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

2 May 2012
[9-12]

FINAL ASSESSMENT REPORT

PROPOSAL P242

FOOD FOR SPECIAL MEDICAL PURPOSES

For Information on matters relating to this Proposal, please refer to http://www.foodstandards.gov.au/foodstandards/proposals/proposalp242foodsforspecialmedicalpurposes/index.cfm

Executive summary

Purpose

The purpose of Proposal P242 is to consider the development of a discrete food standard covering food for special medical purposes (FSMP) for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

There is no explicit standard for FSMP within the Code that recognises this group of products. As a result, the regulation of FSMPs is unclear causing difficulties for FSMP manufacturers, the State and Territory enforcement agencies, DAFF Biosecurity and MAF Biosecurity, New Zealand.

Decision

To approve Standard 2.9.5 – Food for Special Medical Purposes, as amended after submissions were received.

To approve consequential variations to Standards 1.1.1, 1.1A.6, 1.2.1, 1.3.1 and 1.3.4, as amended after submissions were received.

Reasons for decision

FSANZ has approved Standard 2.9.5 which incorporates specific compositional and labelling requirements, including the mandatory labelling statement 'use under medical supervision'. These requirements are generally consistent with overseas regulations or current industry practice.

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

- The inclusion of FSMP as a 'special purpose food' recognises that these foods are designed for a medical purpose for a particular target group, including some who may rely on these products for their sole source of nutrition.

- The regulation of FSMP protects the health and safety of those consumers who require the products.

- The setting of minimum and maximum requirements for vitamins and minerals in FSMP that is represented as being suitable for use as the sole source of nutrition ensures consumers' nutritional needs are met and protects their health and safety. In addition, the permission to vary the micronutrient composition for a specific medical condition ensures that products can be manufactured to meet the particular needs of certain consumers of FSMP.

- Restricting the access to FSMP, along with the requirement to label to the effect that the food must be used under medical supervision, protects the health and safety of users of FSMP by promoting their access to medical or health professional advice on the use of these products.

- There is consistency with relevant international regulations or current practice, wherever possible, to minimise potential barriers to trade that could jeopardise the supply of FSMP to Australia/New Zealand.

Consultation

FSANZ undertook several public consultation rounds over the duration of this project to ensure ongoing input from key stakeholders and interested parties.

Given the lapse in time since the consultation round in 2004, FSANZ held targeted consultations in April-May 2010 as a way of re-engaging with key stakeholders once the project re-commenced. Meetings were held with industry representatives, health professionals and jurisdictions in both Australia and New Zealand. This consultation gathered up-to-date information on the FSMP market and products. Stakeholders also indicated whether issues raised in 2004 were still relevant and also identified new issues.

Individual discussions were also held with key medical and nutritional experts specifically in relation to very low energy diet (VLED) products. These discussions informed FSANZ's decision to exclude VLEDs from the scope of Proposal P242 at that time.

The targeted consultation in mid-2010 assisted FSANZ in revising the approach proposed in 2004 and informed the Consultation Paper released in December 2010 when the project recommenced.

In 2011, discussions with key stakeholders groups continued in response to the issues raised in 2010. A discussion paper was provided in November 2011.

Consultation was also undertaken with the Therapeutic Goods Administration (TGA) in Australia, Medsafe and PHARMAC in New Zealand, Australian and New Zealand Pharmaceutical Societies and several pharmacies in Australia and New Zealand.

Key issues

In the development of Standard, overarching issues included:

- **Harmonisation with overseas regulations**: nearly all FSMPs are imported from the European Union (EU) or the United States of America (USA), with the majority from EU. In order to limit the impost on manufacturers and therefore ensure continued supply of these products to Australia and New Zealand, the compositional and labelling requirements in Standard 2.9.5 align primarily with EU, and the USA or current practice where possible. However, not all labelling requirements could easily be aligned, particularly the labelling requirements pertaining to gluten 'free' claims. This could require some re-labelling of certain imported products.

- **Composition**: the compositional requirements of FSMPs have been aligned with EU minimum and maximum levels for vitamins and minerals. Health professionals and manufacturers requested that formulation be allowed to vary from these requirements to meet particular needs of certain medical conditions. Standard 2.9.5 therefore permits such variation but with an additional labelling requirement. Also, stakeholders requested permission for the addition of certain additives to FSMPs. These additives have been assessed and permitted for addition to FSMPs.

- **Restriction on sale**: as compositional requirements have been made as flexible as possible, a restriction on where and from whom FSMP can be sold has been included in the Standard i.e. FSMP may be sold from or by a range of health care facilities, medical practitioners and dietitians. This is to help manage any potential risk of inappropriate use of these specialised products. Most stakeholders generally support such a restriction.

Distributers also play an important role in the sale and supply of FSMP to consumers. However, some stakeholders had concerns about how the Standard could appropriately permit distributers to sell these products directly to a consumer, while continuing to protect their health and safety. As no evidence has been identified that there is a problem with the current distribution system, Standard 2.9.5 permits distributers to continue to sell FSMP to consumers, but under certain specified conditions.

- **Definition and prescribed name for FSMP**: a range of views on how best to define FSMP for regulatory and enforcement purposes have been expressed. Some jurisdictions requested a prescribed name to assist enforcement agencies to easily identify the products in the market place. A prescribed name is required in the EU but not in the USA where a range of terms are used on product labels. A prescribed name could therefore result in a need for some manufacturers to re-label products imported from the USA. Although some jurisdictions are supportive of a prescribed name, FSANZ is not aware of specific problems associated with the absence of a prescribed name, as is the current situation. FSANZ has determined not to require a prescribed name to avoid additional impost on industry and the potential to stop supply of certain products; rather, the Standard contains a broad definition based on the purpose of these products, their use under medical supervision, and how they are represented. Several mandatory labelling requirements (e.g. the 'medical supervision' statement) will also assist identification.

