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

15 December 2010
[25-10]

CONSULTATION PAPER

PROPOSAL P242

FOOD FOR SPECIAL MEDICAL PURPOSES

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 9 February 2011
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/foodstandards/changingthecode/

Executive Summary

Food for Special Medical Purposes (FSMPs) are principally formulated food products, used under the supervision of medical or other health professionals (e.g. 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 FSMPs that are represented as 'nutritionally complete' (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 supplemental formulas or foods.

Purpose

Currently, there is no explicit standard for FSMPs in the *Australia New Zealand Food Standards Code* (the Code), with the result that FSMPs are subject to generic (Chapter 1) food standards. However, the specially formulated nature and specialised use of FSMPs often makes it difficult for these products to comply with the generic food standards. The lack of an explicit food standard for FSMPs creates difficulties for enforcement agencies and manufacturers of FSMPs in determining the compliance of the products with the Code. These enforcement problems occasionally cause delays in the importation and distribution of FSMPs to consumers.

This Proposal has therefore been raised to develop a new food standard for FSMPs, so that there is explicit recognition and regulation of these products in the Code.

Previous work on Proposal P242

FSANZ previously released a Preliminary Final Assessment Report on Proposal P242 for public comment in August 2004, which included proposed draft Standard 2.9.5 – Foods for Special Medical Purposes. Proposal P242 was deferred after that consultation period, due to the initiation of work by the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) to develop Policy Guidance on the Intent of Part 2.9 - Special Purpose Foods. The Policy Guideline was approved in October 2009, and FSANZ recommenced work on this Proposal in early 2010.

Changes to the scope of Proposal P242

Very low energy diet (VLED) products are those formulated foods intended for use under medical supervision as part of the dietary management of morbid obesity. Until the last round of public consultation in 2004, FSANZ had included VLED products in the range of foods that would be subject to the outcomes of Proposal P242.

However the market for formulated foods used for weight reduction has been evolving since 2004. There is now an overlap of VLED products and other types of formulated foods used for weight reduction (regulated as meal replacements under Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods), both in the presentation of these two food categories and in how the products are consumed/used.

FSANZ has therefore decided to exclude VLED products from further consideration as part of Proposal P242. FSANZ will instead initiate a new project to specifically investigate the regulatory situation for all formulated foods for weight reduction purposes, and identify a workable regulatory solution. Work on this project will commence once Proposal P242 has been completed.

Consultations since Preliminary Final Assessment

Public consultation for Proposal P242 was conducted as part of the Preliminary Final Assessment in 2004. Twenty-three separate submissions were made during that period. Given the lapse in time since that public consultation round, FSANZ also held targeted consultations in April-May 2010 with industry representatives, health professionals and jurisdictions in both Australia and New Zealand.

The outcomes of the two consultation periods are provided in Attachment 2 to this Consultation Paper.

Outcomes of assessments for Proposal P242

FSANZ has undertaken several risk assessments relating to Proposal P242, specifically on the risks relating to food additives/processing aids; and the presence of fermentable oligosaccharides, lactose, fructose and polyols (FOLFAPs) in FSMPs. Previous risk assessments undertaken at Preliminary Final Assessment have also been reviewed.

On the basis of these assessments, and the contributions from stakeholder submissions, FSANZ has revised draft Standard 2.9.5. The following changes are proposed:

- A previously proposed restriction on the advertising of FSMPs to consumers will no longer apply. A previously proposed restriction on the sale of FSMPs will remain, although the wording has been revised. Due to this revision, some questions have been provided for comment by submitters regarding the implementation of this restriction on the sale of FSMPs.

- Nineteen new forms of nutrients /related substances have been determined as safe for addition to FSMPs, and will be permitted in the draft Standard 2.9.5.

- Eleven food additives are determined as safe for use in FSMPs. These food additives are in addition to the food additive permissions in Schedules 2 and 3 of Standard 1.3.1, and the processing aid permissions in Standard 1.3.3, that are already recommended for FSMPs. Permissions in Schedule 4 of Standard 1.3.1 (colours) will no longer apply to FSMPs.

- FSANZ has posed questions in Section 6.2.1 as to whether these changes to food additive permissions will accommodate FSMP manufacturing practices.

- The minimum and maximum micronutrient requirements for FSMPs that are represented as nutritionally complete will remain at the values previously proposed at Preliminary Final Assessment. However, FSMPs that are represented as nutritionally complete will now be permitted to vary from any of the micronutrient requirements, provided a statement is placed on the label detailing the nutrients that have been varied, and the variations from the micronutrient requirements.

- As was proposed at Preliminary Final Assessment, FSMPs will be exempt from the generic labelling provisions of the Code, and will instead comply with a specific set of labelling requirements. FSANZ has now extended these requirements to include:

  – an exemption from all labelling for inner packages of FSMPs that are not for individual sale. FSANZ has posed questions in Section 7.4 of the paper on how this exemption will operate in practice
  – the application of allergen labelling requirements (Clause 4 of Standard 1.2.3) to FSMPs.
  – the application of legibility requirements (Standard 1.2.9) to FSMPs.

FSANZ's assessment of FOLFAPs has indicated that these substances can cause adverse health effects in some people who consume FSMPs. FSANZ has proposed a number of questions in this paper (Sections 6.2.2 and 7.5) for comment by submitters, which relate to proposed further clarification of the risks associated with FOLFAPs and potential regulatory strategies for managing the risks of the FOLFAPs content of FSMPs.

Preferred Approach

FSANZ's preferred approach is Option 2 – Regulation of FSMPs by a discrete Standard.

Under this option, a discrete Standard for FSMPs will be included in Part 2.9 - Special Purpose Food of the Code incorporating specific compositional and labelling requirements, which are in general, consistent with relevant overseas regulations. Additional risk management strategies would be applied, consisting of mandatory advisory labelling for use under medical supervision, and restrictions on the sale of FSMPs. These additional risk management strategies are consistent with the Policy Guideline on the Intent of Part 2.9 of the Code.

The proposed draft Standard 2.9.5 is located at Attachment 1.

Reasons for Preferred Approach

Option 2 is the preferred approach for the following reasons:

- The explicit recognition of FSMPs in the Code provides regulatory certainty for industry and for government enforcement agencies, and reduces the overall regulatory burden on these products.

- The inclusion of FSMPs as a 'special purpose food' recognises that these foods are designed for a particular vulnerable target group.

- The regulation of FSMPs protects the health and safety of consumers, particularly as the target group are a vulnerable population.

- The setting of minimum and maximum compositional requirements for FSMP products that are represented as nutritionally complete protects the health and safety of consumers and ensures their nutritional needs are met. In addition, the permission to vary the composition for a specific medical condition ensures products can be manufactured to meet the particular needs of certain consumers of FSMPs.

- Restricting the access to FSMPs along with the requirement to label 'use under medical supervision' protects the health and safety of users of FSMPs by ensuring there is medical oversight of these products, as is intended.

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

Next Steps

Following this round of public consultation, a Final Assessment Report for this Proposal will be prepared for consideration by the FSANZ Board. If approved by the FSANZ Board, notification will be made to the Ministerial Council and it is anticipated that the proposed revised draft standard would come into effect shortly thereafter upon gazettal, subject to any request from the Ministerial Council for a review.

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SUPPORTING DOCUMENT

The following report was used in the preparation of this Consultation Paper and is available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/proposals/proposalp242foodsforspecialmedicalpurposes/index.cfm.

SD1: Risk Assessment Report – Proposal P242

Invitation for Submissions

FSANZ invites public comment on this Consultation Paper and the draft variations to the Code, based on regulation impact principles, for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ 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. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 9 February 2010

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5636

INTRODUCTION

At the end of 2002 the *Australia New Zealand Food Standards Code* (the Code) was introduced as a joint set of food standards for both Australia and New Zealand. Food Standards Australia New Zealand (FSANZ) has been working on a food standard covering food for special medical purposes (FSMPs) for inclusion in the joint Code. The development of this standard has been progressing under Proposal P242.

FSANZ previously released a Preliminary Final Assessment Report on Proposal P242 in August 2004 for public comment. Proposal P242 was deferred after that consultation period, due to the initiation of work by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) to develop a Policy Guidance on the Intent of Part 2.9 - Special Purpose Foods. The Policy Guideline was approved in October 2009.

Given the complexity of the issues involved in this Proposal and the lapse in time since the Preliminary Final Assessment, FSANZ has included an additional round of public comment to allow further consultation on the proposed standard for FSMPs. Therefore this Consultation Paper has been prepared to discuss issues relevant to FSMPs, including issues raised in submissions to the Preliminary Final Assessment Report. Table 5, Section 12.2 provides a summary of proposed changes to Standard 2.9.5 since the last consultation. Comments are invited on all of the assessments and discussions in this document, including the proposed draft Standard 2.9.5 – Food for Special Medical Purposes (Attachment 1). Comments received will assist in preparing the final assessment of the draft standard for FSMPs.

1. The Scope of Proposal P242

FSMPs are formulated food products, used under the supervision of medical or other health professionals (e.g. dietitians, nurses and pharmacists), for the dietary management of individuals (including children) with ongoing chronic medical or disability conditions, or during acute phases of illness, injury or disease states. They include 'complete nutrition' formulas (i.e. 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.

1.1 Exclusion of very low energy diet products from the scope

Very low energy diet (VLED) products are those formulated foods intended for use under medical supervision as part of the dietary management of morbid obesity. Until the last round of public consultation in 2004, FSANZ had included VLED products in the range of foods that would be subject to the outcomes of Proposal P242.

However the market for formulated foods used for weight reduction has been evolving since 2004. There is now an overlap of VLED products and other types of formulated foods used for weight reduction (regulated as meal replacements under Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods), both in the presentation of these two food categories and in how the products are consumed/used.

FSANZ has therefore decided to exclude VLED products from the outcomes of Proposal P242, and include these products in a subsequent proposal. If VLED products had remained in the scope of Proposal P242, then there is the potential that two different regulatory arrangements could have developed for products that would, for all practical purposes, be sold and used in a similar manner. FSANZ has instead created a new project that will specifically investigate the regulatory situation for all formulated foods for weight reduction purposes, and identify a workable regulatory solution that provides a clear differentiation between VLEDs and other meal replacement products. Work on this project will commence once Proposal P242 has been completed, subject to available resources.

1.2 Other products that are not included in the scope

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, TPNs are 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 forthcoming review of Standard 2.9.1 – Infant Formula Products.

2. The Regulatory Problem

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

FSMPs are suitable for consumption only by those individuals for whom the product has been designed. Each FSMP is suitable for use with certain illnesses and disease states, and should only be consumed by individuals with these medical condition(s). Some FSMPs can also be contraindicated for use during different states of health, and it is therefore important that individuals with these conditions do not inadvertently obtain and consume inappropriate FSMP products.

Currently, there is no explicit standard for FSMPs in the Code, with the result that FSMPs are subject to generic (Chapter 1) food standards. However, the specially formulated nature and specialised use of FSMPs often makes it difficult for these products to comply with the generic food standards. There is an absence of permissions for the addition of unusual forms of nutrients and related substances, and there is no scope to label a product with specific medical information. There are also no controls in the generic food standards that can manage the unique risks that occur with the use of FSMPs, nor is there any recognition of the protection provided to consumers from a supervising medical officer or other health professional.

The lack of an explicit food standard for FSMPs creates difficulties for enforcement agencies and manufacturers of FSMPs in determining the compliance of the products with the Code. These enforcement problems occasionally cause delays in the importation and distribution of FSMPs to consumers.

3. Background

3.1 Current Regulatory Environment

3.1.1 Australia

There is no explicit standard for FSMPs within the Code that recognises the particular features of this group of products. As a result, the regulation of FSMPs is unclear causing difficulties for FSMP manufacturers, the State and Territory enforcement agencies and the Australian Quarantine and Inspection Service (AQIS).

3.1.2 New Zealand

Under the former *New Zealand Food Regulations 1981* (NZFR) there had been no specific regulation solely for FSMPs, although some products may have fallen under Regulation 237 - Special Purpose Foods. The NZFR were repealed in late 2002 and Standard 1.1A.6 – Transitional Standard for Special Purpose Foods incorporates the provisions of Regulation 237 in the Code until such time as a Standard for FSMPs is developed.

In March 2010, the New Zealand Government introduced the *New Zealand Food (Supplemented Food) Standard 2010*, which provided a two-year transition period. This standard covers foods that are represented as having an added substance or substances, or that have been modified to perform a physiological role beyond the provision of a simple nutritive requirement. It is FSANZ's understanding that this Standard does not capture FSMPs, as there are a number of requirements in this standard that conflict with current market practices for FSMPs. For example, the standard prohibits labels from displaying statements to the effect that the product treats or prevents disease.

3.1.3 International and other national regulations

There are a number of international and other national regulations that are relevant to the Australia/New Zealand regulation of FSMPs. These are:

- Codex standards for 'The Labelling of and Claims for Foods for Special Medical Purposes' (codex stan 180-1991)

- European Commission Directive on 'dietary foods for special medical purposes' (Directive 1999/21/EC), and the European Commission Regulation 'on substances that may be added for specific nutritional purposes in foods for particular nutritional uses' (PARNUTS) (EC 953/2009)

- United States of America federal legislation: the *Orphan Drug Amendments 1988* and the *Nutrition Labeling and Education Act 1990* (NLEA); a final ruling by the United States Food and Drug Administration (FDA) in 1993 clarifying the NLEA; and the *Food Allergen Labeling and Consumer Protection Act 2004*

- Canadian Fo*od and Drug Regulations 1954*, Division 24 – Foods for Special Dietary Use, specifically regulations on 'Formulated Liquid Diets' (B.24 100 – 103).

3.1.4 Therapeutic goods/medicines

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, in the absence of any explicit recognition of FSMPs within the Code, FSMPs potentially fall in the regulatory interface of therapeutic goods and food.

If a standard for FSMPs is introduced, it is possible that some products currently positioned under the *Therapeutic Goods Act 1989* will migrate to regulation under this legislation. However, the TGA has advised FSANZ that the number of repositioned products will be small.

Similarly in New Zealand, FSMPs 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. However, the level of formulation of FSMPs and their role in the treatment of particular health conditions can still cloud their distinction as foods rather than as medicines.

3.2 Current market and distribution of foods for special medical purposes

There are three multi-national companies that almost exclusively supply the total Australian and New Zealand market of FSMP-type products. The domestic market is typified by small volume, high value product lines, and there is a very high proportion of imported FSMPs on the market due to the minimal local manufacture of these products. The FSMPs entering Australia or New Zealand are originally manufactured for the markets of either the European Union (including the United Kingdom) or the United States of America.

