight reduction (Directive 96/8/EC)

1 Codex Standard on the Labelling and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).

- a statement concerning adequate precautions, known side effects, contraindications and product-drug interactions, as applicable (Clause 4.5.2);
- the age group(s) the product is intended for, if applicable (Clause 4.5.4); and
- a statement on the nutrient modifications that have taken place (Clause 4.5.5).

The Codex VLED standard [4] provides the following additional labelling requirements under Clause 9.6:

- a statement "for the dietary management of obesity";
- reference to the importance of maintaining an adequate daily fluid intake; and
- a statement that the product should not be used by pregnant, nursing and lactating women or by infants, children adolescents and elderly, except when medically indicated.

These labelling requirements address risks associated with the misuse of FSMP, both by the general public and by the supervised target consumer. Incorrect use represents one of the more significant risks associated with FSMP, and these measures should therefore be included on FSMP labels in Australia and New Zealand.

Conclusion

To harmonise with international regulations that address the risk of misuse of FSMP, additional labelling provisions specified under Clauses 4.4.3, 4.4.4, 4.4.5, 4.5.2, 4.5.4, and 4.5.5 of the Codex Alimentarius Standard for the Labelling and Claims for Food for Special Medical Purposes should be included in domestic FSMP regulations and apply to FSMP. As Codex has provided similar provisions that are more specific and relevant to VLED, an exception to these additional labelling requirements will be made for VLED. In their place additional labelling requirements based on Clause 9.6 of the Codex Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction will apply to VLED only.

Summary of Recommendations

To effectively regulate the labelling of FSMP, the following recommended provisions are proposed for inclusion in the *Food Standards Code*.

- Wherever possible, harmonisation with Codex labelling requirements for FSMP.
- Due to the current methods of distribution, the use of supporting product literature as a means of providing information required by generic labelling standards is not considered a suitable alternative to labelling.

[4] Codex Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction (CODEX STAN 203-1995)

Application of Generic Labelling Provisions

- The majority of the generic labelling requirements in the Code to apply to FSMP including country of origin (Standard 1.1A.3), application of labelling (Standard 1.2.1), food identification and local supplier details (Standard 1.2.2), mandatory warning and advisory statements and declarations (Standard 1.2.3), ingredient labelling (Standard 1.2.4), date marking (Standard 1.2.5), directions for use and storage (Standard 1.2.6), and legibility requirements (Standard 1.2.9).

- The requirements of Standard 1.2.8 - Nutrition Information Requirements to not apply to FSMP except for:

  - definitions; and
  - claims for lactose and gluten.

- Exemption from the provisions of Standard 1.2.10 – Percentage Labelling of Characterising Ingredients.

Specific Labelling Requirements

- Inclusion of a mandatory advisory statement that FSMP are to be used only under medical supervision, preceded by words to the effect of "Importance Notice".
- Permission for the labelling of a statement on the condition, disease or disorder for which the FSMP has been specially formulated.
- For nutrition information requirements:

  - the declaration of a nutrition information statement that may be in the form of a table with: the energy content and the average quantity of protein, fat, carbohydrate, vitamin, mineral and other nutritive substances expressed per 100 g or 100 mL as prepared; and
  - the number of servings per package and serving size.

Additional Labelling Specific to FSMP other than VLED

These recommendations are to be provided as generic labelling requirements that apply to all FSMP, except for VLED.

- The labels of FSMP other than VLED to contain a statement:

  - that the product poses a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the product is intended;
  - that the product is not for parenteral use;
  - that the product is or is not intended as the sole source of nutrition;
  - concerning the adequate precautions, known side effects, contraindications, and product-drug interactions;
  - specifying the nutrient(s) which have been modified relative to normal requirements; and
  - information, where appropriate, on the specific age group(s) that a product is intended for.

Additional Labelling Specific to VLED

The following additional labelling requirements are recommended for VLED only:

- a statement "for the dietary management of obesity";
- reference to the importance of maintaining an adequate daily fluid intake;
- a statement that the product may not be suitable for use by pregnant, nursing and lactating women or by infants, children adolescents and elderly, except when medically indicated; and
- a statement on the recommended daily quantity of the product to be consumed, with the quantity to be established by the manufacturer of the VLED (see Attachment 2 for more detail).