  Further, the proper identification of FSMP for enforcement purposes will be facilitated by the restrictions on the premises and persons from whom FSMP may be sold.

CONTENTS

Supporting documents

The following material, which was used in the preparation of this Report, is available on the FSANZ website
at http://www.foodstandards.gov.au/foodstandards/proposals/proposalp242foodsforspecialmedicalpurposes/index.cfm

SD1	Composition Assessment Report
SD2	Food Technology Assessment Report
SD3	Labelling Assessment Report

INTRODUCTION

As part of the transition into the new joint food regulatory system in July 1996, Food Standards Australia New Zealand (FSANZ) was required to develop a harmonised Australian and New Zealand food standard covering food for special medical purposes (FSMP) for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

FSMPs are principally formulated food products, intended to be used under the supervision of medical and other appropriate health professionals (e.g. dietitians, nurses and pharmacists). FSMP is required for the dietary management of individuals (including children) with ongoing chronic disease, disorders or medical conditions, or during acute phases of illness, injury or disease states. FSMP is required when the dietary management of individuals cannot be easily or completely achieved with other dietary modification including the use of other special purpose foods. FSMP includes formulated dietary products that are 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 supplementary formulated products.

1. Background

1.1 Current regulatory environment

1.1.1 Australia

There is no explicit standard for FSMP 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 DAFF Biosecurity (formerly the Australian Quarantine and Inspection Service) and MAF Biosecurity, New Zealand.

1.1.2 New Zealand

Under the former New Zealand *Food Regulations 1981* (NZFR), there was no specific regulation solely for FSMP, 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 incorporated the provisions of Regulation 237 into the Code. It was intended that Standard 1.1A.6 would remain in place until such time as a Standard for FSMP was developed. However, Standard 1.1.A.6 will be retained but amended so that in New Zealand, it continues to regulate food formulated and represented for the dietary management of obesity, rather than FSMP (see Section 7.6).

In March 2010, the New Zealand Government introduced the New Zealand Food (Supplemented Food) Standard 2010 (NZ Supplemented Food Standard) which regulates food-type dietary supplements. These products are represented as a food that has a substance or substances added to them, or that have been modified to perform a physiological role beyond the provision of a simple nutritive requirement. They were previously regulated under the New Zealand Dietary Supplements Regulations (1985).

The aim of the NZ Supplemented Food Standard is to provide short to medium term regulatory coverage for food products not currently captured by the Code. It is FSANZ's understanding that the NZ Supplemented Food Standard is not intended to regulate FSMPs as these supplemented foods do not comply with some requirements in this Standard.

For example, the NZ Supplemented Food Standard prohibits labels from displaying statements, expressed or implied, which could be interpreted as advice of a medical nature.

1.1.3 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. The European Union (EU) and Codex have specific requirements for FSMPs. However, there is no specific regulation for FSMP in the United States of America (USA).

Relevant regulations are:

- 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).

- USA federal legislation: the Orphan Drug Amendments 1988 and the Nutrition Labelling and Education Act 1990 (NLEA); a final ruling by the United States Food and Drug Administration (FDA) in 1993 clarifying the NLEA.

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

Those relevant to the labelling of FSMP include:

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

- Codex General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (Codex Stan 146-1985).

- Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

- Commission Directive 2007/68/EC of 27 November 2007 amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients.

- Commission Directive 2008/5/EC of 30 January 2008 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 2000/13/EC of the European Parliament and of the Council.

- Code of Federal Regulations, Title 21 – Food and Drugs, Part 101 – Food Labelling (21CFR101), USA.

- Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA).

1.1.4 Therapeutic goods/medicines

In Australia, the TGA is responsible for the regulation of therapeutic goods under the *Therapeutic Goods Act 1989* (TGA Act). 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 FSMP within the Code, FSMP potentially falls in the regulatory interface of therapeutic goods and food.

It is possible that some products currently positioned under the TGA Act will be covered by Standard 2.9.5. However, the TGA has advised FSANZ that the number of repositioned products is likely to 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 meet specific dietary management goals 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 dietary management of particular health conditions can still cloud their distinction as foods rather than as medicines.

1.2 Current market and distribution of FSMP

Three multi-national companies 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. FSMP entering Australia or New Zealand is originally manufactured for the markets of either the EU, including the United Kingdom, or the USA.

With very few FSMPs manufactured in domestic markets, there is no significant trade of FSMP between Australia and New Zealand. Some transfer of products may occur between Australia and New Zealand to balance product shortfalls or excess. 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.

1.2.1 Australian products

The majority of FSMP is provided through healthcare settings (e.g. public and private hospitals, nursing homes, medical clinics or practices) under the advice and supervision of health professionals such as dietitians, nurses or medical staff. The supply of FSMP to healthcare facilities most often occurs through either state-wide or regional health service tendering procedures. 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 currently obtain supplies through several channels:

- regional health services (e.g. hospitals)
- pharmacies (over the counter sales, usually in bulk quantities, and without a prescription)
- directly from manufacturers
- from businesses that wholesale and distribute FSMPs to pharmacies and healthcare institutions. These businesses may also supply some FSMP directly to consumers as a separate retail sale activity in addition to their wholesaling activities.