With very few FSMPs manufactured in domestic markets, there is no significant trade of FSMPs between Australia and New Zealand. Some transfer of products may occur between Australia and New Zealand to balance product shortfalls or excesses, however the multi-national manufacturers of FSMPs ultimately treat both nations as one market.

The local FSMP 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 higher volumes than highly specialised foods for rare disease states that may only be supplied to a very small number of people.

3.2.1 Australian products

The majority of FSMPs 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 FSMPs to healthcare facilities most often occurs through either state-wide or regional health service tendering procedures.

Generally, tenders outline requirements for the supply of specific FSMPs including composition and price. FSANZ is aware that health services at times seek guidance from the Code (e.g. labelling requirements) when preparing tender specifications.

FSMPs, particularly the highly specialised products, can be very expensive for the consumer; a problem that is often compounded by long-term dependence on such products. Individuals who require 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. Currently, FSMPs are not sold 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 small number (approximately 100) of products, predominately for metabolic disorders, are listed on the Pharmaceutical Benefits Scheme.

3.2.2 New Zealand products

Most 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, FSMPs are currently not available through supermarkets or convenience stores.

The majority of foods for special dietary use in New Zealand are currently listed on the NZ Pharmaceutical Schedule, administered by PHARMAC (the Pharmaceutical Management Agency Ltd). PHARMAC has the task of managing pharmaceutical subsidies on behalf of the District Health Boards to ensure that all New Zealanders have access to safe, cost effective, quality medicines to meet reasonable health needs. Due to the listing of many FSMPs 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.

4. Objectives

4.1 Specific objectives for Proposal P242

The specific objectives of Proposal P242 are to:

1. protect public health and safety by ensuring that FSMPs products are formulated to be safe and nutritionally adequate, and by ensuring that consumers of FSMPs receive adequate supervision with the use of these products

2. provide health professionals and consumers with sufficient information to make appropriate choices about the safe and effective use of FSMPs

3. develop a food standard applying to FSMPs in Australia and New Zealand that is consistent, where possible, with relevant international regulations, and allows for a continued supply of FSMPs to Australian and New Zealand consumers.

These objectives are the primary goals for the assessments presented in this consultation paper. However FSANZ is also mindful of the overall importance of the objectives and principles detailed the FSANZ Act, and in policy guidance from the Ministerial Council.

4.2 Objectives and principles in the FSANZ Act

In developing or varying a food standard, FSANZ is required by section 18 of the FSANZ Act to meet three primary objectives. These are:

- the protection of public health and safety; and

- 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, section 18 also requires that FSANZ must 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.

FSANZ has, where relevant, aligned the specific objectives for Proposal P242 with section 18 of the FSANZ Act. Notably, the first two primary objectives of the FSANZ Act are captured directly, as well as consistency between domestic and international food standards.

4.3 Policy guidelines

Of the policy guidelines published by the Ministerial Council, the guideline that applies directly to Proposal P242 is the *Guideline on the Intent of Part 2.9 – Special Purposes Foods of the Code*. The development of a standard for FSMPs is within the scope of this policy guidance, which states:

> *Part 2.9 – Special Purpose Foods of the Code is intended to contain food standards that prescribe specific requirements for foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups.*

The policy guideline details several specific policy principles that are to apply to standards within Part 2.9 of the Code. These principles are:

- Special purpose foods should be targeted only to those population groups satisfying the definition presented in the Scope/Aim section.

- The composition of special purpose food should be consistent with the intended purpose.
- Adequate information should be provided, including through labelling and advertising of special purpose foods, to:

  – assist consumer understanding of the specific nature of the food, the intended population group and intended special purpose of the food; and
  – provide for safe use by the intended population and to help prevent inappropriate use by those for whom the special purpose food is not intended.

- Consideration, where appropriate, should be given to application of controls to restrict access to a special purpose food on the basis of risk to public health and safety.

FSANZ has given consideration to each of these specific policy principles when undertaking its assessments for Proposal P242. The application of these principles is provided in further detail within the relevant sections of this report.

5. Questions to be answered

At this stage of the project, it has been FSANZ's priority to revisit and investigate the key elements of draft Standard 2.9.5. FSANZ has therefore considered the following questions:

- Are there any new substances that have emerged since 2004 that should be granted permission for addition to FSMPs, and should these permissions be given (commensurate with health and safety risks)?

- Can the micronutrient minima and maxima requirements for FSMPs represented as nutritionally complete accommodate the variations required in FSMP formulations to meet the needs of various medical conditions?

- Emerging research has indicated that some individuals may experience adverse health effects with chronic intakes of fermentable oligosaccharides, lactose, fructose and polyols (FOLFAPs). How is information provided on FSMP labels for each of the individual FOLFAPs substances, and is this information sufficient for the use or provision of advice on FSMPs that contain FOLFAPs?

- What types of restrictions are required on the sale, access and advertising of FSMPs? Are the advertising restrictions previously proposed in 2004 considered to be suitable for managing the public health and safety risks of FSMPs?

- What labelling requirements should apply to FSMPs? Do the previously proposed exemptions and additional labelling requirements allow for the provision of adequate information on FSMPs?

RISK ASSESSMENT

6. Risk assessment summary

There are inherent risks associated with the use of FSMPs that primarily relate to their specialised nature and the special dietary circumstances associated with their use. These risks were previously investigated by FSANZ at its Preliminary Final Assessment (2004) for Proposal P242.

Since 2004, there have been further developments on the safety of substances added to FSMPs, and new issues have also emerged relating to the risks associated with the use of FSMPs. FSANZ has therefore reviewed the previous 2004 risk assessments conducted on FSMPs, and has investigated the new scientific developments since 2004. A summary of the outcomes of these risk assessments are provided in the sections below, with full details provided in Supporting Document 1 (SD1) to this Consultation Paper.

6.1 Review of previous risk assessments from 2004

6.1.1 Permitted forms of added nutrients / related substances

There are 18 new forms of nutrients/related substances that have been added to permitted forms lists in overseas regulations. Another form (lutein) has also been added to Standard 2.9.1 – Infant Formula Products since 2004. In 2004, the risk assessment determined that Australian and New Zealand FSMPs permitted forms should harmonise where possible with overseas regulations, and should also include permitted forms that had been established as safe for use in infant formula. In accordance with these decisions, the risk assessment recommends that the 19 new forms should also be permitted for use in FSMPs. A list of these nineteen new forms is provided in Table 1 below.

FSANZ notes that one of the additional permitted forms (selenium enriched yeast) has no purity specification within Standard 1.3.4 – Identity and Purity of the Code. The risk assessment has therefore identified a specification that can be included in Standard 1.3.4.

Table 1: Additional forms of nutrients and related substances

Substance	Permitted form
Calcium	Calcium bisglycinate
	Calcium citrate malate
	Calcium malate
	Calcium L-pidolate
Choline	Choline hydrogen tartrate
Fluoride	Calcium fluoride
Iron	Ferric orthophosphate
	Ferrous L-pidolate
Lutein	Lutein
Magnesium	Magnesium bisglycinate
	Magnesium hydroxide carbonate
	Magnesium L-pidolate
	Magnesium potassium citrate
Pantothenic acid	DL-panthenol
Potassium	Potassium L-pidolate
Selenium	Selenium enriched yeast
Vitamin E	D-alpha-tocopherol polyethylene glycol-1000 succinate (TPGS)
Zinc	Zinc bisglycinate

6.1.2 Micronutrient requirements for FSMPs represented as nutritionally complete

At Preliminary Final Assessment (2004), FSANZ conducted two assessments that investigated the risks associated with micronutrient inadequacy and the safety of excessive micronutrient levels from FSMPs represented as nutritionally complete. From these assessments, FSANZ recommended twenty-six minimum and nine maximum micronutrient requirements for FSMPs represented as nutritionally complete.

FSANZ reaffirms the outcomes of the micronutrient assessments undertaken at Preliminary Final Assessment, and recommends that the minimum and maximum requirements that were proposed in 2004 should be retained. There has been no new evidence provided in submissions to demonstrate that the minima and maxima levels proposed in 2004 are inappropriate for managing the risks of inadequate and/or excessive micronutrient intakes from those FSMPs represented as nutritionally complete.

The minimum and maximum micronutrient requirements that were proposed at Preliminary Final Assessment are listed in Table 2 below. This table has also been updated with corrections of typographical errors that were present in the 2004 drafting.

Table 2: Minimum and maximum micronutrient requirements for FSMPs represented as nutritionally complete

Column 1	Column 2	Column 3
Nutrient	**Minimum Amount per MJ**	**Maximum Amount per MJ**
Vitamins		
Vitamin A	84 µg retinol equivalents	345 µg retinol forms only
Thiamin	0.15 mg	No maximum set
Riboflavin	0.2 mg	No maximum set
Niacin	2.2 mg niacin equivalents	No maximum set
Vitamin B_6	0.2 mg	2.9 mg
Folate	25 µg	No maximum set
Vitamin B_{12}	0.17 µg	No maximum set
Vitamin C	5.4 mg	No maximum set
Vitamin D	1.2 µg	5.7 µg
Vitamin E	0.5 mg alpha-tocopherol equivalents per gram of polyunsaturated fatty acids expressed as linoleic acid, but in no case less than 1 mg alpha-tocopherol equivalents per MJ	No maximum set
Biotin	1.8 µg	No maximum set
Pantothenic Acid	0.35 mg	No maximum set
Vitamin K	8.5 µg	No maximum set
Minerals		
Calcium	84 mg	287 mg
Magnesium	18 mg	No maximum set
Iron	1 mg	No maximum set
Phosphorus	72 mg	No maximum set
Zinc	1 mg	4.6 mg
Manganese	0.12 mg	1.32 mg
Copper	0.15 mg	1.15 mg
Iodine	15.5 µg	115 µg
Chromium	3 µg	No maximum set
Molybdenum	7 µg	No maximum set
Selenium	6 µg	46 µg
Electrolytes		
Sodium	72 mg	No maximum set
Potassium	190 mg	No maximum set
Chloride	72 mg	No maximum set

6.2 Assessments relating to new scientific developments

6.2.1 Food additives and processing aids

At Preliminary Final Assessment, FSANZ proposed to include an entry for FSMPs in Schedule 1 of Standard 1.3.1 – Food Additives. An entry for FSMPs in Schedule 1 provides a mechanism to permit the addition of food additives listed under Schedules 2, 3 and 4 of Standard 1.3.1 to FSMPs.

Since 2004, FSANZ has consulted with the FSMP industry and asked whether the approach proposed at Preliminary Final Assessment would reflect the use of food additives in existing FSMPs sold in Australia and New Zealand. FSANZ was subsequently advised by the FSMP industry of fourteen other food additives that should be specifically included in Schedule 1 of Standard 1.3.1 (eight preservatives, four intense sweeteners, and two antioxidants).

FSANZ has assessed all of the proposed additives and determined that they each have a technological function associated with their addition to FSMPs. All of these additives are familiar to FSANZ, have permissions within the Code, and have a history of safe use. Further assessment on whether maximum levels of use are required for these additives has identified that:

- 11 out of the 14 requested food additives (four sorbates, four benzoates, acesulphame potassium, aspartame-acesulphame salt, and saccharin) can be permitted for use in FSMPs under Schedule 1 of Standard 1.3.1. FSANZ has also identified maximum levels associated with use of these food additives in FSMPs. Submitters should note that the maximum level set for saccharin is lower than its interim level for beverage type special dietary foods in the United States (200 mg/kg versus 400 mg/kg).

- One food additive, aspartame, has permission in Schedule 2 of Standard 1.3.1 for general use in processed foods. This permission is considered to be satisfactory for the manufacture of FSMPs.

- Two of the fourteen requested food additives (butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT)) do not require explicit FSMP permission in Schedule 1 of Standard 1.3.1. FSANZ has concluded that the carry-over provisions in clause 7 of Standard 1.3.1 are sufficient for the presence of these food additives in FSMPs.

Additionally, FSANZ has reassessed the Preliminary Final Assessment permission for Schedule 2, 3 and 4 additives. FSANZ has determined that Schedule 4 colour permissions should not apply to FSMP. Schedule 2 and 3 additives can, however, be used for FSMPs.

On the basis of these outcomes, this risk assessment recommends the inclusion of 11 new permissions in Schedule 1 of Standard 1.3.1 for the use of food additives in the manufacture of FSMPs, and permission to use the additive permissions in Schedules 2 and 3 of Standard 1.3.1 for FSMPs. A list of the 11 permitted additives food additives and their maximum levels of use are provided in Appendix 1 of this risk assessment.

Table 3: Additional food additives recommended for use in the manufacture of FSMPs

INS Number	Additive Name	Max Permitted Level
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	1500 mg/kg
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	1500 mg/kg
950	Acesulphame potassium	450 mg/kg
954	Saccharin	200 mg/kg
962	Aspartame-acesulphame salt	450 mg/kg

Given the changes proposed for Standard 1.3.1, FSANZ poses the following questions below for submitter feedback.

Questions for submitters

- Will the recommended level of 200 mg/kg of saccharin in FSMP pose any problems for current formulations of FSMP products imported into Australia?

- Is there a justified technological need for the addition of Schedule 4 colours to FSMP?

6.2.2 Fermentable oligosaccharides, lactose, fructose, and polyols (FOLFAPs)

Fermentable oligosaccharides, lactose, fructose, and polyols (FOLFAPs) are widespread in the diet. FOLFAPs is an acronym developed by FSANZ since the more commonly used term *FODMAPS* (fermentable oligosaccharides, disaccharides, monosaccharides and polyols) is trademarked. The two acronyms are essentially the same; however, FOLFAPS is more specific in that the literature identifies lactose as the only disaccharide of interest and fructose as the only monosaccharide of interest.

FOLFAPs are readily fermentable carbohydrates which can cause luminal distention of the distal small intestine and the proximal colon in some individuals. Recent scientific opinion considers luminal distention to be the physiological basis for the gastrointestinal symptoms associated with consumption of FOLFAPs. Dietary challenge studies using FOLFAPs have demonstrated that in some individuals, the intake of these substances can induce gastrointestinal symptoms and increase gas production (measured via methane and hydrogen breath testing), while dietary studies limiting FOLFAPs intake have shown symptom reduction.

The relationship between FOLFAPs intake and gastrointestinal symptoms has been demonstrated in both Inflammatory Bowel Disease (IBD) and functional bowel disorders (FBDs), the former consisting of Crohn's disease, ulcerative colitis and indeterminate colitis, and the latter being a term that applies to conditions where signs of pathology associated with IBD are not found. It is likely that a number of individuals with these gastrointestinal conditions will use FSMPs, especially if they are admitted to hospitals or healthcare centres for management of their conditions, or for other non-related medical conditions.