ATTACHMENT 4

Proposal P242 - Foods for Special Medical Purposes (FSMP) Microbiological Evaluation

Foods for medical purposes (FSMP) include ready-to-use liquid products and powdered formulas for the dietary management of individuals with either ongoing chronic medical or disability conditions or during acute phases of illness, injury or disease states. They may be the sole source of nutrition (a complete nutrition formula) or a specialised dietary supplement. The microbiological risks associated with the use of these products may depend on several factors including the health status of the individual consuming them (host susceptibility); the nature of the food and how it is processed, and how the food is to be prepared and handled.

Host Susceptibility

The susceptibility of populations to food-borne illness is influenced by many factors. There are sub-groups within the general population which are at greater risk from food-borne infections, both in the development and severity of illness. These include the elderly, the immunocompromised (including the chronically ill), pregnant women and the very young.

The Elderly

Increased susceptibility to food borne infections in elderly populations (>65 years of age) is due to a number of factors including (Smith, 1998; Morris & Potter, 1997):

- a decrease in humoral and cellular immunity;
- changes in the gastrointestinal tract such as decreased production of gastric acid and decreased motility of the gastrointestinal tract;
- malnutrition; and
- the increased use of antacids and antibiotics.

In particular, the incidence of salmonellosis and *Campylobacter* diarrhoea seems to be higher among the elderly than the general population (Morris & Potter, 1997). The severity of infection is also likely to be more severe. *Salmonella* infections, for example, are more likely to cause bacteremia in the elderly which increases the risk for death.

The Immunocompromised

Immunocompromised individuals include those on chemotherapy or radiation therapy; recipients of organ transplants taking immunocompromising drugs; persons with AIDS or with other chronic diseases. In the case of AIDS, the disease itself results in immunodeficiency in the individual, increasing susceptibility to infection. AIDS patients show a clear increase in susceptibility to *Salmonella* infections with a several fold increase in the risk of septicaemia (Morris & Potter, 1997). For those individuals that have undergone organ transplantation or cancer chemotherapy, the use of immunosuppressive drugs as well as antimicrobial drugs will increase susceptibility to food-borne infection. These patients are at significantly greater risk of dying from enteric viral infections than the general population (Gerba *et al*, 1996).

Pregnancy

The escalated production of progesterone during pregnancy leads to a decrease in cell-mediated immune function. This increases the susceptibility of pregnant women and the foetus to certain food-borne infections, particularly from intracellular pathogens such as *Listeria monocytogenes*, *Toxoplasma gondii*, Hepatitis E virus and *Coxiella burnetii* (Smith, 1999).

The Very Young

In young children, less than 5 years of age, the lack of a fully developed immune system and a smaller infective dose-by-weight required to cause illness increases their susceptibility to food-borne illness. Young children are particularly susceptible to the development of complications as a result of food-borne infection from enterohaemorrhagic strains of *Escherichia coli* (EHEC), which can result in the development of haemolytic uraemic syndrome. Premature infants fed on formula have very little gut immunity and are very susceptible to food-borne infection.

Nutritional Status

Along with the age or health related factors that affect the host's ability to deal with food-borne pathogens, the nutritional status of the host can also play a role in the development and severity of food-borne infection. Studies suggest that clinical and subclinical nutritional deficiencies could lead to greater susceptibility to food-borne pathogens. It is recognised, for example, that nutritional deficiencies in vitamin A and zinc increase the risk of diarrhoeal diseases (King *et al*, 2000). While not fully understood, the nutritional status of the host may have an important impact on gut-mediated immunity.

Food Processing Considerations

FSMP include ready-to-use liquid products and powdered products, which are reconstituted with water for use.

Liquid products

The ready-to-use liquid products available are commercially sterile, shelf stable foods. This means they have been thermally processed to be free of microorganisms capable of reproducing in the food under normal conditions of storage and distribution. Commercially sterile foods should be free of any viable pathogenic microorganisms (including spores).

Powdered products

While powdered products undergo heat processing during their manufacture, they are not subjected to high temperatures for sufficient time to make the final packaged product commercially sterile. Microbiological contamination of the product from the production line or the environment may also occur during processing steps such as cooling, mixing and packaging. Viable microorganisms may slowly die during storage of the dried product but spore forming organisms, being the most resistant, retain viability for long periods of time (ICMSF, 1998). Microorganisms that may be of greatest concern in these powdered products include *Bacillus cereus*, *Salmonella* and *Enterobacter sakazakii*.