These businesses typically provide products to consumers either at a lower price than the above channels or where access to the above channels is limited (e.g. absence of services in remote locations).

Currently, FSMP is not sold in Australia through supermarkets or convenience stores.

The level of financial assistance that is offered to support the purchase of products varies considerably between each Australian state and territory. A small number (approximately 100) products, predominately for metabolic disorders, are listed on the Pharmaceutical Benefits Scheme.

1.2.2 New Zealand products

Certain types of FSMP in New Zealand are currently listed as 'Special Foods' in Section D of the New Zealand Pharmaceutical Schedule, which is administered by PHARMAC (the Pharmaceutical Management Agency Ltd). This listing allows for consumers to obtain access to pharmaceutical subsidies on the product to ensure that all New Zealanders have access to safe, cost effective, quality medicines and special foods to meet reasonable health needs.

'Special Foods' in the New Zealand Pharmaceutical Schedule predominantly consist of enteral feeds, products for use as a sole source of nutrition, or products for very specific or rare conditions. Products that are not suitable for use as a sole source of nutrition may not be included on the list, unless they are for a rare or specific medical condition.

The New Zealand Pharmaceutical Schedule requires a prescription from an authorised 'practitioner' (either a medical practitioner or an appropriate dietitian) before a listed product can be purchased by a consumer. Non-listed FSMP are usually available over the counter in pharmacies.

The practice of wholesalers/distributors selling FSMP directly to consumers does not appear to be widespread in New Zealand. This may be due to access to affordable products as a result of subsidies from PHARMAC.

FSMP are currently not available in New Zealand through supermarkets or convenience stores.

1.3 Background history of the project

In October 2001, FSANZ [then the Australia New Zealand Food Authority (ANZFA)] released an Initial Assessment Report for Proposal P242 and invited public submissions. The comments received were considered during the draft assessment stage which culminated in the release of the Draft Assessment Report (including a draft Standard) in December 2002.

There was some delay following the release of the Draft Assessment Report. Given the complexity of the issues involved and the time period since the Draft Assessment Report had been released, a Preliminary Final Assessment Report was released in 2004 to allow an additional round of public comment on the proposed draft Standard.

Consideration was then further deferred as the then Australia and New Zealand Food Regulation Ministerial Council (now the COAG Legislative and Governance Forum on Food Regulation – the Forum) was developing a Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods. The Policy Guideline was eventually approved in October 2009 (see Section 1.4) and work on Proposal P242 was recommenced in 2010.

Given that the project had been on hold for some years, FSANZ recommenced the project by undertaking targeted consultation with key stakeholders during 2010. A round of public consultation followed in December 2010. Further targeted consultation continued through 2011 as development of the Standard progressed.

1.4 Policy Guideline on the Intent of Part 2.9 of the Code – Special Purpose Foods

The Policy Guideline was approved in October 2009. The development of a standard for FSMP 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*
  - *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.

2. The issue / problem

FSMP is specifically formulated for the dietary management of individuals with particular medical conditions whose dietary management cannot be completely achieved without the use of the food. These individuals rely either fully or partially on FSMPs to meet specific nutritional requirements. It is therefore essential that FSMP is always available to the target population, as well as being formulated to be effective and safe in meeting their needs. FSMP is suitable for consumption only by those individuals for whom the product has been designed. Since FSMP is formulated for use with certain medical or disability conditions, or acute phases of illness or injury, it should be consumed by individuals only under these circumstances. Some FSMP 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. Because there is no explicit standard for FSMP in the Code, these products are subject to generic (Chapter 1) food standards. However, the specially formulated nature and specialised use of FSMP often makes it difficult for these products to comply with the generic food standards.

There are no permissions for the addition of specific forms of nutrients and related substances, and there is no requirement to label a product with particular medical information to help inform health professionals and consumers. There are also no controls in the generic food standards that can manage the potential risks that could occur with the use of FSMP.

The lack of an explicit food standard for FSMP creates difficulties for enforcement agencies and manufacturers of FSMPs in determining the compliance of these products with the Code.

As nearly all of these products are imported into Australia and New Zealand, these enforcement problems occasionally cause delays in the importation and distribution of FSMPs to consumers.

2.1 The Scope of Standard 2.9.5

Proposal P242 has considered the composition, labelling, advertising, sale and supply of FSMP. Also, given that nearly all of these products are imported, relevant overseas regulations have considerably informed the scope of this project.

2.1.1 Exclusion of very low energy diet products from the Standard

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. In the Preliminary Final Assessment Report in 2004, FSANZ included VLED products in the range of foods that would be subject to the outcomes of Proposal P242.

FSANZ undertook specific targeted and public consultation on this issue in 2010 and determined that the market for formulated foods used for weight reduction had evolved since 2004. This decision then raised broader issues. There is now an overlap between VLED products and other types of formulated foods used for weight reduction, both in the presentation of these two food categories and in the way in which the products are used. Other categories regulated by the Code include meal replacements under Standard 2.9.3 – Formulated Meal Replacements (FMRs) and Formulated Supplementary Foods.

In response to stakeholder comment, FSANZ decided to exclude VLED products from the Proposal. Instead, a new project will be initiated to specifically investigate the most appropriate way to regulate VLEDs relative to all other formulated foods for weight reduction purposes. Work on this project will commence after Proposal P242 has been completed. Stakeholders supported this approach.

2.1.2 Other products that are not included in the Standard

Total parenteral nutrition (TPN) products are formulated to be administered intravenously and therefore fall outside the definition of food in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). For this reason, TPN is not considered to be within the scope of this Proposal.