Due to the emerging evidence of an association between FOLFAPs and the gastrointestinal conditions noted above, FSANZ has undertaken a review of the literature to determine the significance of the presence of FOLFAPs in FSMPs. The literature identified by FSANZ was not specifically focused on the health effects of FOLFAPs, rather the review was designed to observe the variance in symptoms in relation to exclusion and re-challenge of diets with FOLFAP substances. This material demonstrated the following:

- Seven studies that examined the health effects of increasing the FOLFAP content of the diet demonstrated an association between increasing FOLFAP intakes and increased gastrointestinal symptoms (diarrhoea, abdominal distention, abdominal pain and flatulence). Tolerance to different types and amounts of FOLFAPs varied among individuals which may be related to individually-determined non-dietary factors such as lactase and glucose transporter proteins. The balance of bowel biota was also identified as a potentially important influence on the tolerance to different FOLFAPs in individuals. Certain FOLFAPs have been shown to exert a laxative effect at high enough doses, and some (e.g. lactulose) are utilised medically for these effects.

- For those that consume FSMPs (specifically enteral nutrition products containing FOLFAPs), there is an increased risk of diarrhoea during or following enteral nutrition regardless of the principal underlying condition being treated. FSANZ notes, however, that the evidence of health effects related to FOLFAPs in FSMPs is very limited (one pilot retrospective case-control study on enteral nutrition products only).

On the basis of the available evidence, FSANZ considers that the presence of FOLFAPs in FSMPs may produce adverse health effects, especially for FSMP consumers with pre-existing gastrointestinal disorders. However, it is difficult to quantify the magnitude of this health risk given the limited available literature. As a result, FSANZ has posed several questions for submitter comment in this Section , which relate to the magnitude of the risk.

Questions to Submitters

- Are FSMPs used in the management of FBDs and/or IBD (including during hospitalisation)?
- What is the prevalence of FBDs and/or IBD in consumers of FSMPs?
- Do FOLFAPs exacerbate FBDs and/or IBD in consumers of FSMPs that are used in the management of these conditions?

Do FOLFAP ingredients in FSMPs promote the development of FBDs and /or IBD in patients with no earlier signs of these conditions?

RISK MANAGEMENT

The outcomes of the risk assessments in Section 6 have been considered in determining the risk management for FSMPs. The proposed strategies discussed in this part of the Consultation Paper have been developed to manage any potential risks to the public's health and safety. The risk management has also considered the comments and issues raised in consultations with stakeholders, specifically:

- submissions made to the round of public consultation in 2004 following the release of the Preliminary Final Assessment Report

- an additional round of targeted consultations with industry, government and health professional stakeholders in April-May 2010.

At Preliminary Final Assessment, FSANZ determined that there are significant potential risks associated with the unsupervised and inappropriate use of FSMPs. To manage these risks and also to clearly distinguish FSMPs from other foods, FSANZ proposed a risk management framework that would allow for reduced prescription in composition and labelling requirements. As a result, the 2004 draft Standard 2.9.5 contained fewer compositional and labelling requirements for FSMPs, and in addition:

- required manufacturers to place a mandatory advisory statement on the label to the effect that FSMPs are to be used only under medical supervision

- restricted the outlets and sources of sale of FSMPs by permitting the sale of FSMPs only from medical practitioners, pharmacies, hospitals, nursing homes, FSMP manufacturers, and wholesale distributors of FSMPs to the aforementioned medical practitioners and establishments

- restricted advertisements directly to consumers, with advertising permitted only to health professionals, wholesalers, healthcare facilities (e.g. hospitals and nursing homes), and to members of disease and disorder support groups.

Since Preliminary Final Assessment, there have been a number of developments that are relevant to the regulation of FSMPs. These developments led FSANZ to revise the additional risk management strategies listed above, with the result that there are now only requirements on the sale, composition and labelling of FSMPs. The previously proposed restriction on the advertising of FSMPs directly to consumers will no longer apply. The revised strategy is reflected in the 2010 draft Standard 2.9.5 at Attachment 1 and is outlined in the following sections below.

The following sections provide detail on:

- the approach taken at Preliminary Final Assessment in relation to the sale, advertising, composition and labelling of FSMPs
- feedback from targeted stakeholder consultations undertaken in 2004 and again in 2010 when Proposal P242 recommenced (see Section 11 and Attachment 2)
- FSANZ's revised risk management strategies and the rationale for each strategy.

7. Risk Management Issues

7.1 Availability, sale and access for FSMPs

7.1.1 Approach taken at Preliminary Final Assessment

At Preliminary Final Assessment, FSANZ proposed a restriction on the sale of FSMPs so that these products may be sold by medical practitioners, pharmacies, hospitals, nursing homes and wholesalers only. This was part of an overarching risk management framework to reduce the potential risks associated with the unsupervised and inappropriate use of FSMPs.

7.1.2 Consultation

Many submitters to the 2004 Preliminary Final Assessment considered a restriction on the sale of FSMPs to the general public to be unnecessary, stating that there was a lack of evidence of market failure and no reported risk to public health and safety. Submitters also considered that consumers would be protected by the requirement to display 'use under medical supervision' on the label of FSMPs. In addition, some submitters requested an amendment to the restriction on sale to allow wholesalers/distributors of FSMPs to sell directly to consumers.

However, feedback from the 2010 targeted consultations indicated that stakeholders generally supported the proposed restrictions on sale of FSMPs as this was largely the current arrangement. One industry submitter requested a change to draft Standard 2.9.5 to allow for access to oral supplements directly through supermarkets.

7.1.3 FSANZ revised approach

FSANZ proposes to retain a restriction on the sale of FSMPs. A restriction on sale is in accordance with the *Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods of the Code,* released in 2009.

The Policy Guideline (outlined in Section 4.3) states that consideration, where appropriate, should be given to the application of controls to restrict access to a special purpose food on the basis of risk to public health and safety. The intent of the restriction on sale is to ensure that consumers receive, or have access to medical supervision prior to purchasing a FSMP, thus minimising the risk of incorrect product use by persons for whom the product is not intended.

The restriction on sale in clause 4 of draft Standard 2.9.5 has been revised, noting the comments received in submissions. The revised clause is intended to reflect current FSMP access and purchasing practices in Australia and New Zealand and is therefore is not intended to regulate the current supply chain or alter current access arrangements for consumers of FSMPs.

Clause 4 of draft Standard 2.9.5 now states that FSMPs may be offered for sale by:

(a) a pharmacy, hospital or nursing home; or
(b) a medical practitioner or dietitian; or
(c) a manufacturer of food for special medical purposes, or a distributor of a manufacturer of food for special medical purposes.

Draft Standard 2.9.5 has been revised to include sale by a 'dietitian' as well as a 'medical practitioner'. FSANZ recognises it is becoming more common for dietitians in private practice to sell FSMPs and that these individuals are suitably trained to provide professional advice and supervision.

The revised draft Standard now explicitly permits the sale of FSMP by manufacturers and their distributors. Submitters to the PFAR requested an amendment to the draft Standard to allow for the sale of FSMP directly from wholesalers/distributors to consumers. However, as the term 'wholesaler' generally refers to a business involved in the sale of products to anyone other than a consumer, the terms manufacturer and distributor[1] have been used instead.

FSANZ is aware that FSMP distributors cannot provide medical supervision or advice on FSMPs to consumers. However, FSANZ recognises that arrangements exist in the Australia and New Zealand marketplace where distributors sell FSMPs directly to consumers once a referral or advice has been obtained from a trained health professional. Some manufacturers are also staffed with qualified individuals that can provide appropriate advice if a consumer purchases a product directly from their business.

Although the intent of the revised restriction on sale is the same as the version proposed at Preliminary Final Assessment, it accommodates the various groups of sellers in a different manner. Therefore, FSANZ is proposing the following questions for submitters in relation to the revised wording of the restriction on sale of FSMP.

Questions to submitters

- Does the revised restriction on the sale of FSMP accurately reflect current sale and access arrangements for FSMPs in Australia and New Zealand? If not, please describe the current arrangements, providing examples where possible.
- Will the revised restriction on the sale of FSMP result in any difficulties in the sale of, or access to FSMP?

[1] The word distributor is intended to be a generic term covering both distributors and wholesalers.

7.2 Advertising

7.2.1 Approach taken at Preliminary Final Assessment

At Preliminary Final Assessment, the proposed draft Standard 2.9.5 restricted advertisements directly to consumers, with advertising permitted only to select health professionals, scientists working in medical laboratories, wholesalers of FSMPs, healthcare facilities (e.g. hospitals and nursing homes) and members of disease and disorder support groups. The restriction on advertising of FSMPs to the general public was proposed as a means of managing the public health and safety risks associated with the unsupervised and inappropriate use of FSMPs, in particular VLED products. VLED products have now been removed from the scope of P242, leading FSANZ to reconsider the proposed restriction.

7.2.2 Consultation

Submitters to the Preliminary Final Assessment generally disagreed with the proposed restriction on advertising of FSMPs, stating that there was no evidence of risk to public health and safety. Feedback from the 2010 targeted consultations was similar, with industry, health professionals and jurisdictions generally supporting the removal of advertising restrictions for FSMPs. Stakeholders mentioned that restrictions would have little effect when advertising is available through the internet. They also stated that advertising restrictions are unnecessary while consumers are protected under the *Trade Practices Act 1974 as* administered by the Australian Competition and Consumer Commission (ACCC). In New Zealand, the *Fair Trading Act 1986* would also apply.

7.2.3 FSANZ revised approach

FSANZ proposes to remove the restriction on advertising of FSMPs to allow direct advertising to the general public. The rationale for this decision is outlined below:

- The potential for inappropriate use of FSMPs as a result of direct advertising to consumers is considered to be low, particularly with the removal of VLED products from the scope of Proposal P242. In particular, it is considered unlikely that FSMPs would be promoted to individuals for whom they are not intended, given the specialised use associated with these products.

- Removing the prohibition on advertising harmonises with European regulations (Directive 1999/21/EC) and Codex (Codex STAN 180-1991). There will also no longer be any potential conflict with the increasing practice to globally advertise FSMPs (e.g. via websites).

- It is considered that other risk management strategies (including restrictions on access, compositional limits and labelling of FSMPs for use under medical supervision) provide sufficient management of potential public health and safety risks.

7.3 Composition

Specific compositional requirements were proposed at Preliminary Final Assessment to manage the risks associated with the formulation and use of FSMPs.

The compositional requirements related to chemical forms for nutrients and related substances, which encompasses food additives and processing aids, as well as prescribed micronutrient minima and maxima.

7.3.1 Chemical Forms for Nutrients/Related Substances

7.3.1.1 Approach taken at Preliminary Final Assessment

At Preliminary Final Assessment, the proposed list of permitted forms of nutrients and related substances was based primarily on European legislation, but was extended to include permitted forms from:

- Schedule 1 of Standard 2.9.1 – Infant Formula Products
- Codex Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979 revised in 2008)
- Some additional nutritive substance forms that were assessed as safe for addition to FSMPs.

7.3.1.2 Consultation

At the 2004 Preliminary Final Assessment, submitters requested a wider range of permitted forms and food additives for inclusion in Schedule 1 of draft Standard 2.9.5 and greater alignment with European regulations. Stakeholder feedback received from the targeted consultations in 2010 indicated support for those substances considered safe by Codex Alimentarius, the European Commission and the USA Food and Drug Administration. In addition, submitters requested:

- an extension of the proposed list of permitted forms to include substances listed in Standard 2.9.1 – Infant Formula Products
- the adoption of an overarching statement for amino acids similar to the European (EC No 953/2009) and US (21CFR172.320) regulations
- a number of new forms of substances that are not currently permitted in overseas regulations, including ferrous ammonium phosphate and L-arginine acetate.

7.3.1.3 FSANZ revised approach

FSANZ is proposing to include permissions for the addition of nineteen new forms to FSMPs. As discussed in the risk assessment, these forms are approved as safe for addition to FSMPs in overseas regulations (i.e. European PARNUTS framework, and Codex Advisory List for Infants and Young Children). This decision is consistent with the previous decision at Preliminary Final Assessment to base Australian and New Zealand permitted forms on those already approved in European legislation (Regulation 953/2009), Standard 2.9.1 and Codex.

FSANZ proposes that these new permitted forms be added to Schedule 1 of Standard 2.9.5. The full list of the nineteen forms is provided in Section 6.1.1 above. Any other additional new forms required by the food industry (including ferrous ammonium phosphate and L-arginine acetate) will require an Application to FSANZ to amend the Code once Standard 2.9.5 has been gazetted, as these substances do not have any existing overseas recognition at the present time.

7.3.2 Food additives and processing aids

7.3.2.1 Approach taken at Preliminary Final Assessment

At Preliminary Final Assessment FSANZ proposed an approach to permit the use of food additives in FSMPs by adding a specific entry for FSMPs in Schedule 1 of Standard 1.3.1. This would enable the addition of those food additives listed under Schedules 2, 3 and 4 of Standard 1.3.1 to FSMPs.

It was also proposed in 2004 that clause 7 of Standard 1.3.1 – Carry-over of additives would apply to FSMPs. Also, FSANZ considered that the permissions for processing aids in Standard 1.3.3 – Processing Aids were appropriate for FSMPs, so no amendments were proposed.

7.3.2.2 Consultation

During consultations in 2010, the FSMP industry requested specific permission for additional food additives, all of which are currently permitted for use in a range of other foods in Schedule 1 of Standard 1.3.1. The risk assessment has considered the safety and suitability of these additional additives and recommends the inclusion of eleven additional food additive permissions in Schedule 1 of Standard 1.3.1 for FSMPs (see Section 6.2.1).

7.3.2.3 FSANZ proposed approach

FSANZ has considered the recommendations of the risk assessment including the need to establish maximum levels for the additional food additives requested. FSANZ has also considered relevant international regulations to ensure harmonisation where possible. FSANZ's proposed approach and rationale follows:

- An entry for FSMPs will be added into Schedule 1 of Standard 1.3.1, which would then provide for the additives permitted in Schedules 2 and 3. FSANZ has concluded that the food additives listed in Schedules 2 and 3 are technologically justified and safe and suitable for use in FSMPs, which include aspartame. However, Schedule 4 additives (colours) will be explicitly prohibited for addition to FSMP. FSANZ has not identified a reason for permitting the use of these colours in FSMPs, and the FSMP industry has not requested the use of these additives.

- Application of carry-over permissions (clause 7) of Standard 1.3.1 will apply to FSMPs. This allows for the use of foods and ingredients in FSMPs that may contain food additives, which will accommodate the presence of BHA and BHT in FSMPs.

- New permissions and maximum levels of use will be provided for each of the eleven new food additives recommended by the risk assessment. These additives are already approved in a range of other foods listed in Schedule 1 of Standard 1.3.1.