Food Handling Considerations

Liquid Products

As liquid products are processed to be commercially sterile, they should not pose a microbiological risk to a consumer unless they are administered under conditions of poor hygienic practice. This would be unlikely in a hospital or clinical environment. Liquid foods consumed at home would be provided as canned or UHT products and either are administered enterally (via tube feeding) or drunk directly from the package (via a straw or poured into a glass), practices which raise no particular microbiological concerns. Once these products have been opened, however, they can no longer be considered to be commercially sterile and must be handled appropriately to avoid microbiological contamination and growth. Any opened product should be covered and refrigerated and used within 24 hours. Any leftover product should be discarded after this time. Products hung for enteral feeding should be replaced with new product once the recommended hang time has been reached.

Dry Products

Dry products require more handling and preparation than ready-to-use liquid products and this increases the risk for microbiological contamination. Food powders are generally reconstituted with water, which, for infant feeding, should be sterilised by boiling before use. The equipment used to prepare and administer the food may also be a source of contamination and so should be thoroughly cleaned and, if appropriate, sterilised (such as infant feeding bottles).

Microorganisms are unable to grow in dry food products however, once the powder has been reconstituted in water, any pathogens present may begin to grow if the product is not stored appropriately. Once the powdered food has been made up it should be used immediately or refrigerated and used within 24 hours. (Prolonged storage of the made up food at room temperature could allow the growth of pathogens present). Any partially consumed product should be discarded and not kept to be re-used at a later feed. Powdered products made up for continuous enteral feeding should not have excessive hang times. The United States Food and Drug Administration (FDA) have recently recommended that hang times for powdered formula products should not exceed 4 hours (Weir, 2002).

Incidence of Food-borne Illness

There is little data relating specifically to FSMP and their association with food-borne illness except in the context of infant formula. While infant formula *per se* is outside the scope of Proposal P242, the association of food-borne illness with their use is applicable to FSMP and is discussed below.

While a number of microorganisms have been associated with infant formula (including *Bacillus cereus*, *Clostridium perfringens*, *Staphylococcus aureus*), outbreaks of food-borne illness attributable to contaminated infant formula have largely been associated with *Salmonella* and *Enterobacter sakazakii*. Outbreaks of *Salmonella* infections after consumption of contaminated infant formula were reported in the United Kingdom in 1985 (Committee on the Microbiological Safety of Food, 1990) and in Canada in 1992 from infant formula produced in the United States (ICMSF, 1998).

Another outbreak of Salmonellosis occurred in Spain in 1994 (Usera *et al*, 1996). These outbreaks were traced back to contamination from processing equipment during manufacture.

Enterobacter sakazakii has been found in a number of infant formula products at low levels (Nazarowec-White & Farber, 1997). Over the past several years, clusters of *E. sakazakii* infections in neonates have been reported internationally (van Acker *et al*, 2001; Himelright *et al*, 2002; Weir 2002). This organism causes sepsis, meningitis or necrotizing enterocolitis in infants, resulting in a high fatality rate (as high as 33%). Most recently (March/April 2002), an international recall of the product Portagen (a formulated product for infants and children under 2 years who do not efficiently digest or absorb conventional fat) was initiated following an outbreak of *E. sakazakii* infection in a neonatal intensive care unit in the United States, in which the Portagen product was used. The FDA has subsequently recommended that non-commercially sterile infant formula products should preferably not be used within neonatal intensive care units where commercially sterile liquid products are available.

Conclusions

Individuals consuming FSMP may be more susceptible to food-borne illness because of their health status and/or age (such as young infants). As these foods may be the sole source of nutrition for "at risk" individuals, it is critical that these products are of a high microbiological quality.

Ready-to use liquid products are commercially sterile and if handled and prepared hygienically, pose no particular microbiological concern. Published data on food-borne illness associated with these products is not readily found in the literature. Control over the microbiological quality and safety of these products is achieved primarily through strict adherence to good manufacturing and hygienic practices at the manufacturing facility. Tests for commercial sterility may provide an additional check on the production systems in place. Guidance on the handling of these products after opening and subsequent use (such as storage instructions and keeping time) should be provided.