Infant formula products, including those formulated for special dietary use have also been excluded from the scope of Standard 2.9.5. The infant formula products for special dietary use could potentially be regulated under Standard 2.9.5 or under Standard 2.9.1 – Infant Formula Products. This could result in inconsistency, potential confusion and difficulty for enforcement purposes. Therefore, for clarity and consistency, all infant formula products will continue to be regulated by one standard i.e. Standard 2.9.1 at this time. FSANZ will consider the infant formula products for special dietary use under a planned review of Standard 2.9.1 commencing in 2012.
Standard 2.9.5 also lists the Standards and clauses that will not apply to FSMP (refer to subclause 3(1)).

Clause 9 of Standard 1.1.1 has not been applied to allow flexible composition of FSMP; exclusion of Standard 1.3.2 also allows flexible composition and minimises re-labelling costs (as discussed in SD3), exclusion of Standard 1.1A.2 reduces confusion and minimises re-labelling costs (as discussed in SD3); exclusion of Standard 1.5.1 allows for specialised formulation of products recognising they are to be used under medical supervision; Standards 2.9.2, 2.9.3 and 2.9.4 are other special purpose foods that have prescribed names and are excluded to ensure clarity of regulation; and parts of Part 1.2 are not applied, as described in SD3.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. 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, FSANZ must also have regard to:

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

3.1 Specific objectives of Proposal P242

The specific objectives of Proposal P242 were to:

1. Protect the health and safety of intended users of FSMP by: ensuring FSMPs are formulated to meet their nutritional requirements; assisting consumers to access medical or health professional advice about the safe and appropriate use of FSMP; maintaining the availability of FSMPs for intended consumers; and preventing the misuse of FSMPs by unintended users.
2. Provide health professionals and consumers with sufficient information to make appropriate choices for the safe and effective use of FSMP.
3. Develop a food standard applying to FSMP in Australia and New Zealand that is consistent, where possible, with relevant international regulations.

4. Key assessment questions

FSANZ noted in the Preliminary Final Assessment that there were inherent risks associated with the use of FSMP that primarily relate to nutritional adequacy and safety. These were categorised into five areas:

- the inadequate provision of nutrition when an FSMP does not contain sufficient quantities of micronutrients
- safety concerns from the excess intake of certain micronutrients
- the safety of reducing minimum micronutrient requirements to cater for certain medical conditions
- macronutrient requirements in VLED products
- the safety of various nutritive substance forms.

Managing the potential risks included consideration of the composition, availability, sale, advertising and labelling of FSMP.

Since the Preliminary Final Assessment, FSANZ investigated the following questions to further develop and finalise Standard 2.9.5:

- Are there any new substances or substance forms that have emerged since 2004 that should be granted permission for addition to FSMP and are they safe for use in FSMP?

- Do the proposed micronutrient minima requirements for FSMP represented as being suitable for use as the sole source of nutrition pose a health and safety risk for FSMP consumers?

- Do the micronutrient maxima requirements for FSMP represented as being suitable for use as the sole source of nutrition pose a health and safety risk for FSMP consumers?

- Do the micronutrient minima and maxima requirements for FSMP represented as being suitable for use as the sole source of nutrition allow for specific formulation of these products for particular medical purposes, while protecting the health and safety of FSMP consumers?

- With regard to fermentable oligosaccharides, lactose, fructose and polyols (FOLFAPs[1]):

  - How prevalent in the community are:
    - functional bowel disorders
    - inflammatory bowel disease?

  - What are the adverse health consequences from consumption of FOLFAPs from general dietary sources for those with:
    - functional bowel disorders (including Irritable Bowel Syndrome)?
    - small intestine bacterial overgrowth syndrome?
    - inflammatory bowel disease?

  - What are the adverse health consequences from consumption of FOLFAPs by:
    - consumers of FSMP as a partial dietary replacement?
    - those receiving total or near total nutrition through enteral feeding?

  - Is current labelling information sufficient for the use or provision of advice on FSMP that contains FOLFAPs?

- With regard to the food additives requested for addition to FSMP:

  - has the technological function in FSMP been articulated clearly for these food additives?
  - are these food additives safe for use in FSMP?
  - is there a need to establish maximum levels for the use of these food additives in FSMP, in order to protect public health and safety? If so, what should they be?

[1] FOLFAPs is an acronym developed by FSANZ for this proposal because the more commonly used term *FODMAPS* (fermentable oligosaccharides, disaccharides, monosaccharides and polyols) is trademarked by the original researchers, P Gibson and S. Shepherd (2010). 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

- With regard to overarching strategies to manage potential risk given the specialised nature of these products:

  - is there a need to manage access to, or sale and advertising of FSMP? If so, what type and level of restriction is appropriate?
  - what labelling requirements should apply to FSMP? Do the proposed labelling requirements and statements allow for the provision of adequate information on labels and safe use of FSMP?
  - does the proposed Standard prevent barriers to trade and supply, and ensure continued availability of FSMP for consumes, particularly those who rely on products as a sole source of nutrition?

RISK ASSESSMENT

5. Summary

5.1 Compositional Assessment

FSANZ conducted several risk assessments of the composition and safety of FSMP throughout the life of this project; firstly, at Preliminary Final Assessment (2004), for the 2010 consultation (December 2010), and both prior to and following the 2011 targeted consultation (November 2011). The final risk assessment is at SD1.