- The existing permissions for the processing aids as listed in Standard 1.3.3 will be retained, as they are considered appropriate for use in FSMPs and are already approved in a range of other foods in Standard 1.3.1. Also, the FSMP industry is not anticipated to have any technological need for processing aids outside of the current permissions.

7.3.3 Micronutrient requirements for FSMPs represented as nutritionally complete

7.3.3.1 Approach taken at Preliminary Final Assessment

In the 2004 version of draft Standard 2.9.5, FSANZ proposed that those FSMPs represented as nutritionally complete would have to comply with minimum micronutrient limits, as well as prescribed maximum limits for those micronutrients assessed as presenting a risk to safety from excessive intake. The minimum limits were based on European FSMP requirements, whereas the maximum limits were based on a FSANZ safety assessment. FSMPs were permitted to vary from the minimum limits for sodium, potassium and phosphorus for particular medical reasons.

7.3.3.2 Consultation

Submitters to the Preliminary Final Assessment called for more flexibility with compositional requirements, particularly the micronutrient minima and maxima, to support product development and meet consumer needs. Similarly, feedback from the 2010 round of consultations indicated that stakeholders generally supported micronutrient compositional requirements, provided they are flexible enough to accommodate the formulation of products for different medical conditions. However, one health professional group noted there were benefits with removing compositional requirements. Industry stakeholders also supported the harmonisation of Australian and New Zealand micronutrient content requirements with European FSMP regulations.

7.3.3.3 FSANZ proposed approach

FSANZ is proposing that FSMPs represented as nutritionally complete will need to meet the same list of minima and maxima that was proposed at Preliminary Final Assessment.

However, FSANZ is now proposing that manufacturers be permitted to vary the micronutrient content of those FSMPs represented as nutritionally complete from any of the specified limits for a specific medical purpose (including a particular medical condition, disease or disorder), but only if they meet additional labelling requirements. If an FSMP has varied from the micronutrient minima or maxima, then the label must state each of the nutrients that have been varied, and describe the variation relative to the micronutrient limits set out in Schedule 2 of Standard 2.9.5. As a result of these changes, the previous permission to vary the minimum level for specific micronutrients (i.e. sodium, potassium, phosphorus) has been deleted from the draft Standard.

This change to draft Standard 2.9.5 has been proposed so that:

- the formulation of FSMPs will meet the needs of consumers with particular medical conditions, while ensuring that product formulations are adequate for use as complete dietary replacements

- health professionals and consumers are sufficiently informed about the content of those FSMPs represented as nutritionally complete that vary from the micronutrient limits set out in Schedule 1 of Standard 2.9.5

- manufacturers cannot vary from the prescribed compositional requirements for FSMP represented as nutritionally complete unless they inform end users of this variation by way of labelling

- FSMP manufacturers have greater flexibility and can plan for future product innovation

- draft Standards 2.9.5 harmonises with European and Codex FSMP regulations. This will reduce trade barriers for industry and ensure continuity of supply of these special purpose foods to consumers who may require them as a sole source of nutrition.

FSANZ is of the view that this new approach to the formulation of FSMPs represented as nutritionally complete will accommodate both the important considerations of flexibility in FSMP formulations, and the need for supervising health professionals to have confidence that these products have been designed correctly for their intended purpose.

7.4 Application of labelling requirements to FSMPs

The majority of FSMPs in Australia and New Zealand are imported predominately from the USA or Europe and are therefore, labelled according to the regulations of these regions. For the most part labelling features such as food identification including the food name, lot and batch number and manufacturer/supplier contact details, date marking, warning statements, directions for use and storage, ingredient listing and nutritional information are applied consistently across the majority of different FSMPs, and are often consistent with the Codex labelling standards.

Most manufacturers of FSMPs customise labelling information for the Australia and New Zealand market by providing supporting product literature to health professionals. However, the information provided and that contained on the label do not always comply with the existing generic labelling requirements of the Code.

7.4.1 Approach taken at Preliminary Final Assessment

At Preliminary Final Assessment, FSANZ reassessed the labelling requirements for FSMPs and proposed that the general provisions in Parts 1.1A and 1.2 of the Code would not apply, and instead applied a specific set of labelling provisions. The specific labelling provisions reflected generic labelling requirements wherever the current range of FSMPs could accommodate them.

A summary of how the generic labelling requirements were applied to FSMPs at Preliminary Final Assessment is provided in Table 4 below:

Table 4: Summary of previous applications of labelling requirements to FSMPs

Labelling requirement	Recommendation at Preliminary Final Assessment
Health Claims *(Currently Transitional Standard 1.1A.2)*	• Transitional Standard 1.1A.2 applied to FSMPs as previously proposed at Draft Assessment, pending the development of the new standard for health claims. • Permission to label with the disease or disorder for which a FSMP is specifically formulated was provided.
Application of Labelling requirements *(Standard 1.2.1)*	• Standard 1.2.1 (how labelling is generically applied to food) did not apply to FSMPs.
Food Identification Labelling *(Standard 1.2.2)*	• Food identification requirements apply to FSMPs, with an allowance for local supplier details to be included on a transportation outer.
Mandatory Warning and Advisory Statements and Allergen Declarations *(Standard 1.2.3)*	• Standard 1.2.3 did not apply to FSMPs, except for the following statements that were added to the Standard specifically for FSMPs: - All FSMPs to be labelled with the statement 'use only under medical supervision'; and - the mandatory advisory statement 'not for parenteral use' applied to FSMPs represented as nutritionally complete.
Ingredient Listing *(Standard 1.2.4)*	• Included flexible ingredient labelling requirements for FSMPs, which covered the aspects from relevant countries.
Date Marking *(Standard 1.2.5)*	• Included date marking for FSMPs and allowed flexibility in the format.
Directions for Use and Storage *(Standard 1.2.6)*	• Included directions for use and storage for FSMPs.
Nutrition Information Panel *(Standard 1.2.8)*	• Standard 1.2.8 did not apply to FSMPs, except for conditions for lactose and gluten claims in clauses 15 and 16. • Included specific nutrition information requirements for FSMPs and allowed flexibility in the presentation of the information.
Legibility Requirements *(Standard 1.2.9)*	• This standard was not discussed at Preliminary Final Assessment. This issue is reviewed below.
Percentage Ingredient Labelling *(Standard 1.2.10)*	• Percentage labelling requirements in Standard 1.2.10 did not apply to FSMPs.
Country of Origin Labelling *(Standard 1.2.11)*	• Country of origin labelling requirements did not apply to FSMPs.
Other Specific Labelling for FSMPs	• The 2004 version of draft Standard 2.9.5 included: – a requirement for a statement 'advising where the product has been formulated for a specific age group'. – a requirement to label FSMPs with a condition, disease or disorder for which they have been specifically formulated.

7.4.2 Consultation

Submitters to the Preliminary Final Assessment Report and stakeholder comments during the 2010 targeted consultations indicated support for many of the proposed labelling requirements. Comments were specifically made in support of harmonising with European definitions of FSMPs, and the requirement for a statement specifying that the product must be used under medical supervision. It was noted that any changes to labelling requirements that are not consistent with international regulations would have significant implications for industry and consumers.

Additionally the following specific issues regarding the proposed labelling for FSMPs were raised:

- Several stakeholders did not support the proposed exemption on allergen labelling, noting that obscure ingredients are difficult to identify as potential allergens, and therefore present a public health risk. The use by food industry of the Voluntary Incidental Trace Allergen Labelling (VITAL) system was also raised, noting that this system appears to be assisting consumers to make informed choices and may be useful for FSMPs. It was considered that allergen labelling on FSMPs would benefit consumers and health professionals and therefore reduce risk.

- Some industry stakeholders recommended the adoption of EU standards with regard to lactose and gluten claims (clauses 15 and 16) of Standard 1.2.8 that applied to FSMPs in the draft Standard 2.9.5.

- Several industry stakeholders mentioned that clarification was needed with date-marking provisions for FSMPs. These stakeholders mentioned that it was not clear whether these provisions permitted 'best-before' statements.

- There was some support for the use of a statement that identifies if a product is 'suitable as a sole source of nutrition, intended for a specific age group and where appropriate, identifies precautions and contraindications' (the requirement for such a statement on FSMPs was removed from the 2004 version of draft Standard 2.9.5).

- Legibility requirements are absent which means that there are no restrictions on the type size of the mandatory warning statements.

7.4.3 FSANZ's assessment of labelling issues

7.4.3.1 Allergen Labelling

At Preliminary Final Assessment, FSANZ proposed the exemption of FSMPs from mandatory allergen declaration requirements contained in Standard 1.2.3. At that time, only European and Codex generic labelling regulations had similar allergen declaration requirements, with the United States having no such requirements. It was determined that if FSMPs had to comply with Australian and New Zealand generic allergen labelling requirements, it was likely that importers may withdraw products from the domestic market.

FSANZ has since reassessed European, Codex and United States generic allergen declaration requirements. Europe and Codex requirements have remained similar to the Code, while the USA now requires labels to abide by regulations under the *Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)*. The new United States allergen declaration requirements are now very similar to those provided in the Code.

As the allergen requirements in the Code are now similar to all major overseas allergen declaration requirements that apply to FSMPs, FSANZ is now proposing to apply the allergen declaration requirements in clause 4 of Standard 1.2.3 to FSMPs (note that this will not extend to inner packages – see Section 7.4.3.6 below). FSANZ expects that in the vast majority of circumstances, the labelling of overseas products would comply with the allergen labelling requirements in the Code. The application of Australia/New Zealand allergen labelling requirements will also ensure that the risks associated with these substances are also adequately managed.

7.4.3.2 Legibility

It was noted that the requirement to comply with legibility requirements (Standard 1.2.9) was inadvertently omitted at Preliminary Final Assessment. As there is no indication that these provisions would adversely affect the labelling of imported FSMPs, and that these requirements are intended to ensure the prominence of labelling statements, FSANZ proposes to apply Standard 1.2.9 to all FSMPs.

7.4.3.3 Sole source of nutrition

The mandatory advisory statement 'the product is intended/not intended (as the case may be) as the sole source of nutrition' was removed from the drafting at Preliminary Final Assessment. This information was originally designed to protect against inappropriate use, by providing information to supervising health professionals so that they could clearly identify what FSMPs are nutritionally complete products.

However, FSANZ's reconsidered position at Preliminary Final Assessment was that supervising health professionals would ordinarily be familiar with how to use a product, and so the absence of the statement would be unlikely to increase risks to health and safety through inappropriate use. FSANZ considers that this reason is still applicable and therefore we reaffirm the previous proposal not to require this statement on FSMPs.

7.4.3.4 Date marking

At Preliminary Final Assessment, FSANZ decided to apply date marking to FSMPs, but also allowed flexibility in the format to account for different overseas date marking requirements.

Submitters to the Preliminary Final Assessment were uncertain whether only 'use-by' or 'exp' could be used and not 'best-before' on the labels of FSMPs. In reviewing these comments, FSANZ has determined that the wording of the drafting did not clearly indicate that the decision between using a 'best-before' or 'use-by' date on FSMPs would operate according to the requirements in Standard 1.2.5, and that only if a 'use-by' date applied to the product could FSMP manufacturers use 'exp' date as an alternative. FSANZ has therefore reworded the conditions associated with the application of Standard 1.2.5 to FSMPs in draft Standard 2.9.5 to provide clearer instructions for manufacturers.

7.4.3.5 Lactose and Gluten claims

At Preliminary Final Assessment, FSANZ proposed that lactose and gluten free claims on FSMPs will be required to meet the criteria stipulated in clauses 15 and 16 of Standard 1.2.8 of the Code. However, stakeholders recommended the adoption of EU standards with regard to lactose and gluten claims for FSMPs. At the 2010 targeted consultations, stakeholders clarified that their concerns related to 'free' claims.

The European Union currently allows a tolerance of up to 20 ppm of gluten for foods carrying gluten free claims whereas in the Code, the gluten must not be detectable. FSANZ is not aware of any European regulations for lactose free claims.

The decision at Preliminary Final Assessment was made to ensure the health and safety of consumers, consistency throughout the Code and with fair trading legislation.

FSANZ has previously discussed this matter with the ACCC. The ACCC has advised FSANZ that it has generally formed a view that 'free' claims mean 'no presence of' and that a 'gluten free' claim on products that contain gluten (i.e. less than 20 ppm of gluten) would be misleading. FSANZ does not therefore have the discretion to permit 'gluten free' claims when gluten is present.

FSANZ therefore reaffirms the decision at Preliminary Final Assessment to apply clauses 15 and 16 of Standard 1.2.8 to FSMPs.

7.4.3.6 Inner packages

At Preliminary Final Assessment, FSANZ proposed that Standard 1.2.1 did not apply to FSMPs. However, FSANZ has since identified that this approach would inadvertently result in the exclusion of FSMPs from the inner package labelling exemption in Standard 1.2.1. This would unintentionally require inner FSMP packages (not for individual sale) to carry all of the information that was required on an outer FSMP package.

FSANZ has since determined that this was not the original intent, and so we are now proposing to apply an exemption from all labelling requirements for inner packages. As these packages are not for individual sale, the labelling requirements in draft Standard 2.9.5 will still apply as part of the outer packaging (the exemption applies to the inner packaging only). FSANZ therefore anticipates that health professionals or consumers of FSMP will continue to have access to labelling information, although we note that requiring information on an outer package only could be insufficient for all situations of product purchase or usage. Because of this uncertainty, FSANZ would appreciate feedback on how the exemption would operate in practice from submitters with experience in the use of FSMP.

Question to submitters

What is the standard industry practice on the labelling of inner FSMP packages? Should certain labelling information be required on inner FSMP packages, and if so, then what generic labelling requirements should apply?

7.4.3.7 Additional labelling requirements specific for FSMPs

At Preliminary Final Assessment, FSANZ recommended that where FSMPs 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 modified. This requirement was included under subclause 8(5) of the 2004 version of draft Standard 2.9.5.

FSANZ is proposing a new labelling statement for FSMPs represented as nutritionally complete that relates to nutrient variations. Given the overlap of this new labelling statement (outlined in Section 7.3.3) with the above original statement, FSANZ has revised the wording of the original statement so that it more accurately captures the original intended outcome. Draft Standard 2.9.5 now requires a statement:

- indicating the medical purpose of the product, which must include information on any conditions, diseases, or disorders for which the product has been specifically formulated

- describing the properties or characteristics which make the product appropriate for the condition, disease or disorder as indicated.

The element of the original statement relating to the 'condition, disease or disorder' has been expanded so that it covers situations where the product is designed for a broad range of medical conditions rather than a specific one (e.g. situations of high energy/protein requirements). The element of the original statement relating to the 'nutritional modifications' has been reworded so that it now reflects the wording of a similar requirement in Codex FSMP regulations (clause 4.5.3 of Codex Standard 180-1991). FSANZ has determined that 'modifications' was not a specific enough description, as it did not indicate what baseline measure the modifications were made from.