Powdered products to be fed to "at risk" groups pose a higher microbiological risk than commercially sterile liquid products. Food-borne illness data indicates that neonates are at particular risk from *E. sakazakii* contamination of powdered formula, including specialised formula preparations. Powdered products cannot be produced to be commercially sterile, but a high microbiological quality should be achieved through adherence to good manufacturing and hygienic practices at the manufacturing facility. Microbiological testing should provide an additional check on the production systems in place. Specialised infant formula products should comply with the microbiological limits specified in the *Food Standards Code*. Guidance on the hygienic preparation and handling of these products should be provided.

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ATTACHMENT 5

Proposal P242 – Foods for Special Medical Purposes (FSMP)
Summary of Submissions

List of Submitters

A public consultation period occurred from the 10 October 2001 to 5 December 2001 for comment on the Initial Assessment of Proposal P242. During this period, 26 separate submissions were received by ANZFA (now FSANZ). A list of the submitters that provided comment on the Initial Assessment Report is provided below.

- ACT Department of Health Housing and Community Care (ACTDHACC)
- Australian Medical Association of Australia Ltd. (AMA)
- Australia and New Zealand Enteral Nutrition Manufacturers Association (Abbott Australasia, Nestlé Australia, Novartis Consumer Healthcare, Nutricia Australia) (ANZENMA)
- Australia Self Medication Industry Inc. (ASMI)
- Australian Therapeutic Goods Administration (TGA)
- Carer's Association of Australia
- Consumer's Association of South Australia Inc. (submission in support of the submission made by the National Council of Women Australia)
- Dietitians Association of Australia (DAA)
- Food Technology Association of Victoria Inc. (provided two submissions) (FTAV)
- Fonterra Co-operative Group (FCG)
- Mr Carapiet, J
- Mr James, Richard (provided two separate submissions)
- Ms James, Valerie (provided two separate submissions)
- Mr Johnson, DR
- Ms McIlroy, Kerry - Clinical Dietitian (KM)
- Medsafe (NZ Medicine and Medical Devices Safety Authority)
- National Council of Women Australia Inc. Ltd. (NCWA)
- National Council of Women New Zealand (NCWNZ)
- Nestlé Australia (separate submission in support of the ANZENMA submission)
- New Zealand Dietetic Association
- Novartis Consumer Healthcare Australasia Pty. Ltd. (NV)
- Queensland Health (QH)
- Tatua Nutritionals (TN)

Submitter Comments

Preferred Regulatory Option

Option	Submitters Supporting Option	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text	
		Supported	**Not Supported**
1. Status Quo			Those submitters that discussed Option 1 mentioned that: • FSMP must be lawful foods [FCG]; • this option is no longer acceptable [NCWA]; and • no legal recognition of FSMP would result in regulatory ambiguity and enforcement problems [TN].
2. Recognition in Volume 2 with minimal regulatory control.	ANZENMA KM, TN (Total = 3)	• Support for this option was provided mostly by industry, including FSMP manufacturers. • Support for minimal regulatory control was provided because: - To date there has been no evidence of market failure in the production of FSMP [ANZENMA]. - Detailed regulations are not necessary as sales of FSMP are controlled by health professionals and hospital tenders [KM, ANZENMA].	Comments opposing Option 2 were received from the National Council of Women Australia. It was stated that Option 2 would rely solely on definitions that could easily be misinterpreted.
3. Co-regulation	ASMI, DAA (Total = 2)	Support for this option was given on the basis that it provides flexibility within regulations [DAA], allows for the development of a code of practice on advertising and promotion of FSMP [DAA], and is able to cater for a small number of market players [ASMI].	• Industry groups have indicated that Option 3 would be cost prohibitive for all parties to implement [ANZENMA, TN]. • A code of practice cannot be readily enforced [NCWA] and could allow products onto the market that are detrimental to consumers [FTAV]. • A code of practice allows for the government to shift its enforcement responsibilities onto industry [ANZENMA, NCWA].