The final risk assessment revised consideration of FOLFAPs in FSMP and extended the previous Draft Assessment of the nutrient composition requirements of FSMP. A summary of these two components of the composition assessment is included in Section 8.7 of this Report. FSMP is primarily imported into Australia and New Zealand. As such, the need for international harmonisation has determined the scope of the various assessment components.

The composition assessment concluded the following:

- *New permitted substances or permitted forms*
  - In 2010, an additional nineteen permitted forms of micronutrients and nutritive substances were determined as safe for addition to FSMP. These forms were obtained from Schedule 1 of Standard 2.9.1, regulations of the European Commission and the Codex Advisory List CAC/GL 10-1979.
  - In 2011, chromium picolinate was considered safe and technologically suitable for use in FSMP.

- *Micronutrient minimum composition values in FSMP*
  Aligning the minimum micronutrient composition values for FSMP with the European minimum micronutrient values poses no risk to public health and safety.

- *Micronutrient maximum composition limits in FSMP*
  Adopting the European maximum composition limits for vitamin A, vitamin B_6, vitamin D, selenium, iodine, zinc, calcium, manganese and copper poses no risk to public health and safety.

- *FOLFAPs in FSMP*
  - Data on the prevalence of inflammatory bowel disease and functional bowel disorders in the Australian and New Zealand populations are limited, although estimates for IBD in the New Zealand population suggest its prevalence may be increasing.

The limited availability of data means there is uncertainty in determining the proportion of the Australian and New Zealand population that is affected.

- There is evidence demonstrating that general dietary consumption of FOLFAPs can induce several adverse gastrointestinal symptoms including abdominal discomfort, bloating, cramps, flatulence, stomach rumbling, and diarrhoea.

- The evidence for these effects is well demonstrated in functional bowel disorders particularly irritable bowel syndrome (which is thought to incorporate small intestine bacterial overgrowth syndrome). Given the individual differences in carbohydrate digestion and tolerance to FOLFAPs, it is not possible to quantify a relationship between FOLFAP consumption and adverse gastrointestinal symptoms.

- The evidence for FOLFAPs inducing adverse gastrointestinal effects in inflammatory bowel disease is limited. The use of FSMP in patients with this disease varies depending on the phase of disease (i.e. active or remission), with FSMP occasionally used as a sole source of nutrition in active phases of the disease.

- Evidence of the effects of FOLFAPS in enteral feeding (as a total source of nutrition) is mainly based on addition of fibres which incorporate FOLFAPs. Results from studies examining these are mixed, thus it is difficult to confirm the effects of FOLFAPs alone.

5.2 Food Technology Assessment

At Preliminary Final Assessment, FSANZ proposed to include an entry for FSMP in Schedule 1 of Standard 1.3.1. Unless otherwise specified in Schedule 1 of Standard 1.3.1, food additives in Schedules 2, 3 and 4 may be added to processed foods in accordance with GMP. FSANZ concluded that, as FSMPs are processed foods containing a number of food ingredients, permission for the use of Schedule 2, 3 and 4 food additives was technologically justified.

After the project recommenced in 2010, FSANZ consulted with the FSMP industry and asked whether that approach would satisfactorily reflect the use of food additives in existing FSMPs sold in Australia and New Zealand, noting that nearly all were sourced from overseas markets.

In response, stakeholders requested further consideration of additional additives to FSMPs. Section 6.8 discusses this request and SD2 outlines the assessment undertaken.

Therefore, on the basis of the further food technology assessment, FSANZ has permitted the addition of 16 food additives to FSMPs, in addition to the additives listed in Schedules 2, 3 and 4 of Standard 1.3.1, in accordance with GMP. FSANZ concluded these additives are safe for use in FSMP and that their use is technologically justified in FSMP.

RISK MANAGEMENT

6. Risk management issues and strategies

6.1 Background to overarching risk management strategies

The outcomes of the risk assessments in Section 5 have been considered in determining the final risk management approach for FSMP.

The approach aims to manage any potential risks to the public's health and safety and also responds to issues raised by stakeholders during consultation undertaken in 2004, 2010 and 2011.

At Preliminary Final Assessment, FSANZ determined that there were potential risks associated with the unsupervised and inappropriate use of FSMPs by both intended and unintended consumers. To manage these risks and also to clearly distinguish FSMPs from other foods, FSANZ proposed an overarching risk management framework, rather than highly prescriptive compositional and labelling requirements. As a result, the draft Standard 2.9.5, released with the Preliminary Final Assessment Report in 2004 contained specific compositional and labelling requirements for FSMP, and also risk management strategies that:

- 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 retail sale of FSMPs by permitting the sale of FSMPs only from medical practitioners, pharmacies, hospitals, nursing homes and wholesalers
- restricted advertising 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.

When the project recommenced in 2010, further consultation identified new developments in relation to advertising e.g. greater use of the internet which led FSANZ to revise the risk management strategy. Requirements on the sale, composition and labelling of FSMPs remained, but the proposed restriction on advertising of FSMPs directly to consumers was removed (see Section 6.4).

This approach maintained controls over the potential health and safety risks for consumers. The revised strategy was proposed in December 2010 and was further discussed with key stakeholder groups in 2011. Following this consultation the risk management strategies were further refined and are outlined in the following section, and incorporated into the Standard at Attachment 1.

The following sections provide information on:

- the approach taken at Preliminary Final Assessment in relation to the sale, advertising, composition and labelling of FSMPs
- key issues identified from consultations in 2004, 2010 and 2011
- FSANZ's risk management strategies at Final Assessment and the rationale for each strategy.