The revised labelling requirements have been added to the current version of draft Standard 2.9.5 at paragraphs 6(3)(b) and 6(3)(c).

7.4.4 Health Claims as they relate to the labelling of FSMPs

At Preliminary Final Assessment, the FSMP labelling provisions included the requirement to meet the conditions contained in Standard 1.1A.2 – Transitional Standard for Health Claims, except for the prohibition (subclause 3(d)) on the reference to a disease or physiological condition. This approach has been maintained at this stage of Proposal P242.

A new draft health claims Standard (Standard 1.2.7 – Nutrition, Health and Related Claims) is being developed under Proposal P293 – Nutrition, Health & Related Claims. In May 2008, the Ministerial Council requested a Review of Proposal P293. The reporting timeframe for the Review has been extended by the Ministerial Council to October 2011. Following gazettal of Standard 1.2.7 (subject to any requests for a review of the FSANZ decision by the Ministerial Council), it is anticipated that Standard 2.9.5 will be amended to include application of the provisions of Standard 1.2.7 (with a two-year transition period for implementation).

7.4.5 Summary of FSANZ's proposed approach to the labelling of FSMPs

Revised draft Standard 2.9.5 will:

1. apply the following generic labelling requirements from Part 1.2 of the Code:

- inner packaging labelling exemptions
- food identification requirements for FSMP allowing the name of the local supplier to be included on a transportation outer or in accompanying documentation (note that a definition of 'transportation outer' has been added to draft Standard 2.9.5)
- allergen declaration requirements
- ingredient labelling requirements, with allowances for the use of overseas ingredient labelling
- legibility requirements for FSMP
- date marking for FSMP and allow flexibility in the format
- directions for use and storage of FSMP
- legibility requirements
- lactose and gluten claim requirements.

2. require the following additional labelling specifically for FSMP:

- nutrition information requirements and allow flexibility in the presentation of this information
- that FSMP are to be used 'only under medical supervision'
- a statement advising where the product has been formulated for a specific age group
- a statement indicating the medical purpose of the product, which must include information on any conditions, diseases, or disorders for which the product has been specifically formulated
- a statement describing the properties or characteristics which make the product appropriate for the condition, disease or disorder as indicated
- if a FSMP product that is *represented as nutritionally complete* has been nutritionally modified to vary from Schedule 2, then the label must indicate each (any) variation relative to this Schedule (see section 7.3.3 above)
- for nutritionally complete FSMP the mandatory advisory statement 'not for parenteral use'.

3. exempt FSMPs from:

- the application of generic labelling requirements in Standard 1.2.1, with the exception of the requirements for inner packages as mentioned above
- mandatory warning and advisory statement requirements, except for allergen declarations as mentioned above
- percentage labelling requirements
- relevant aspects of the transitional standard on health claims
- country of origin labelling.

7.5 Fermentable Oligosaccharides, Lactose, Fructose, and Polyols (FOLFAPS)

The targeted consultation with health professionals in 2010 raised the issue of intolerance to Fermentable Oligosaccharides, Lactose, Fructose and Polyols (FOLFAPs). It was noted that dietitians are advising consumers on a regular basis to limit their intake of FOLFAPs to manage food intolerance symptoms. Some submitters considered that consumers of nutritionally complete FSMPs may be exposed to concentrated amounts of FOLFAPs, given that these products are used as complete dietary replacements. They stated that this could result in adverse health outcomes for individuals intolerant to FOLFAPs, such as those with irritable bowel syndrome (IBS).

It was mentioned in the 2010 consultations that dietitians are currently experiencing difficulties identifying products that contain FOLFAPs and that FOLFAP ingredients should be more clearly stated on the labels of FSMPs. There were also some comments that the provision of information on FOLFAPs could be available either online or at the place of purchase, rather than on packaging.

There are some generic labelling requirements that will apply to FSMP that may already cover the provision of information on FOLFAPs. These requirements are discussed in the following section.

7.5.1 FOLFAPs in the Code

7.5.1.1 Current permissions

Currently, there are provisions for certain FOLFAP ingredients in the Code, specifically inulin-derived substances. Inulin-derived substances are defined under clause 2 of Standard 1.1.1, as:

> ***inulin-derived substances*** *means mixtures of polymers of fructose with predominantly β (2→1) fructosyl-fructose linkages, with or without a terminal glucose molecule and includes inulin, but does not include those polymers of fructose produced from sucrose by enzymatic action.*

Inulin-derived substances and galacto-oligosaccharides are explicitly permitted for addition to certain special purpose foods regulated by:

- Standard 2.9.1 – Infant formula products
- Standard 2.9.2 – Infant Foods
- Standard 2.9.3, Division 4 – Formulated Supplementary Foods for Young Children

It should be noted that the term inulin-derived substance does not encompass all of the fructose-based oligosaccharides included under the term FOLFAPs.

7.5.1.2 Current labelling requirements

There are currently generic labelling provisions in the Code that apply to FSMP which would require the presence of FOLFAPs to be declared on a food label.

Standard 1.2.4 – Labelling of Ingredients, requires every ingredient added to a food to be listed on its label. Clause 4 of Standard 1.2.4 requires ingredients to be declared using the common name, a name that describes the true nature of the ingredient or a generic name where applicable. Clause 4 would therefore require the listing of FOLFAPS in an ingredient list.

Under clause 4, the generic name ‘sugar’ cannot be used to describe FOLFAPs. The word ‘sugars’ also cannot be used. Therefore the common name or a name that describes the true nature of each ingredient would need to be used. Lactose, oligosaccharides and fructo-oligosaccharides are examples of common names that can be used. If a FOLFAP is added to a food as part of an ingredient rather than as the pure FOLFAP ingredient, a common name or name that describes the true nature of that ingredient could be used, such as ‘high fructose corn syrup’ in the case of fructose.

Food additives added to a food e.g. polyols, must be declared in the ingredient list using their class name (e.g. sweetener) followed by the prescribed name or number (e.g. lactitol or 966) under clause 8.

It should be noted that ingredients of a compound ingredient do not require declaration on the label if the amount of the compound ingredient is less than 5%, unless the ingredient is a food additive that performs a technological function in the final food, or is required to be declared under clause 4 of Standard 1.2.3 (i.e. certain allergens) (clause 6 of Standard 1.2.4).

As outlined above, it is proposed that Standard 1.2.4 or the USA or EU ingredient labelling requirements apply to FSMPs. In the USA, a statement of ingredients is required for most packaged foods and the ingredients are required to be listed by their common or usual name. In the EU, ingredients are required to be declared by their specific name, and food additives must be declared by the name of their category followed by their specific name or EC number.

7.5.2 Market practices

FSANZ has investigated the current labelling practices for FOLFAPs ingredients, using publicly available information on the labels of FSMPs, and by contacting major FSMP manufacturers regarding the labels on their products. The current level of information that is provided regarding the presence of FOLFAP ingredients is mostly consistent across the range of FSMPs, with some minor variations in the wording of ingredient names.

If added to a product, fermentable oligosaccharides are typically listed within the ingredient list. Common terms used include 'fructo-oligosaccharide (FOS)', 'galacto-oligosaccharide (GOS)', 'fructans' and 'oligofructose'. Polyols are also listed using their common chemical description (e.g. 'maltitol'). The term 'lactose' is used regularly in an ingredient list when this disaccharide is present. 'Fructose' also appears within ingredient lists, however 'high fructose corn syrup solids' is also used for describing the presence of this high-fructose containing ingredient.

Most FSMP labels do not list the content of individual FOLFAP ingredients on a nutrition information panel (NIP), although some product labels do specify the content of fermentable oligosaccharides (e.g. a listing for 'FOS'). FSANZ has not identified any FSMP labels that specify the lactose or fructose content, rather the NIP will usually list either the total carbohydrate content, or total sugars content as a subset of carbohydrate.

7.5.3 FSANZ proposed approach

The risk assessment indicates that there is a potential health and safety risk from the presence of FOLFAPs in FSMPs. However, uncertainty remains as to the size of this risk. FSANZ also notes that there are already regulations in place and market practices occurring that will result in the display of FOLFAPs information on the labels of FSMPs. Therefore, FSANZ is not proposing any amendments to the revised draft Standard 2.9.5 in relation to FOLFAP ingredients at this time.

However, FSANZ recognises that FOLFAPs is an emerging issue for FSMPs, and so we are seeking additional information from stakeholders to determine whether there is a need for a regulatory response. The following questions on the regulatory approach to FOLFAPs are posed for submitter comment; submitters should also note that there are additional questions relating to the risks associated with FOLFAPs in Section 6.2.2.

Questions for submitters

- Is there sufficient information on both the product's ingredient list and nutrition information panel (NIP) to allow for identification of FOLFAP content? If not, what type of additional information is required, and where/how should it be displayed on the label?

- Is the information on FOLFAPs currently provided by manufacturers in supporting material (e.g. on information provided with the products or on company websites) considered to be sufficient if product labels do not provide all the necessary information on these ingredients?

8. Options

Since Preliminary Final Assessment, the options for the regulation of FSMPs have been further considered. The option of regulating FSMPs by a discrete standard has been further developed on the basis of stakeholders' comments. Two options are proposed in this Consultation Paper.

8.1 Option 1 – Reject the Proposal

This option maintains the *status quo* as there would be no specific regulation of FSMPs in the Code, and therefore no overt recognition of FSMPs under food law in either Australia or New Zealand.

8.2 Option 2 – Regulation of FSMPs by a discrete Standard

Under this option, a discrete Standard for FSMPs would be included in Part 2.9 - Special Purpose Food of the Code incorporating specific compositional and labelling requirements, which are in general, consistent with relevant overseas regulations. Additional risk management strategies would be applied, consisting of mandatory advisory labelling for use under medical supervision, and restrictions on the sale of FSMPs.

9. Impact Analysis

The Office of Best Practice Regulation has deemed that the impacts of this proposal are minor in nature, and that the preparation of a Regulatory Impact Statement is not required for Proposal P242. This advice was originally provided by OBPR's predecessor, the Office of Regulatory Review, referenced as ID number 2544 on 16 June 2004.

Communication and Consultation Strategy

10. Communication

These special purpose foods are used under medical supervision in specific circumstances and are produced by a small number of specialist manufacturers. FSANZ will work closely with health professionals and manufacturers of these foods during the development of the standard and develop a communication strategy for when the standard is finalised.

11. Consultation

11.1 Public Consultation

Public consultation for Proposal P242 was conducted on the Preliminary Final Assessment in 2004. Twenty-three separate submissions were made during this period. A summary of the submissions can be found at Attachment 2.

The key points from this consultation are included in Section 7 of this Report.

The comments and information provided in those submissions has assisted with FSANZ's consideration of Proposal P242 since it re-commenced early in 2010.

11.2 Targeted Stakeholder Consultation

Given the lapse in time since the public consultation round in 2004, FSANZ held targeted consultations in April-May 2010. Meetings were held with industry representatives, health professionals and jurisdictions in both Australia and New Zealand. The purpose of this consultation was to gather up-to-date information on the FSMP market and products currently available. It also provided an opportunity for stakeholders to indicate whether issues raised in 2004 are still relevant and to identify any new issues at this time.

Stakeholders indicated some support of the regulatory approach proposed at Preliminary Final Assessment but there were a range of views on some aspects of the draft Standard. Stakeholder views are noted in Section 7 of this Report in relation to the proposed risk management strategies. In addition, a summary of further stakeholder comments provided following the consultation meetings can be found at Attachment 2.

The targeted consultation has assisted FSANZ in revising the approach to regulation of FSMPs as proposed at Preliminary Final Assessment.

In addition, individual teleconference discussions were held with key medical and nutritional experts specifically in relation to VLED products. This targeted consultation informed FSANZ's decision to exclude VLEDs from the scope of Proposal P242 at this time).

11.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards, and/or the proposed measure may have a significant effect on trade.

The WTO was notified in 2003 of Proposal P242 through notifications G/TBT/N/AUS/13 and G/TBT/N/NZL/12. The European Commission commented on these notifications that FSMPs should be able to deviate from compositional requirements. These concerns were previously addressed at Preliminary Final Assessment (August 2004), and have been given further consideration as part of the compositional issues discussed at Section 7.3 above, with subsequent changes made to the draft variations proposed in Attachment 1.

Conclusion

12. Conclusion and Preferred Approach

Preferred Approach

FSANZ's preferred approach is Option 2 – Regulation of FSMPs by a discrete Standard.

Under this option, a discrete Standard for FSMPs will be included in Part 2.9 - Special Purpose Food of the Code incorporating specific compositional and labelling requirements, which are in general, consistent with relevant overseas regulations. Additional risk management strategies would be applied, consisting of mandatory advisory labelling for use under medical supervision, and restrictions on the sale of FSMPs. These additional risk management strategies are consistent with the Policy Guideline on the Intent of Part 2.9 of the Code.

12.1 Reasons for the preferred approach

Option 2 is the preferred approach for the following reasons:

- The explicit recognition of FSMPs in the Code provides regulatory certainty for industry and for government enforcement agencies, and reduces the overall regulatory burden on these products.

- The inclusion of FSMPs as a 'special purpose food' recognises that these foods are designed for a particular vulnerable target group.

- The regulation of FSMPs protects the health and safety of consumers of FSMPs, particularly as the target group is a vulnerable population.

- The setting of minimum and maximum compositional requirements for FSMPs that are represented as nutritionally complete protects the health and safety of FSMPs consumers and ensures their nutritional needs can be met. In addition, the permission to vary the composition for a specific medical condition ensures products can be manufactured to meet the particular needs of certain consumers of FSMPs.

- Restricting the access to FSMPs along with the requirement to label 'use under medical supervision' protects the health and safety of FSMP consumers by ensuring there is medical oversight of these products, as is intended.

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

12.2 Summary of proposed changes to draft Standard 2.9.5

FSANZ has proposed a number of changes to the version of draft Standard 2.9.5 that was released in 2004. These changes are listed in Table 5 below.