Option	Submitters Supporting Option	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text	
		Supported	**Not Supported**
			• Option 3 would be a waste of resources as there is no evidence of market failure of FSMP [ANZENMA]. • Co-regulation is unacceptable for consumers due to the specialised nature of FSMP [NCWA].
4. Full regulation	AMA, FCG, NCWA, NCWNZ, QH (Total = 5)	• Support for Option 4 was provided mostly by consumer and government organisations. • Support was given as this option provides the greatest level of protection to public health and safety [FCG, NCWA, NCWNZ, QH], provides a clear and consistent regulatory approach, and allows for adequate provision of product information [NCWNZ, QH].	The majority of industry submitters do not support Option 4 as: • it is far too prescriptive and cost prohibitive for the production of FSMP [ANZENMA, ASMI, TN]; • a standard that is too prescriptive will stifle FSMP innovation [FTAV]; and • it would not allow for harmonisation with international FSMP regulations, and therefore result in the removal of certain FSMP from the Australian and New Zealand markets [ANZENMA, ASMI].
5. Pre-market notification	ACTDHACC, FTAV (Total = 2)	Supporters of this option mentioned that pre-market notification would: • remove any ambiguity over enforcement activities [ACTDHACC, FTAV], • be less prescriptive than full regulation [ACTDHACC, FTAV], • ensure claims / statements were reviewed prior to approval [FTAV], and • prevent future revision of the standard resulting from unforseen eventualities [FTAV].	Industry groups have indicated that Option 5 would be unfeasible as it would delay the launch of products [ANZENMA, TN], hamper the ability to expand the range of FSMP into new areas, and increase the time taken for consumers to obtain FSMP [ANZENMA].

Regulatory Considerations

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Costs and benefits associated with regulatory systems other than Option 4 - full regulation	<u>Benefits:</u> Industry groups have indicated that they have extensive experience undertaking the enforcement and monitoring activities in the management of a regulatory system that is less than full regulation. This has occurred either through the current manufacturing of FSMP in an unregulated environment or through the manufacturing of non-FSMP products under other governmental codes of practice [ANZENMA, ASMI]. <u>Costs:</u> Tatua Nutritionals indicated that smaller, new FSMP manufacturers entering the market may not have the resources to support a code of practice and therefore may decide not to comply.
Costs and benefits of Option 4 full regulation	<u>Benefits:</u> • Full regulation offers the greatest protection to government and consumers, and provides consistency and assurance for industry [NCWA, QH]. • There is a guarantee of quality [NCWNZ]. • Full regulation promotes harmonisation between Australia and New Zealand [QH]. • Misleading and deceptive conduct is prevented [QH]. • Full regulation allows for informed consumer choices to be made [QH]. <u>Costs:</u> • Many products would be withdrawn from local markets [ANZENMA, KM]. • There would be an increase in prices for most lines of FSMP [ANZENMA, KM]. • Full regulation will not allow for harmonisation with European or United States regulations (where the majority of these products are currently manufactured) resulting in the need to reformulate or relabel products [ANZENMA, ASMI]. • There would be a lessening of competition in the FSMP market [ANZENMA]. • There would be delays in FSMP innovation [ANZENMA]. • Australia and New Zealand does not have the population base to support a prescriptive standard [ANZENMA].
Regulation of FSMP as special purpose foods	• Comments were received from all sectors supporting the requirement that FSMP be regulated as special purpose foods [ACTDHACC, AMA, KM, NCWA, QH, TN]. - As they are designed for vulnerable groups with particular physiological needs, FSMP meet the definition and requirements associated with special purpose foods [ACTDHACC, QH, TN]. - FSMP should be considered as special purpose foods, as there is the potential for misuse by the general public if classified otherwise [KM, NCWA]. - The Australian Medical Association Ltd. stated that FSMP should be treated in the same way as therapeutic products, including the need for high standards on quality, efficacy, and safety.

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
	• FSMP Manufacturers [ANZENMA] suggested that FSMP should be placed in a separate section of Volume 2. Creation of a separate section would therefore reflect that these products fall outside of Volume 2 and should not be subjected to current prohibitions contained therein. FSMP Manufacturers also argue that as the products would be positioned outside of the code, they would not require positive permission for the addition of nutritive substances and are thus not unlawful at the point of sale. • **Mr J Carapiet** supported the classification of FSMP as therapeutic goods, as these products require medical supervision. It was indicated that this classification will make claiming, testing, and efficacy requirements easier for industry.
Use under medical supervision	• Submissions on this issue – from all sectors – mentioned that the requirement for FSMP to be used under medical supervision was a necessary feature (both in a definition and on a label) that distinguishes these products from other foods [AMA, ANZENMA, DAA, FCG, JC, KM, NCWA, QH, TN]. - The majority of these submitters were also in favour of additional requirements that permit a 'use under medical supervision' statement to cover use by other qualified health professionals [ANZENMA, DAA, KM, NCWA, TN]. Several of these submitters indicated that in this context, the term "health professionals" should be further defined [ANZENMA, NCWA, TN]. - The Dietitians Association of Australia proposed that on the label, 'use under medical supervision' should incorporate the additional words of 'dietitian' or 'dietetic supervision'. A definition of FSMP should also include the words "use under medical and/or dietetic supervision". FSMP manufacturers [ANZENMA] do not, however, support a change to this statement, preferring a clarification of "medical supervision" within food regulations only. To do otherwise would require label changes. • **Tatua Nutritionals** stated that medical supervision could imply either "by prescription only" or "on medical recommendation", and that such ambiguity needs to be addressed. • The **Fonterra Co-operative Group** stated that it might be better for a statement to be given as a recommendation as there are cases where the products may not be under supervision.