6.2 Definition

6.2.1 Previous approach and submitter comments

At Preliminary Final Assessment, the definition of FSMP focussed on the purpose of these products, including reference to food specifically processed or formulated, and presented, for the dietary management of persons for use solely under medical supervision.

This harmonised with the European definitions of FSMP; this decision was supported by stakeholders.

Since then, several options for defining FSMP have been considered. When the project recommenced, FSANZ considered that a definition should not include reference to the way in which a product is used by a consumer, or how its use is supervised.

The intended need for supervision is addressed in the Standard through a mandatory labelling requirement to indicate 'use under medical supervision'. Therefore, the reference to 'use solely under medical supervision' was removed from the definition.

However, in response, a range of stakeholders considered that 'medical supervision' was fundamental to the characterisation of FSMP products, and were concerned that the intent for medical supervision was removed from the amended definition. After further consideration, FSANZ held the view that the primary purpose of a definition is to identify whether a particular food is an FSMP by its representation alone and thus enable FSMPs to be distinguished from other foods not regulated under Standard 2.9.5. In 2011, FSANZ discussed this approach with stakeholders but maintained its position to focus only on the way in which FSMPs are represented at the point of sale.

The draft Standard at that time provided that a food is an FSMP if it is represented as being for the dietary management of a disease, disorder or medical condition, or an FSMP, or a medical food. The three different representations listed in the above text were included to recognise the various descriptions used on FSMP labels. Many FSMP labels indicate the disease, disorder or medical condition for which the food is formulated; also the European FSMP Directive requires 'food for special medical purposes' to be displayed on product labels and, although it is not prescribed, 'medical food' is used in the USA[2] to identify this category of food and is sometimes used on FSMP labels. Some jurisdictions did not support this emphasis on representation only, however, and considered that the definition should also include reference to the purpose and use of FSMPs.

Specifically, reference to the intended use of FSMPs under medical supervision should be included. One government stakeholder considered that such a reference was an essential enforcement requirement for FSMPs and others considered it critical to align the purpose and the definition.

6.2.2 Decision

At Final Assessment, FSANZ reviewed and considered the views of stakeholders throughout the project and relevant international regulations. The definition in Standard 2.9.5 now includes three key elements of FSMP:

- the special purpose of the products
- the intent for use under medical supervision
- the way in which the products are represented.

These elements provide further clarity for enforcement to enable FSMP to be identified and distinguished from other foods. Other specific mandatory labelling requirements will also assist in this identification e.g. the requirement to include on the label the medical purpose of the food, and wording to the effect that the product is to be used under medical supervision.

The definition will apply to FSMP that is suitable as a sole source of nutrition as well as to FSMP used as a supplementary food product.

6.3 Prescribed name

6.3.1 Previous approach and submitter comments

No prescribed name has been recommended or proposed for FSMP since the project commenced in 2001.

[2] USA federal legislation: the Orphan Drug Amendments of 1988

However in 2011, some jurisdictions recommended that a prescribed name be included in the Standard to clearly identify FSMPs and to provide certainty for enforcement purposes. FSANZ requested additional information from manufacturers and further reviewed the range of wording used on current labels in both Europe and the USA.

The EU FSMP Directive requires a prescribed name (i.e. foods for special medical purposes) but products from the USA are not subject to such a requirement. The term 'medical food' is the name of the food category for FSMP in US regulation, but that term is not prescribed in labelling. Some of the US FSMP labels include the words 'medical foods' whereas others include variants of that term. If the words 'food for special medical purposes' were prescribed to align with the EU requirements, all US FSMP would require re-labelling. Because there is no standardised term used on US FSMP, prescribing an alternative term such as 'medical foods' would still leave a proportion of US FSMPs requiring re-labelling.

Manufacturers expressed concern that requiring a prescribed name for FSMP imported from the USA would have a considerable financial impact. Two of the three main companies importing FSMP into Australia and New Zealand indicated that approximately 50–70% of their FSMP products come from the USA. Because imported FSMPs are manufactured for the global market, the local companies advised that re-labelling would likely need to occur within Australia and New Zealand. The cost of this, plus the additional logistical costs of transport, storage, unpacking and re-packaging products for distribution would be significant and might not be cost effective for the local market. Should re-labelling be required, manufacturers indicated that the supply of some products to Australia and New Zealand might be reconsidered.

6.3.2 Decision at Final Assessment

No prescribed name is required in Standard 2.9.5. FSANZ is not aware of specific problems associated with the absence of a prescribed name, as is the current situation, and products from the USA do not have a prescribed name so their labelled designation varies across products. If the need to re-label resulted in cessation of importation of some products, FSANZ's key objective of maintaining the supply of FSMPs to consumers of these products would be compromised.

FSANZ considered that the expanded definition (see Section 6.2.2) would enable FSMPs to be identified and distinguished from other foods. Also, other special purpose foods under Part 2.9 of the Code e.g. formulated supplementary foods, have prescribed names which would distinguish them from FSMPs.

In addition, Standard 2.9.5 includes mandatory labelling requirements that will help identify an FSMP, including statements that indicate:

- the name or description of the food sufficient to indicate the true nature of the food
- that the product is to be used under medical supervision
- the medical purpose of the food
- whether the product is suitable as a sole source of nutrition
- precautions and contraindications, if applicable.

Should there be any difficulty with identification of a product for enforcement purposes, the restriction on sale may also assist with distinguishing FSMP from general foods i.e. FSMP can be sold only from or by certain health care facilities, certain health professionals or related distributers, which indicates that the food is of a medical nature.