Table 5: Proposed changes to draft Standard 2.9.5

Component of the 2004 version of the draft amendments	Changes in the proposed 2010 version of the draft amendments	New location of the changes in draft Standard 2.9.5
All provisions and references to VLED products, including parts of Clauses 1, 4, and 5 and also Schedules 3 and 4 of the 2004 draft Standard 2.9.5.	These components have been removed from the current version of draft Standard 2.9.5.	Deleted.
Consequential amendments to other existing food standards, specifically Standards 1.1.1, 1.1A.6, 1.2.3, and 1.3.1.	The amendments to Standard 1.2.3 consisted of advisory statements specific for FSMPs. The requirements for these statements have been moved into draft Standard 2.9.5. Permissions for eleven food additives have been added to the amendments to Schedule 1 of Standard 1.3.1.	The advisory statements in the amendments to Standard 1.2.3 have been moved to **subclauses 6(3)(a) and 6(4)** of draft Standard 2.9.5. Other consequential amendments remain unchanged.
The definitions at Clause 1 of the 2004 draft Standard 2.9.5.	The definition of 'food for special medical purposes' has been modified to remove reference to 'use under medical supervision'. FSANZ has received legal advice that definitions should not include reference to how a product is used, rather they should reflect the presentation of the product at the point of sale. FSANZ does, however, note that the labelling requirement for 'use under medical supervision' has been moved into the Standard itself (subclause 6(3)(a)), and that medical supervision is mentioned as part of the Purpose statement for the Standard.	The definitions remain located in **Clause 1**, comprising of a definition for 'food for special medical purposes' only. An additional definition for 'transportation outer' has been added at subclause 1(3), so that the labelling requirement for these outers in the Table to subclause 5(1) is adequately captured in the drafting. The wording of this definition is the same as the definition of 'transportation outer' in Standard 1.2.1. The definition for 'nutritionally complete FSMP' has been reworded and added as a separate provision within the Standard (subclause 1(4)).
Permission to add particular substances to FSMPs (subclause 4(1) and Schedule 1 of the 2004 draft Standard 2.9.5, plus permitted forms in Schedule 1 of Standard 2.9.1)	These permissions have been retained and expanded since 2004. Nineteen new forms have been added to the list of permitted forms. The permissions for salt and hydrochloride forms of amino acids have also been condensed into two broad permissions (rather than listing every salt and hydrochloride form).	The permission to add particular substances has been moved into **Clause 2**. The list of permitted forms is still located in **Schedule 1**, along with a permission to use the forms listed in **Schedule 1 of Standard 2.9.1**.

Component of the 2004 version of the draft amendments	Changes in the proposed 2010 version of the draft amendments	New location of the changes in draft Standard 2.9.5
Minimum and maximum micronutrient requirements for FSMPs represented as nutritionally complete (subclause 4(2) of the 2004 draft Standard 2.9.5)	FSMPs that are represented as nutritionally complete can now vary from any of the minima and maxima limits specified in Schedule 2. A new clause has been added so that products that vary in this manner must comply with a new labelling requirement for a statement indicating: • the nutrient or nutrients which are affected; and • the variation from the prescribed maximum or minimum amount.	The requirement for FSMPs represented as nutritionally complete to comply with minimum and maximum micronutrient limits is now located at **Clause 3**, along with the new provision to vary from this requirement. The minima and maxima remain unchanged at **Schedule 2**. The previous clause relating to variations from sodium, potassium, and phosphorus minima has been deleted. The new labelling requirement is located in Division 3 – Sale and Labelling at **subclause 6(5)**.
Prohibition on the sale and advertising of FSMPs (subclause 1(2), and Clauses 6 and 7 of the 2004 draft Standard 2.9.5).	The restriction on the advertising of FSMPs has been removed from the current version of draft Standard 2.9.5. The restriction on 'the premises at which and the persons by whom FSMPs may be sold' has been retained (and reworded) in the current version of draft Standard 2.9.5.	The restriction on advertising was previously located in subclause 1(2) and Clause 6 of the 2004 draft Standard 2.9.5. These provisions have been deleted. The restriction on the sale of FSMP has moved to **Clause 4**.
Labelling standards that are not exempt for FSMPs, located in the Table to subclause 8(2) of the 2004 draft Standard 2.9.5.	All of the labelling standards that are not exempt have been retained in the Table, with the rewording of the conditions for Standard 1.2.5 to improve clarity. There are several additional labelling requirements that will now apply to FSMPs: • A labelling exemption for inner packages that are not for individual sale; • Allergen labelling requirements of clause 4 of Standard 1.2.3; and • Legibility requirements of Standard 1.2.9.	The Table of labelling requirements that apply to FSMPs has been moved to **subclause 5(1)**. The labelling exemption for inner packaging is provided at **subclause 5(2)**.

Component of the 2004 version of the draft amendments	Changes in the proposed 2010 version of the draft amendments	New location of the changes in draft Standard 2.9.5
The labelling requirements for: • Nutrient content information (energy, macronutrients, vitamins, minerals, and other nutrients) located at subclause 8(3) of the 2004 draft Standard 2.9.5. • A statement on the age group for the product's use (subclause 8(4) of the 2004 draft Standard 2.9.5).	These requirements will continue to apply as was proposed in 2004. The wording of the age group statement subclause has been modified to improve clarity.	The two labelling requirements are now located at **subclauses 6(1) and 6(2)**.
The labelling requirement for a statement on the condition, disease, or disorder; and the nutritional modifications to the product (subclause 8(5) of the 2004 draft Standard 2.9.5).	The labelling requirement has been reworded to accommodate the 'medical purpose' of a product.	The labelling requirement has been split into two separate provisions, located at **subclauses 6(3)(b) and 6(3)(c)**.

13. Implementation and Review

Following this round of public consultation, a Final Assessment Report for this Proposal will be prepared for consideration by the FSANZ Board. If approved by the FSANZ Board, notification will be made to the Ministerial Council and it is anticipated that the proposed revised draft standard would come into effect shortly thereafter upon gazettal, subject to any request from the Ministerial Council for a review.

FSANZ is proposing a transition period of two years following gazettal to allow manufacturers and importers of FSMPs sufficient time to comply with the proposed new Standard for FSMPs.

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.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Summary of Submissions

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Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

Subsection 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

To commence: Two years after gazettal

[1] ***Standard 1.1.1*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to clause 8 –

MJ	megajoule

[2] ***Standard 1.1A.6*** *of the Australia New Zealand Food Standards Code is varied by omitting clause 2, substituting –*

2 Application

(1) Subject to subclause (2), for the matters regulated in this Standard, food produced in or imported into New Zealand must comply with this Standard or Standard 2.9.5, but not a combination of both.

(2) This Standard does not apply to food produced in or imported into Australia.

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

[5] ***Standard 1.3.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[5.1] *omitting from* Schedule 1, *the heading to Item* 13 FOODS INTENDED FOR PARTICULAR DIETARY USES, *substituting –*

13 SPECIAL PURPOSE FOOD

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

13.5 Food for special medical purposes

Additives in Schedule 4 must not be added to foods for special medical purposes

200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	1500	mg/kg
210 211 212 213	Benzoic acid and sodium, potassium and calcium benzoates	1500	mg/kg
950	Acesulphame potassium	450	mg/kg
954	Saccharin	200	mg/kg
962	Aspartame / acesulphame salt	450	mg/kg

[6] ***Standard 1.3.4*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Schedule –

Specification for selenium enriched yeast

Selenium enriched yeasts are produced by culture in the presence of sodium selenite as a source of selenium. These yeasts contain selenium according to the following criteria –

Total selenium content	No more than 2.5 mg/kg of the dried form as marketed
Levels of organic selenium species (% total extracted selenium)	
1. Selenomethionine	No less than 60% and no more than 85%
2. Other organic selenium compounds (including selenocysteine)	No more than 10%
Levels of inorganic selenium (% total extracted selenium)	No more than 1%

[7] *The **Australia New Zealand Food Standards Code** is varied by inserting after* Standard 2.9.4 –

STANDARD 2.9.5

FOOD FOR SPECIAL MEDICAL PURPOSES

Purpose

This Standard provides for the compositional and labelling requirements of food specially formulated for the dietary management of individuals with certain medical conditions, disease states or disabilities. Food regulated in this Standard is characterised by the need for medical supervision in its 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.

General labelling requirements contained in Part 1.2 do not apply to food for special medical purposes unless specified in this Standard. Standard 1.3.1 contains permissions for food additives that may be used. Standard 1.5.1 contains provisions relating to the sale of novel food and novel food ingredients.

Table of Provisions

Schedule 2 Minimum and maximum amounts of vitamins, minerals and electrolytes in food for special medical purposes represented as being nutritionally complete

Division 1 – Preliminary

Clauses

1 Interpretation

(1) In this Code –

food for special medical purposes means food specifically processed or formulated for –

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

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

(2) To avoid doubt, food for special medical purposes does not include infant formula products or formulated meal replacements and formulated supplementary food standardised in this Code.

(3) In this Standard –

transportation outer means a container or wrapper which encases packaged or unpackaged foods for the purpose of transportation and distribution and which is removed before the food is used or offered for retail sale or which is not taken away by the purchaser of the food.

(4) In this Standard, a reference to a representation that a food is nutritionally complete includes a representation that a food 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 instructions.

Division 2 – Composition

2 Permitted forms of particular substances

A substance listed in column 1 of Schedule 1 of this Standard or column 1 of Schedule 1 of Standard 2.9.1 may be added to food for special medical purposes provided that the substance is in one or more of the corresponding forms listed in column 2 of Schedule 1 of this Standard or column 2 of Schedule 1 of Standard 2.9.1.

3 Compositional requirements for food represented as being nutritionally complete

(1) If a food for special medical purposes is represented as being nutritionally complete, the food must contain –

(a) no less than the minimum amount, as prescribed in column 2 of Schedule 2, of each vitamin, mineral and electrolyte in column 1; and
(b) if applicable, no more than the maximum amount, as prescribed in column 3 of Schedule 2, of each vitamin and mineral contained in column 1.

(2) However, food which is represented as being nutritionally complete does not need to comply with subclause (1) if –

(a) the food does not comply with subclause (1) because it is formulated for a particular medical condition, disease or disorder; and
(b) the food is labelled in accordance with subclause 6(5) of this Standard.

Division 3 – Sale and Labelling

4 Restriction on premises at which and the persons by whom food for special medical purposes may be sold

Food for special medical purposes may be offered for sale only by –

(a) a pharmacy, hospital or nursing home; or
(b) a medical practitioner or dietitian; or
(c) a manufacturer of food for special medical purposes or a distributor of a manufacturer of food for special medical purposes.

5 Application of labelling requirements

(1) The labelling requirements contained in Standards in Parts 1.1A and 1.2 of this Code do not apply to food for special medical purposes, except for the Standards listed in column 1 of the Table to this subclause subject to any conditions or variations listed in column 2 of the Table to this subclause.

Table to subclause 5(1)

Column 1	Column 2
Provisions which apply	**Conditions**
Standard 1.1A.2, except paragraph (3)(d)	
Standard 1.2.2	The information required by clause 3 is required only on the transportation outer or in documentation accompanying the food
Clause 4 of Standard 1.2.3	

Standard 1.2.4	Food for special medical purposes must comply with – (a) Standard 1.2.4; or (b) *Commission Regulation (EC) No 2000/13 of 20 March 2000 relating to the labelling, presentation and advertising of foodstuffs* [2000] OJ L 109/29, 6; or (c) 21 CFR § 101.4; but not a combination of any of these
Standard 1.2.5	If a food for special medical purposes is required to include a use-by date on its label, the words 'Expiry Date', or words to similar effect, may be used on the label instead of the words 'Use By'. Standard 1.2.5 will continue to apply to the label as if the words 'Use By' had been used.
Standard 1.2.6	
Clauses 15 and 16 of Standard 1.2.8	
Standard 1.2.9	

(2) The labelling requirements contained in the Table to subclause 5(1) and clause 6 of this Standard do not apply to a food for special medical purposes which is in an inner package not designed for individual sale.

6 Labelling requirements

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

(a) the average or minimum energy content expressed per given quantity of the food; and
(b) the average or minimum quantity of protein, fat and carbohydrate expressed per given quantity of the food; and
(c) the average or minimum quantity of vitamins, minerals and electrolytes expressed per given quantity of the food; and
(d) the average or minimum quantity of any of the other substances listed under column 1 of Schedule 1, if added to the food, expressed per given quantity of the food.

(2) If a food for special medical purposes has been formulated for a specific age group, the label must include a statement specifying this age group.

(3) The label on a package of food for special medical purposes must include a statement –

(a) to the effect that the product must be used under medical supervision;
(b) indicating the medical purpose of the product, which must include information on any conditions, diseases, or disorders for which the product has been specifically formulated; and
(c) describing the properties or characteristics which make the product appropriate for the condition, disease or disorder as indicated.

(4) The label on a package of food for special medical purposes represented as being nutritionally complete must include a statement to the effect that the product is not for parenteral use.

(5) If a food for special medical purposes is represented as being nutritionally complete, and the food has been modified to vary from the compositional requirements prescribed in Schedule 2, the label must include a statement indicating -

(a) the nutrient or nutrients which are affected; and
(b) the variation from the prescribed maximum or minimum amount.

SCHEDULE 1

PERMITTED FORMS OF PARTICULAR SUBSTANCES

Column 1	Column 2
Substances	**Permitted Form**
Vitamins	
Niacin	Nicotinic acid
Vitamin B_6	Pyridoxine dipalmitate
Folate	Calcium L-methylfolate
Vitamin E	D-alpha-tocopherol
	D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS)
Pantothenic acid	Sodium pantothenate
	D-panthenol
	DL-panthenol
Minerals and Electrolytes	
Calcium	Calcium bisglycinate
	Calcium citrate malate
	Calcium malate
	Calcium L-pidolate
Chromium	Chromium chloride
	Chromium potassium sulphate
Chloride	Choline chloride
	Sodium chloride, iodised
	Hydrochloric acid
Copper	Copper-lysine complex
	Cupric carbonate
Fluoride	Potassium fluoride
	Sodium fluoride
Iodine	Sodium iodate
Iron	Carbonyl iron
	Electrolytic iron
	Ferric citrate
	Ferric gluconate
	Ferric orthophosphate
	Ferric pyrophosphate, sodium
	Ferric saccharate
	Ferric sodium diphosphate
	Ferrous bisglycinate
	Ferrous carbonate
	Ferrous carbonate, stabilised

	Ferrous L-pidolate
	Iron, reduced (ferrum reductum)
Magnesium	Magnesium acetate
	Magnesium L-aspartate
	Magnesium bisglycinate
	Magnesium citrate
	Magnesium glycerophosphate
	Magnesium hydroxide
	Magnesium hydroxide carbonate
	Magnesium lactate
	Magnesium phosphate, monobasic
	Magnesium L-pidolate
	Magnesium potassium citrate
Manganese	Manganese glycerophosphate
Molybdenum	Ammonium molybdate
Potassium	Potassium glycerophosphate
	Potassium lactate
	Potassium L-pidolate
Selenium	Selenium enriched yeast
	Sodium hydrogen selenite
	Sodium selenate
Zinc	Zinc bisglycinate
	Zinc carbonate
	Zinc citrate
	Zinc lactate
Other substances	
Amino acids	Sodium, potassium, calcium, magnesium salts of single amino acids listed in this Schedule
	Hydrochlorides of single amino acids listed in this Schedule
	L-alanine
	L-arginine
	L-asparagine
	L-aspartic acid
	L-citrulline
	L-cysteine
	L-cystine
	L-glutamic acid
	L-glutamine
	Glycine
	L-histidine
	L-isoleucine
	L-leucine
	L-lysine
	L-lysine acetate
	L-methionine
	L-ornithine
	L-phenylalanine
	L-proline
	L-serine
	L-threonine
	L-tyrosine
	L-tryptophan
	L-valine
	L-arginine-L-aspartate
	L-lysine-L-aspartate
	L-lysine-L-glutamate