Definition and Scope of FSMP

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Products to be included under a standard for FSMP	• Submissions were received supporting regulation of the following product categories as FSMP: - Nutritionally complete formula [ANZENMA, DAA, KM, QH, TN]; - Supplemental formula designed for specific medical conditions [ANZENMA, DAA, KM, QH, TN]; - Formula for Very Low Energy Diets (VLED) [ANZENMA, DAA, NV, QH]. The **Dietitians Association of Australia** mentioned that a separate definition and set of regulatory measures should be developed for this class of FSMP to prevent their misuse; - Tube/enteral feeds and oral feeds [ANZENMA, QH, TN]; - Solid foods designed for specific medical conditions [ANZENMA, KM]; - Thickened Liquids (of varying consistencies) [AZNENMA]; - Modular (single nutrient) formula [ANZENMA]; and - Paediatric formula for specific medical conditions [KM]. • **Medsafe** has indicated that a standard on FSMP should not include Total Parental Nutrition (TPN) solutions that are typically regarded as a therapeutic product.
Use of the term "Foods for Special Medical Purposes"	The term FSMP was viewed by representatives from all sectors as being consistent with the intent of the proposed regulation [ANZENMA, KM, NCWA, QH, TN].
The use of the Codex definition for FSMP	• Support for use of the definition for FSMP provided in Codex Standard *STAN 180-1991* was provided for the most part by health professionals with some support from other sectors [AMA, DAA, KM, QH, TN]. • FSMP manufacturers [ANZENMA] indicated that the Codex definition was not complete enough. An alternative definition was proposed: "*Medical Foods:* - are a food that may or may not be fortified; - are enterally (or otherwise) administered; - involve medical supervision; - are indicated for the management of special dietary needs that exist because of a disease, physiological condition or treatment; - are for patients with special dietary needs by virtue of disease, inborn error or chronic medical need, has limited capacity to ingest, digest and absorb or metabolise".

Composition of FSMP

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Inclusion of compositional requirements for FSMP	• Several submitters representing consumers, health professionals and government agencies indicated that compositional requirements were necessary for any FSMP standard [AMA, FCG, NCWA, QH]. - FSMP should have product-type specific compositional requirements [NCWA, QH]. - All FSMP should be able to meet a set of compositional requirements. If a product (imported or otherwise) cannot meet compositional requirements of a medical condition, then it should not be suitable for use in the treatment of that condition [NCWA]. - Due to the dependence of patients on FSMP, there is a risk to public health and safety. FSMP should therefore have compositional requirements to minimise this risk [QH]. - The **Fonterra Co-operative Group** indicated that they supported maximum requirements only for safety reasons. • Industry groups were the most outspoken opponents to the inclusion of any compositional requirements for FSMP, although comments against compositional requirements were provided from other sectors [ANZENMA, ASMI, KM, TN]. - FSMP are already formulated to meet European or United States compositional requirements that are internationally recognised standards. Creating separate compositional requirements that differ from these countries will prevent many non-compliant products from being imported into Australia [ANZENMA, ASMI, KM]. - The provision of FSMP through healthcare settings and/or under health professional supervision minimises the risks associated with their composition [ANZENMA, ASMI, KM]. - No evidence exists to date of the health and safety needs of the target population being compromised through the composition of FSMP [ANZENMA, ASMI]. - The wide range of FSMP will create difficulties in detailing compositional requirements that cover all products. A generic permission for the incorporation of vitamins, minerals and other components into FSMP may be more appropriate [TN].