FSANZ therefore considered that there are sufficient requirements in Standard 2.9.5 to adequately identify FSMP for enforcement purposes. This approach avoids re-labelling for the small Australia and New Zealand market and limits additional costs for products imported from the USA. The availability of FSMPs will likely be maintained, particularly the specialised, small volume imported products.

Also, the absence of a prescribed name does not preclude imported FSMPs from using the prescribed name required by the EU FSMP Directive.

In the absence of any evidence of problems with the identification of FSMPs, this approach is in line with minimal effective regulation.

6.4 Advertising

6.4.1 Previous approach and submitter comments

At Preliminary Final Assessment, draft Standard 2.9.5 restricted advertising 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 potential health and safety risks associated with the unsupervised and inappropriate use of FSMP, in particular VLED products.

Submitters 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 considered that restrictions would have little effect when advertising is available through the internet.

Also, because VLED products were removed from the scope of P242 following consultation in 2010, this led FSANZ to reconsider the restriction on advertising. Stakeholders also considered that advertising restrictions were unnecessary since consumers are protected through the Australian Competition and Consumer Commission under the *Competition and Consumer Act 2010*. In New Zealand the *Fair Trading Act 1986* also applies.

Although stakeholders generally supported removing the advertising restrictions, jurisdictional stakeholders did so, on the basis that a restriction on the sale of FSMP would be retained, and if possible strengthened.

6.4.2 Decision at Final Assessment

Standard 2.9.5 does not include a restriction on advertising of FSMPs directly to the general public. The rationale for this decision is as follows:

- The potential for inappropriate use of FSMP as a result of direct advertising to consumers is considered to be low, particularly with the removal of VLED products from the scope of P242. It is considered unlikely that FSMPs would be used by individuals for whom it is not intended due to the cost and often unpalatable nature of these products.

- Removing the prohibition on advertising harmonises with European requirements (Directive 1999/21/EC) and Codex (Codex STAN 180-1991). It also overcomes the difficulties in managing global advertising of international products (e.g. via websites).

- Permitting advertising to the general public may facilitate consumer knowledge and awareness of the FSMP product range, enabling consumers to make informed choices.

- Other risk management strategies (including the restriction on sale and the labelling of FSMPs for use under medical supervision) were considered sufficient to manage any potential risks.

6.5 Sale of and access to FSMP

6.5.1 Previous approach and submitter comments

A restriction on the sale of FSMP has been considered a necessary part of the overall risk management for FSMPs, given the minimal prescribed compositional requirements for these products.

At Preliminary Final Assessment, FSANZ proposed to permit the sale of FSMPs directly to consumers only by medical practitioners, pharmacies, hospitals, nursing homes and wholesalers. This approach aimed to reduce the potential risks associated with unsupervised and inappropriate use of FSMPs. It was also expected to discourage manufacturers or importers from positioning inappropriate products as FSMP in order to take advantage of the less restrictive compositional requirements.

At that stage, submitters generally considered that such a restriction on sale was unnecessary given the lack of evidence of market failure or reported issues regarding consumers' health and safety. Submitters also noted that consumers were protected by the proposed labelling requirements in draft Standard 2.9.5.

However, when the project recommenced in 2010, stakeholders tended to support the proposed restrictions on the sale of FSMP as these largely reflected the current arrangement.

Jurisdictions particularly supported a restriction on sale given that advertising restrictions had been removed. However, it was noted that the approach could impact on distributors of FSMPs who sold products directly to consumers. Consultation confirmed that distributors play an important role in the FSMP supply chain and that their business would be adversely affected if not permitted to sell directly to consumers.

Stakeholders also noted that it was common for dietitians e.g. in private practice, to sell FSMPs as they were suitably trained to provide professional advice and supervision; also, in New Zealand certain dietitians are permitted to prescribe, as well as sell, FSMPs.

Therefore, the restriction on the sale of FSMPs was revised to permit a dietitian to sell these products as well as a medical practitioner. The revised Standard also permitted the sale of FSMPs directly to consumers by manufacturers and their distributors[3]. This approach reflected the existing practice in Australia and New Zealand in which some patients are referred to distributors by health professionals since distributors can generally sell these products more cheaply than pharmacies. Distributors provide a service to consumers, including those who cannot easily access FSMPs from pharmacies or hospitals (e.g. due to a disability, or because they lived in remote communities).

[3] 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 were used instead. The word distributor was intended to be a generic term covering both distributors and wholesalers.

Stakeholders generally supported the revised restriction on sale and also supported ensuring direct supply to consumers through distributors. However, the revised Standard was considered to potentially allow any distributor to sell FSMPs without reference to health professional advice for the consumer. Some stakeholders recommended that distributors be permitted to sell directly to consumers only on a 'written request' e.g. from a health care facility or medical practitioner etc. This was added to the revised Standard in response to the concerns raised, particularly by jurisdictions.

In 2011, health professionals, manufacturers and distributors of FSMPs provided further information in relation to the supply chain. Distributors noted that the supply of FSMPs directly to consumers is only a small part of their business; the majority of these consumers are under medical supervision and they are often part of an established referral system e.g. the Home Enteral Nutrition program (HENS). Some distributors require the patient to be registered first whereas others provided 1800/0800 numbers. Requests are received by phone (often on the advice of a health professional), or occasionally in person. Some distributors would contact a dietitian or doctor if no formal referral was received to validate a consumer's request. One distributor, aware of the medical nature of these products and the need for health professional advice, referred new clients to its nutritionist if a product was requested without a referral. Also, one distributor indicated that they do not provide any FSMP directly to consumers that are not already available in pharmacies.