	N-acetyl-L-methionine
Carnitine	L-carnitine
	L-carnitine hydrochloride
	L-carnitine L-tartrate
Choline	Choline
	Choline bitartrate
	Choline chloride
	Choline citrate
	Choline hydrogen tartrate
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 AMOUNTS OF VITAMINS, MINERALS AND ELECTROLYTES IN FOOD FOR SPECIAL MEDICAL PURPOSES REPRESENTED AS BEING NUTRITIONALLY COMPLETE

Column 1	Column 2	Column 3
Nutrient	**Minimum Amount per MJ**	**Maximum Amount per MJ**
Vitamins		
Vitamin A	84 µg retinol equivalents[1]	345 µg retinol forms only
Thiamin	0.15 mg	No maximum set
Riboflavin	0.2 mg	No maximum set
Niacin	2.2 mg niacin equivalents[2]	No maximum set
Vitamin B_6	0.2 mg	2.9 mg
Folate	25 µg	No maximum set
Vitamin B_{12}	0.17 µg	No maximum set
Vitamin C	5.4 mg	No maximum set
Vitamin D	1.2 µg	5.7 µg
Vitamin E	0.5 mg alpha-tocopherol equivalents[4] per g of polyunsaturated fatty acids expressed as linoleic acid, but in no case less than 10 mg alpha-tocopherol equivalents[4] per MJ	No maximum set
Biotin	1.8 µg	No maximum set
Pantothenic Acid	0.35 mg	No maximum set
Vitamin K	8.5 µg	No maximum set
Minerals		
Calcium	84 mg	287 mg
Magnesium	18 mg	No maximum set
Iron	1 mg	No maximum set
Phosphorus	72 mg	No maximum set

Zinc	1 mg	4.6 mg
Manganese	0.12 mg	1.32 mg
Copper	0.15 mg	1.15 mg
Iodine	15.5 µg	115 µg
Chromium	3 µg	No maximum set
Molybdenum	7 µg	No maximum set
Selenium	6 µg	46 µg
Electrolytes		
Sodium	72 mg	No maximum set
Potassium	190 mg	No maximum set
Chloride	72 mg	No maximum set

[1],[2] and [4] – these numbers refer to the corresponding numbers in the footnotes in Schedule 1 in Standard 1.1.1

To commence: four years after gazettal

[8] *The* ***Australia New Zealand Food Standards Code*** *is varied by omitting* Standard 1.1A.6

Attachment 2

Summary of Submissions

Proposal P242 – Food for Special Medical Purposes

FSANZ undertook public consultation with stakeholders in 2004 through the Preliminary Final Assessment Report and also targeted consultation in 2010 when Proposal P242 recommenced.

The following tables summarise:

- Comments from submitters to the Preliminary Final Assessment Report released in 2004.
- Information provided by stakeholders following consultation meetings held in 2010.

Consultation at Preliminary Final Assessment

FSANZ received 23 submissions in response to the Preliminary Final Assessment Report during the public consultation period of 4 August to 22 September 2004.

There were two regulatory options proposed at Preliminary Final Assessment namely:

- Option 1 – reject Proposal thus maintaining the *status quo*
- Option 2 – Regulation of FSMPs by a discrete Standard with the application of an overarching risk management framework.

Submitter	Comments
Australian Food and Grocery Council (AFGC)	**Supports Option 1** Maintains that FSANZ has failed to demonstrate market failure that requires regulatory intervention Considers that FSANZ is proceeding for the sole purpose of uniform regulation in Australia and New Zealand to provide regulatory certainty for enforcement agencies. **Restriction on sale and advertising** If Option 2 is maintained considers the restriction on the sale and advertising of FSMPs to the general public to be unnecessary because: • FSANZ has failed to demonstrate risk of such sale and advertising; • labelling requirements are present if risk does exist; and • it is harsher than restrictions applied to medicinal products which are readily available to the general public. **Labelling** Recommends that the User Guide for Standard 1.2.5 – Date marking be revised as it currently specifies that a use-by date must be used on all FSMPs which is different to what draft Standard 2.9.5 has proposed (i.e. *An expiry date may be used as an alternative to a use-by.* **Composition** Supports the use of the EU minimum (biotin) and maximum (vitamin A, vitamin D, copper) values in Schedule 2.

Submitter	Comments
Australia New Zealand Enteral Nutrition Manufacturers Association (ANZENMA)	**Supports Option 2** Represents Enteral Nutrition Manufacturers of Australia and New Zealand (notes that the enteral nutrition market is valued at approx. $A50 million). Believes FSANZ has not demonstrated any market failure that requires a prescriptive regulatory intervention. Supports Option 2 with modifications in the following areas: • Restriction of advertising to the general public • Distribution channels to the general public • Compositional adjustments • Labelling adjustments • Ingredient additions **Restriction on sale and advertising** Considers the restriction on direct advertising to the consumer as overly restrictive and unnecessary as contends that: • FSANZ has failed to demonstrate risk to public health and safety • advertising may actually enhance public health with such conditions as diabetes • the restriction is more harsher than that applied to complementary medicines and over-the-counter medications • enforcement agencies will not be able to 'police' the standard beyond manufacturers e.g. Retail pharmacy • labelling requirements (use under medical supervision) exist in the unlikely event that a risk is present • the restriction on retail sale will in the main allow health care professional supervision • the proposed restriction will be the most restrictive in the world – the EU legislation provides more flexibility. Seeks clarity and amendment to the restriction of sale (Clause 6) by including provision for: • sale from businesses owned and operated by non-healthcare professionals but who employ healthcare professionals e.g. Metabolic clinics (current distribution practise) • sale by manufacturers. **Labelling** Requests adoption of EU standards to clauses 15 (lactose claims) and 16 (gluten claims) of Standard 1.2.8 that apply to FSMPs (table to subclause 8(2)). This recognises the broad range of medical conditions these products are used for. Requests addition of the words 'if added' to subclause 8 (3)a, b and c – reflects usage of products where zero tolerance of a nutrient is required. Seeks definitive clarity on the use of the wording 'best before'. Seeks inclusion of 'best before' in Standard 1.2.5. **Composition** Requests adoption of EU standards for minimum values (unless otherwise applied for). Seeks greater flexible in maximum nutrient values (because patients with chronic conditions require elevated nutrient levels). Provides list of requested changes to Schedule 2. Requests that the wording of subclause 4(2)b (permission to deviate from minimum amount of sodium, potassium and phosphorus to satisfy particular medical conditions) reflect EU specifications.

Submitter	Comments
	Food additives Requests consideration of listed ingredients/additives that are commonly used in current FSMP formulations that are missing from the draft standard. **Typographical errors** Schedule 1 – 'chlorine' should be 'chloride' Clause numbering for 8(1) is missing
Atlas Health Care	**Restriction on sale and distribution** Currently supplies products to nursing homes, hospitals and direct to the general public (upon referral from health professionals). Seeks amendment to the restriction on retail sale (subclause 6(c)) to allow wholesalers to sell directly to consumers. Believes there is currently no failure in terms of public health and safety.
Axcess Home Health Direct	**Restriction on sale and distribution** Distributes FSMPs direct to the public (upon referral of health professionals). Considers the proposed regulation will change current distribution arrangements, which is unfair and unreasonable and not in the best interests of people using and paying for FSMPs. Does not consider there to be any risk of endangerment to public health and safety through this current distribution method.
Ceres Enterprises	**Repeal of Transitional Standard 1.1A.6** In support of continuation of Transitional Standard 1.1A.6 (proposed to be repealed when Standard 2.9.5 is gazetted) to permit the continued importation of Rice Dream Enriched (a cereal-based beverage predominately used by consumers with milk/soy allergies). Acknowledges that Rice Dream is not a FSMP (generally available). Is concerned that when Std 1.1A.6 is repealed that Rice Dream will no longer be legally sold.
Dietitians Association of Australia (DAA)	**Labelling** Concern that some FSMPs may not have adequate allergen labelling. Supports inclusion of this information in product supporting literature. **Composition** Concerned that there appears no flexibility in the draft standard for new products with additional nutrients. Consumers may be disadvantaged if products incorporating new nutrients based on sound scientific research were not available to them.
Fonterra Cooperative Group	**Supports Option 2** No additional comments.
Food Liaison David Panasiak	**Food Additives** There appears gaps in the permissions for food additives specifically for VLED e.g. intense sweeteners, colours, preservatives. **Composition of VLED (Clause 5)** It is not clear whether the term 'calorie' or 'joule' can be substituted for 'energy' e.g. very low joule diets. Notes the NHMRC definition of a VLED provides an energy range of 1.7 MJ to 3.3 MJ which is different to that specified in the draft standard (1.88 MJ to 3.35 MJ). There is a mandatory requirement for α-linolenic acid (0.5 g/day) but no permission for use of alternatives e.g. DHA/EPA – is an unnecessary bias to α-linolenic acid. Considers there is no justification for the minimum prescribed level (50 g) of carbohydrate. Also there is no provision for dietary fibre.

Submitter	Comments
	Restriction on sale and distribution The restriction on sale and advertising is appropriate. However other health professionals, including dietitians, may also be appropriate to supply VLED.
The then Food Technology Association of Victoria Inc (FTAV) (now called Food Technology Association of Australia)	**Supports Option 2** No additional comments.
McNeil Surgical	**Restriction on sale and distribution** Provides products for aged and hospice care (upon referral from health professionals). Seeks amendment to the restriction on retail sale to allow wholesalers to sell directly to consumers. No reported failure in terms of public health and safety.
Nestlé	**Supports Option 2** Supports the submissions of the ANZEMNA and AFGC. **Restriction on sale and advertising** Does not agree with the restriction on advertising to the general public as there is no evidence of market failure and the prohibition is tighter than the advertising requirements for therapeutic products. The prohibition on sale if advertised to consumers is very broad. What would be the situation if it were not the manufacturer that advertised the product but a retailer instead? Does not seem that this aspect of the standard can be enforced properly. **Permitted forms** Notes that Selenium selenate is now permitted in Standard 2.9.1 so this permission should also apply to FSMPs.
New South Wales (NSW) Food Authority	**Supports Option 2** No additional comments.
New Zealand Food Safety Authority (NZFSA)	**Supports Option 2** Supports the objectives of the proposal but does not want the introduction of regulatory restrictions to adversely affect the supply of specialist products in New Zealand. Believes that any regulatory control should be no more restrictive than relevant overseas regulation, and wherever possible should be consistent. **Repeal of Transitional Standard 1.1A.6** Asks that consideration be given to products that are currently covered by Transitional Standard 1.1A.6 that will however not fall under FSMPs (e.g. cereal-based beverages). NZFSA would not support the repeal of Standard 1.1A.6 until all products currently provided under that standard (which are an important dietary addition for some populations) are covered elsewhere in the Code. **Restriction on sale and advertising** The proposed restriction on sale is consistent with current New Zealand practice. Raises concern however about the sale of VLED which are not currently subsidised. Supports the proposed restriction on advertising of FSMPs however notes the access to information through electronic media e.g. websites.

Submitter	Comments
Novartis Consumer Health	**Permitted Forms** Provides safety data on seeking permission for use of chromium acetate, as a source of chromium in FSMPs. Currently uses this form in FSMPs available in Australia and New Zealand **Additives** Seeking permission for various additives including phosphoric acid, butylated hydroxytoluene, acesulphame potassium. Also seeks clarification on a number of other substances.
Nutricia Australia New Zealand	**Supports Option 2** Supports the submission by ANZENMA. **Additives** Requests permission to use additives listed in Item 7 of Schedule 1 of Standard 1.3.1 for FSMPs that low protein baked products e.g. biscuits. Recommends that FSMPs be permitted to contain additives that would be allowed in normal foods of the same type under Schedule 1 of Standard 1.3.1. **Permitted forms** Requests the permission to use zeaxanthin (a natural carotenoid) as a permitted nutritive substance citing that recent research has shown benefits for the elderly.
Nutrition Australia	**Sale and distribution** Provides products to consumers (general public, veterans affairs clients, nursing homes, pharmacies, private hospitals) upon referral from health professionals. Seeks amendment to the restriction on retail sale to allow wholesalers to sell directly to consumers. No reported failure in terms of public health and safety.
Pharmacy Health Solutions	**Food Additives** Disappointed in the lack of provision for the use of food additives in schedule 1 of Standard 1.3.1 specifically for VLED e.g. intense sweeteners, colours, preservatives. **Transitional arrangements** Supports a reduction in the proposed lead-in time from 2 years to 1 year. **Composition of VLED (Clause 5)** Prefer use of the 'internationally recognised term' of very low calorie diet (VLCD) as an available alternative to VLED. The NHMRC *Clinical Practise Guidelines for Management of Overweight and Obesity in Adults* define a VLCD as usually providing an energy range of 1.7 MJ to 3.3 MJ. Considers the lower limit should be 1.7 MJ rather than the proposed 1.88 MJ. The requirement to have 3 g/day linoleic acid is restrictive and is not justified. Cites 1.5 g/day as the minimum limit due to manufacturing difficulties. There are no provisions for omega-3 fatty acids other than α-linolenic acid. The requirement of 0.5 g/day does not take into account alternative sources of omega-3 fatty acids. In accordance with Standard 1.2.8 (clause 13) EPA and DHA should be permitted. Supports a minimum daily requirement for total DHA and EPA of 180 mg (meets good source claim criteria of 60 mg/serve). Does not support the minimum prescribed level (50 g) of carbohydrate as defined by Standard 1.2.8. This does not include dietary fibre and is contrary to international practice. There appears no justification for the carbohydrate level excluding fibre. Suggests 40 g would be a more reasonable level (inclusive of dietary fibre).