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Addition of more nutritive and other substances to FSMP	• Comments were received from all sectors in support of the permission for the addition of "non-standard" nutritive substances to FSMP. All comments indicated that these substances should only be permitted on the basis of scientific investigations into their efficacy and safety [DAA, KM, NCWA, QH, TN]. • Some of these comments also indicated that the definition of a "nutritive substance" should be clarified. - **Ms K McIlroy** suggested that the definition should include the requirement of 'an added health benefit' or 'improved outcome'. - **Tatua Nutritionals** stated that the current definition in Volume 2 should be expanded to cover essential fatty acids, substances containing ACE inhibitory peptides / anti-thrombotic peptides, or substances that play a role in oral health. - **Fonterra Co-operative Group** mentioned that lactic acid bacteria may be beneficial but are not defined as a nutritive substance. • The **National Council of Women Australia** suggested that a schedule similar to those used for vitamins and minerals could also be provided for nutritive substances and an upper limit established for their use. • The **Australian Therapeutic Goods Administration** commented that there is the potential for some substances added to FSMP (e.g. selenium) to be included within the *Australian Standard for the Uniform Scheduling of Drugs and Poisons*. A clear regulatory approach on this issue is therefore required.

Distribution and Access of FSMP

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Restricting access to FSMP	• There was support for restrictions on the sale of FSMP from all sectors. [ACTDHACC, ANZENMA, DAA, KM, NCWA, QH, TN]. • There were, however, differences between submitters on the level of restriction that was supported: - Sales should be restricted to pharmacies and hospitals [ACTDHACC, NCWA]. - Sales should be restricted to pharmacies, hospitals or direct from FSMP manufacturers [ANZENMA, DAA, QH]. - Products designed for specific medical conditions should be available from pharmacies, hospitals or direct from FSMP manufacturers. Generic products that present a lower health risk from misuse by the public should be made available for retail sale over the counter [KM, TN]. • **Tatua Nutritionals** A risk assessment framework should be drafted that will allow each FSMP to be assessed as to the biological, physiological, health and safety risks. FSMP could be categorised by this framework and restricted accordingly.

Labelling of FSMP

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Exemptions from generic labelling requirements	• Comments supporting exemptions were received from both industry and health professional groups. Supporters indicated that labelling requirements specific to FSMP are a necessary component of the proposed standard [AMA, ANZENMA, DAA, TN]. - FSMP Manufacturers [ANZENMA] supported exemption from the majority of generic labelling requirements on the basis that these products are not general foods by composition and are not targeted directly at consumers. - Other submitters [DAA, TN] were in favour of an exemption that allowed for FSMP to be associated with certain disease states. Other generic requirements should however remain mandatory for FSMP. • Several submitters did not support any exemptions to generic labelling requirements being made for FSMP [FCG, KM, NCWA, NCWNZ, QH]. The general reasoning provided was that consumers should have access to the same level of information on FSMP as required on general-purpose foods. - The importation from international markets was not seen as sufficient justification to relax local labelling requirements, including the requirement for provision of supplier contact details [NCWA, NCWNZ, QH].
Provision of labelling information on supporting product literature	• Industry and health professionals indicated that permissions should be made for the placement of Australia/New Zealand-specific labelling requirements onto product brochures and leaflets. This support varied amongst submitters, with a number of stakeholders in support of allowing supplier details on supporting literature [DAA, KM, TN]. FSMP manufacturers however supported the provision of all locally specific information onto supporting literature, including mandatory warning and advisory statements and local supplier details [ANZENMA]. **Tatua Nutritionals** also indicated that nutrition information in domestic reference values could be provided on supporting literature. • Submissions were received from consumer organisations stating that product literature should not be used as a partial of full means of providing product information in substitution for the label itself [NCWA, NCWNZ]. - The **National Council for Women Australia** stated that even under medical supervision, the information on a label is still relevant as it is possible that many consumers of FSMP would utilise these products in the home setting. • **Queensland Health** stated that although certain information could be provided in supporting literature, the actual label of FSMP products should contain the same type and amount of information as available on general-purpose foods.

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Permission for reference to disease states	• A large proportion of submitters commenting on this issue indicated a need for FSMP to make some reference to disease states. Submissions mentioned that such information was necessary, as it would prevent misuse of FSMP by consumers and health workers [ANZENMA, ASMI, DAA, KM, NCWA, NCWNZ, TGA, TN]. • Two submitters [ACTDHAAC, ANZENMA] were supportive of the term "convincing" for substantiation of claims as listed in the Initial Assessment Report. A number of other submitters [NCWA, KM, TN] indicated that a stronger, more conclusive definition was required. - The **ACT Department of Health, Housing and Community Care** mentioned that any health claims made on the label of a FSMP should conform with the proposed health claims standard (currently the subject of Proposal P153). • Several submitters were adamant in stating that a permission for reference to disease states should not be a permission for FSMP to make therapeutic health claims [ASMI, NCWA, TGA]. • **Queensland Health** stated that reference to a disease state is not necessary on the label of a FSMP, as the use of these products should occur following medical advice. This information could however be provided on supporting product material distributed to health professionals.
Exemptions from mandatory warning and advisory statements	• FSMP manufacturers [ANZENMA] indicated that mandatory warnings and advisory statements should apply to FSMP, however provisions should be made to enable the placement of these statements on labels or product supporting literature. Otherwise many products would require relabelling as these warnings were unique to Australia / New Zealand, and there is often insufficient space on FSMP labels for all applicable warnings. • A number of submitters were in favour of retaining generic requirements on mandatory warning statements for FSMP labels. Such information was deemed to be necessary to meet the risks for those consumers of FSMP whose medical conditions rely on this information [DAA, FCG, NCWA, QH]. - The **National Council for Women Australia** indicated that mandatory warning statements should be provided on the label regardless of any supporting material.

Additional Comments Made in Submissions

Genetic Modification / Food Irradiation

- The National Council for Women Australia indicated that it does not consider biological substances derived from genetic modification to be safe. They will not, therefore, support any permission for the addition of nutritive substances to FSMP that are produced by this method.

- The Dietitians' Association of Australia stated that FSMP should indicate on leaflets and brochures as whether they are a genetically modified or irradiated food as consumers are entitled to this information.

Microbiological Requirements

- Tatua Nutritionals commented that microbiological requirements greater than those for general-purpose foods should be required of FSMP given the higher at-risk status of the target population.

Comments Made on Issues Outside the Scope of Proposal P242

Infant Formula

- Because of the composition of infant formula, the Australian Medical Association Ltd. suggested these products should be treated as pharmaceuticals and thus given special mention in a standard for FSMP. Tighter regulation, better labelling and appropriate pricing would allow choices to be made in the best interests of infants.

Cholesterol Lowering Products and Phytosterol Containing Margarines

- Mr R James, Ms V James, and Mr DR Johnson indicated that foods promoting cholesterol-lowering properties have unproven benefits, are potentially unsafe for consumption, and should therefore either be prohibited from sale or restricted to pharmacies only. Mr R James and Ms V James also stated that "nutraceutical" foods such as phytosterol containing margarines should only be allowed for sale following rigorous testing via randomised controlled trials similar to those conducted for medicines.

Meal Replacements

- The Dietitians' Association of Australia commented that meal replacements (products currently covered by Standard 2.9.3 in Volume 2) should, in addition to the current mandatory labelling statements, include warnings that these products are not a complete source of nutrition, and should be consumed as part of a balanced diet in conjunction with regular physical activity.

GLOSSARY OF ACRONYMS

ANZENMA	Australia and New Zealand Enteral Nutrition Manufacturers Association
ANZFRMC	Australia and New Zealand Food Regulation Ministerial Council (formerly known as the Australia New Zealand Food Standards Council)
AQIS	Australian Quarantine and Inspection Service
Codex	Codex Alimentarius Commission
EC	European Commission
FAO	Food and Agriculture Organization
FDA	The United States Food and Drug Administration
FSANZ	Food Standards Australia New Zealand (formerly the Australia New Zealand Food Authority (ANZFA))
FSMP	Foods for Special Medical Purposes
FTDS	Food-Type Dietary Supplements
NZDSR	New Zealand Dietary Supplement Regulations
NZFR	New Zealand Food Regulations 1984
RIS	Regulation Impact Statement
TBT	Technical Barriers to Trade
TGA	Therapeutic Goods Administration
VLED	Formulas for very low energy diets
Volume 1	Australian Food Standards Code (repealed)
WHO	World Health Organization
WTO	World Trade Organization