Submitter	Comments
	Restriction on sale and distribution Supports the restriction on sale and advertising but suggests inclusion of dietitians and weight loss clinics as being also appropriate to supply VLED.
Queensland Health	**Supports Option 2** **Labelling** Does not support exemption of FSMPs from mandatory allergen declaration. Believe that such declarations are an added safeguard (to use under medical supervision) that on balance will cost little when compared to potential benefits. Could be contained as an added label sticker. Considers there seems little reason why FSMPs involving imported food should be exempted from this important disclosure. **Typographical errors** Clause numbering for 8(1) is missing. In [10.1] there is a reference to the Table of Contents whereas it is described on page 37 as the Table of Provisions.
South Australian Department of Health	**Supports Option 2** **Restriction on sale and advertising** Supports the restriction on advertising especially for VLED but has concerns about the accessibility of VLED outside of health facilities. Concerned that the labelling of VLED as for the treatment of obesity could encourage misuse. Appears safer not to identify the purpose of VLED in order to dissuade non-target users.
SSS Australia	**Restriction on sale and distribution** Has provided products to consumers since 1976. Seeks amendment to the restriction on retail sale to allow wholesalers to sell directly to consumers. No reported failure in terms of public health and safety.
Superior Health Care	**Restriction on sale and distribution** Is a distributor for at-home products including FSMPs. Seeks amendment to the restriction on retail sale to allow wholesalers to sell directly to consumers. No reported failure in terms of public health and safety.
Surgical House	**Restriction on sale and distribution** Considers FSMPs should be available for retail sale through wholesale distribution outlets that supply hospitals, medical practitioners and provide a home health care service. Restricting the sale of FSMPs is anti-competitive and would disadvantage the consumer, as products will not be available at competitive prices. Doubts that pharmacies will have the necessary volume to ensure that consumers are provided with stock with adequate dating.
Wesley Corporate Health	**Restriction on sale and advertising** Operates a Weight Management Clinic involving VLED. Dietitians and Nutritionists are responsible for selling and dispensing VLED. Supports amendment to the restriction on sale (Clause 6) to include dietitians and nutritionists. Recommends that advertising directly to consumers (Clause 7) be permitted for appropriate consumer groups but with specific statements qualifying the use and supply of VLED under the supervision of approved health professionals.

Targeted stakeholder meetings in 2010

In April and May 2010, a series of consultation meetings was held with FSMP manufacturers, health professionals and jurisdictions. The purpose of these meetings was to obtain feedback on the current state of the FSMP market, given the period of time since the last round of consultations in 2004. Key points raised at these meetings are addressed elsewhere in the body of this report.

Following the meetings participants provided FSANZ with further information relevant to the proposed Standard 2.9.5 for FSMPs. A summary of these comments is provided in table 2 below.

Information provided by stakeholders in 2004:

No. Submitter	Comments
Industry	
Abbott Nutrition	Abbott supplies an extensive range of FSMPs, all of which is imported from Europe and the USA. Abbott distributes nutrition products in Australia, NZ and worldwide. ***Sales*** Growth within Abbott Nutrition Australia in the last 3 years indicates an increase in local demand for FSMPs. ***Composition and labelling*** Abbott Nutrition supports compositional requirements that align with CODEX STAN 180-1991 (i.e. recommends omitting compositional requirements as proposed in Standard 2.9.5). Considers that any changes to labelling requirements that are not consistent with international regulations would have significant implications for industry and consumers. Notes FSMPs by definition are intended for use under medical supervision. Abbott Nutrition supports greater communication between industry and health professionals to ensure that FSMPs are formulated to meet individual needs. Expresses concern over the imposition of micronutrient minima and maxima for the following reasons: • Industry formulates products that are safe and meet the nutritional requirements of the persons for whom they are intended, as specified in CODEX STAN 180-1991 and EC Directive 1999/21/EC. Considers there is a requirement to formulate products according to sound medical and nutritional principles and an obligation to those individuals using FSMPs. • FSMPs are formulated for the dietary management of patients with special nutritional needs resulting from their disease or condition. The nutritional needs of people with specific conditions are continually evolving through characterisation of the impact of nutrients on new functional and biochemical endpoints. For this reason flexibility is required. • Under the proposed micronutrient minima in Standard 2.9.5, many patients with low energy requirements would not meet their micronutrient requirements on FSMPs represented as nutritionally complete. • Continued flexibility with compositional requirements, including general exemptions, is needed to maintain a competitive edge and ensure supply of FSMPs to these patients. If compositional requirements are included in Standard 2.9.5, Abbott Nutrition requests that unlimited nutrient exemptions be allowed for the following diseases and conditions: – Renal disease – Diabetes Mellitus – Acute Respiratory Distress Syndrome (ARDS) – Metabolic disorders (acute or chronic) requiring hydrolysed formulas – Cancer

No. Submitter	Comments
	Supports the FSANZ intention to provide permissions in Standard 2.9.5 for all existing permitted forms of nutrients and related substances currently listed in Standard 2.9.1. Agrees with the requests from 2004 to include additional nutrient forms including L-histidine monohydrochloride, L-arginine acetate, high molybdenum yeast or high chromium yeast. Requires no additional additives to be added to Schedule 1 of Standard 1.3.1 and recommends that additives previously assessed and deemed safe for use in FSMPs by the international authorities, CODEX, EU and the USA Food & Drug Administration, be given permissions for use in Standard 2.9.5. Notes that any changes to labelling requirements may result in removal of products from the market and reduced supply for vulnerable patients. The cost of over-labelling products may not be justified. Requests clarification on FSANZ's approach to monitoring for imported products that do not meet the proposed specifications. Assessment of supporting evidence for out of specification formulations needs to be completed in a timely manner to ensure there is no delay in releasing products. It is important there is certainty of supply for consumers who often rely on these products. ***Access and advertising*** FSMPs are readily available from pharmacies. Considers that consultation with a pharmacist is infrequent despite labelling of products for 'use under medical supervision'. Notes advertising of FSMPs on internet but does not exercise control in this area. Recommends that the proposed Standard 2.9.5 be modified to allow free advertising of FSMPs directly to consumers. This would form part of a risk management strategy to educate consumers on product use and would align FSMPs with other oral supplements available through supermarkets that are advertised freely. Abbott Nutrition stated that the benefits of improved patient outcomes from advertising to consumers outweigh the low risk of misuse. Recommends changing proposed Standard 2.9.5 in relation to oral supplements to allow for direct advertising to consumers and access through supermarkets. ***Medical supervision*** Supports a definition of 'use under medical supervision' for enteral feed products only (due to the vulnerability of patient group and use of products as a sole source of nutrition).
Nestlé	***Composition and labelling*** Supports a pragmatic and flexible approach to compositional limits that fosters research and development, provides room for innovation and supports growth of the FSMP industry. A flexible approach would allow consumers to benefit from scientific advancement and ensure that Australia keeps up with Europe and the US with FSMPs. Notes that FSMPs may deviate from compositional limits for sodium, potassium and phosphorus for particular medical conditions. Recommends extension of these variations to other micronutrients only when specific formulations are necessary for the intended use in the target population and substantiated by scientific evidence.

No. Submitter	Comments
	Considers that scientific substantiation is an automatic requirement of manufacturing nutritional products. Manufacturers should hold evidence on formulations and claims and be able to produce this evidence if requested by an Enforcement Authority. Proposes 3 categories of FSMPs that are harmonised with EU regulations. 1. Nutritionally complete foods with a standard nutrient formulation. 2. Nutritionally complete foods with a nutrient-adapted formulation specific to particular medical conditions. 3. Nutritionally incomplete foods with a standard formulation or nutrient-adapted formulation specific to particular medical conditions. Considers it is very difficult, or impossible, to provide an exhaustive list of medical conditions that require products with a formulation outside the proposed compositional limits. ***Permitted forms*** Notes the list of permitted forms is omitted from Schedule 1 of draft Standard 2.9.5 but included in EC No 953/2009, including magnesium L-aspartate, zinc bisglycinate, L-carnitine-L-tartrate. Notes the magnesium salts of amino acids are not included in the drafting at Preliminary Final Assessment. The sodium, potassium salts of amino acids and the hydrochlorides of amino acids do not extend to some other amino acids e.g. L-histidine hydrochloride. Supports the adoption of a blanket statement for amino acids similar to EU/USA regulations. EU: *For amino acids, as far as applicable, also the sodium, potassium, calcium and magnesium salts as well as their hydrochlorides may be used (*EC No 953/2009*).* USA: *The food additive consists of one or more of the following individual amino acids in the free, hydrated or anhydrous form or as the hydrochloride, sodium or potassium salts'*(21CFR172.320*).* Supports the addition of the following amino acids to draft Standard 2.9.5 (as listed in Commission Directive 2001/15/EC and EC No 953/ 2009 and permitted in Standard 2.9.1 - except for N-acetyl-L-cysteine): a. L-histidine b. L-Isoleucine c. L-lysine d. L-methionine e. L-phenylalanine f. L-threonine g. L-tryptophan h. L-tyrosine i. L-valine j. N-acetyl-L-cysteine In relation to the use of selected nutrient forms, Nestle notes that L-histidine monohydrochloride (equivalent to L-histidine hydrochloride) is permitted under EC No 953/2009 and FDA 21CFR172.320. Provided supporting scientific evidence on Ferrous Ammonium Phosphate (FAP) which is intended for use in FSMPs. .

No. Submitter	Comments
	To align with EU and USA, supports separate permissions for FSMPs in Schedule 1 of Standard 1.3.1 for the following food additives: sorbic acid, potassium sorbate, calcium sorbate, benzoic acid, sodium benzoate, potassium benzoate, calcium benzoate and sodium sorbate. ***Access and advertising*** Consumers generally obtain FSMPs from pharmacies, online pharmacies and community distributors. ***Medical supervision*** Notes statements about medical supervision are not always included with products sold through online pharmacies.
Orfam Jack Steggall	***Composition and labelling*** Refers to information provided under *Application of Labelling Requirements* in the Preliminary Final Assessment Report, which states that the labelling requirements contained in Standards in Parts 1.1A and 1.2 of the Code do not apply to FSMPs, except for the Standards listed in column 1 of the Table to subclause 8(2) subject to any conditions or variations listed in column 2. Considers that under the proposed labelling exemptions, the following are either not allowed or exempt: 1. Nutrition Information Requirements (Std 1.2.8): although there are no nutrition information requirements in place, Standard 1.2.8 states that packaging must contain information an average or minimum energy, protein, fat, carbohydrate , vitamins and minerals, nutritive substance content per given quantity. 2. Legibility requirements (Std 1.2.9): the absence of a legibility requirement means that there are no restrictions on the type size of the mandatory warning and advisory statements. 3. Characterising ingredients (Std 1.2.10): software generates this information automatically, therefore considers it strange that this is exempt. 4. Country Of Origin Statement (Std 1.2.11): considers it an unnecessary risk to omit country of Origin labelling. Dismisses argument that country of origin labelling may interfere with supply of FSMPs in Australia/NZ. Notes that the figures provided in the Preliminary Final Assessment Report on the percentage of FSMPs imported into Australia (99%) and estimated size of the domestic market ($40 million) may need to be updated.
Health Professionals	
Australian Society for Inborn Errors of Metabolism (ASIEM) Susan Thompson	***Public health and safety*** Recognises the need for harmonisation with international regulations to maintain certainty of supply of FSMPs to consumers. Notes the rigorous product review system that precedes Australian Pharmaceutical Benefit Scheme (PBS) and New Zealand PHARMAC listing. ***Composition and labelling*** Notes the wide range of FSMPs available for complete or partial feeding of individuals with inherited metabolic conditions. States the benefits of removing minimum and maximum composition requirements on FSMPs including: • Harmonisation with international regulations.

No. Submitter	Comments
	• Products are intended for use under medical supervision. Dietitians supervising use of products defined as 'nutritionally complete' should be aware of their nutritional composition and understand they will not meet the requirements of individuals at all ages and life-stages. • Products will be 'regulated' in part by health professionals who will be hesitant to use products that require extensive nutrient supplementation. Supports allergen labelling and ingredient listing to protect public health and safety. ***Access and advertising*** Notes that FSMPs other than VLED products are accessed through PBS, PHARMAC, wholesalers, pharmacies and internet pharmacies. States that FSMPs for inherited metabolic conditions are promoted through patient support groups, professional conferences/meetings and the internet. Agrees with this level of promotion for FSMPs for inherited metabolic conditions given other measures are in place to protect public health and safety e.g. PBS listing, cost, use under medical supervision. Suggests use of a disclaimer page on websites to protect consumers.
Dietitians Association of Australia Holly Smith *Includes NZDA comments*	***Composition and labelling*** Agrees with compositional guidelines for FSMPs represented as nutritionally complete but recognises the need for flexibility to satisfy certain medical conditions. States that the following medical conditions may require products to be formulated outside of the minimum limits: renal disease, liver disease, Wilson's disease and conditions requiring ketogenic diets. Recommends expansion of the proposed exemptions to include copper, manganese and carbohydrate or a general exemption to any nutrient based on the intended use of the product (in line with European regulations). Supports harmonisation with European regulations on standard definitions for FSMPs. Agrees with the requirement for a statement specifying the product must be used under medical supervision. Supports use of a statement specifying a product is suitable as a sole source of nutrition, intended for a specific age group and where appropriate, identifies precautions and contraindications. Recommends inclusion of product instructions within packaging, with no additional fee. Recommends internationally standardised allergen declarations. Notes use by food industry of the Voluntary Incidental Trace Allergen Labelling (VITAL) system. Notes that this system appears to be assisting food allergic consumers to make informed choices and may be useful for FSMPs. Recommends allergen labelling on individual FSMP bottles and packets to reduce consumer risk. DAA would like the listing to extend to FOLFAPs ingredients (Fermentable Oligosaccharides, Disaccharides, Monosaccharides and Polyols). ***Access and advertising*** Supports restrictions on sale and advertising of FSMPs. Recommends that pharmacists be directly involved in the sale of FSMPs to consumers (to screen individuals for potential risks).

No. Submitter	Comments
	Also recommends increased training for pharmacy staff (e.g. screening consumers) and use of a screening checklist. Supports promotion of FSMPs for inherited metabolic conditions through patient support groups and internet sites, given the likelihood of medical and dietetic supervision associated with use of these products.
NZDA Bariatric SIG Contributed to DAA submission	***Composition and labelling*** Recognises the need to consider risk of micronutrient deficiency and toxicity in compositional requirements. Notes the variation in micronutrient requirements between individuals (with differing medical conditions) and the need for health professionals to assess and monitor suitability and use of FSMPs on an individual basis. Suggests listing of common side effects and inclusion of a statement to seek medical attention if side effects occur. Agrees that FODMAP ingredients should be available either on line or at place of purchase (not necessarily on the box) for use by medical practitioner or dietitian. The need for medical supervision should be written in clear, large text on the label. ***Access and advertising*** Supports the advertising restrictions proposed in draft Standard 2.9.5. Considers that free consumer advertising 'de-medicalises' these products.
Lyn Gillanders Senior Clinical Dietitian Auckland New Zealand	***Composition and labelling*** Recommends further consultation with clinical dietitians to ascertain the medical conditions that require product formulations outside of the proposed minimum and maximum limits. Considers allergen labelling is unnecessary.