Distributors and health professionals were opposed to the extra impost of a written referral for the small number of consumers involved; they queried how the validity of a request would be verified and how current and frequent a request would need to be. It was noted that this requirement would increase the impost disproportionately on some providers when there is no evidence of failure with the current system.

Several jurisdictions considered that the requirement for a written request was too vague and might not be enforceable. They questioned how such a system would be consistently applied, the time period in which a written request would be valid, who would validate the referrer and how this approach would work for phone orders.

An alternative option was suggested for jurisdictions to implement a system to 'oversee' the distributors of FSMPs within their region. However, this was not considered appropriate by jurisdictions. It was also noted that consumers would not likely use these products unless necessary for their medical condition due to the cost and palatability of FSMP.

Stakeholders considered that permissions to sell and/or authorise a sale of FSMPs directly to consumers should include nurses and speech therapists in certain situations, such as when a medical practitioner was not directly involved (e.g. pre-operative, immuno nutrition products in a surgical clinic).

6.5.2 Decision at Final Assessment

FSANZ retained the restriction on sale given the minimal prescribed compositional requirements for FSMPs and the removal of a restriction on advertising in Standard 2.9.5.

Standard 2.9.5 permits an FSMP to be sold by medical practitioners and dietitians, and from medical practices, pharmacies and responsible institutions as defined in the Standard, e.g. hospitals. In practice, the sale, authorisation and/or supervision of the use of FSMPs extends to health professionals other than medical practitioners, specifically to qualified dietitians, and some nurses and speech therapists in certain situations. In addition, in New Zealand certain appropriately qualified dietitians are permitted to prescribe FSMPs. Therefore, the restriction on the sale of FSMP is intended to recognise the range of persons and premises that sell these products to a consumer, and to reflect the existing arrangements.

An FSMP may also be sold to a consumer by a distributor who also supplies that particular FSMP to the above health professionals or premises, provided that the distributor sells the majority (more than half) of the stock of that particular FSMP to the above health professionals or premises within a 24-month period. This ensures that distributor sales directly to consumers continue to comprise only a small component of a distributor's FSMP business. This provision enables bone fide distributors of FSMPs, who are aware of the medical nature of these foods, to continue to sell directly to consumers, and reflects the existing practices in Australia and New Zealand. FSANZ understands that it is a small proportion of consumers who might not go through an established 'formal' referral system of some type. Also, some distributors noted that they do not provide any FSMP directly to a consumer that is not already available in pharmacies. In addition, in New Zealand, a prescription is commonly used for obtaining a PHARMAC subsidy for FSMP which ensures health professional advice is provided.

The restriction on sale is intended to balance the need for consumers to have access to health professional advice about the appropriate use of FSMPs, with the need to ensure the supply chain is maintained and that consumers, particularly those who rely on these products for long periods, can access FSMPs through an appropriate distributor.

The approach is also in accordance with the Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods (see Section 1.4). The Policy Guideline 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.

As there is no evidence of problems in the current distribution system, this approach maintains the current supply chain, avoids additional impost on distributors or health professionals, and is aligns with minimum effective regulation.

6.6 Transitional Standard 1.1A.6 – Special Purpose Foods and regulation of VLED products in New Zealand

Following the 2010 public consultation, FSANZ decided to exclude VLED products from Proposal P242 (see Section 2.1.1).

Submitters' comments on the December 2010 Consultation Paper noted that the New Zealand only Transitional Standard 1.1A.6 – Special Purpose Foods was currently used in New Zealand to regulate VLED products as an interim measure in the absence of binational regulation for these products. As the December 2010 Consultation Paper proposed to repeal this Standard when the new FSMP regulations were gazetted, submitters noted that VLED products would be unregulated in New Zealand.

Therefore, Transitional Standard 1.1A.6 will cease to have effect on the date of commencement of Standard 2.9.5, other than in relation to food formulated and represented as being for the dietary management of obesity i.e. it will continue to apply to foods formulated and represented for the dietary management of obesity in New Zealand. This will maintain the status quo in regulating VLED products manufactured in or imported into New Zealand (see consequential variations to the Code in Attachment 1). Also, Standard 2.9.5 excludes foods represented as being formulated for the dietary management of obesity.

6.7 Composition

Some compositional requirements for FSMP have been established. They relate to the chemical forms of nutrients and related substances, micronutrient minima and maxima for FSMPs intended to be used as a sole source of nutrition, and for food additives and processing aids (see SD1 and SD2).

6.7.1 Chemical forms for nutrients/related substances

6.7.1.1 Previous approach and submitter comments

Because FSMP is a special purpose product, vitamin and mineral permissions in Standard 1.3.2 do not apply. At Preliminary Final Assessment, a list of permitted forms of nutrients and related substances was proposed primarily on the basis of European legislation. Permitted forms of nutrients from Schedule 1 of Standard 2.9.1 – Infant Formula Products were included in the proposed list as well as forms of several nutritive substances which had previously been assessed as safe for use in FSMP products. It was considered that chemical forms of nutrients that had been established as safe for use in infant formula products were safe for use in FSMP.

In 2004, submitters requested a wider range of permitted forms and food additives and greater alignment with European regulations. Consultation in 2010 also supported a wider range of permitted forms of nutrients to align with recent amendments to overseas regulations. Submitters requested inclusion of substances considered safe by the European Commission, the US Food and Drug Administration and Codex Alimentarius.

Submitters also requested permissions for several new forms of substances not currently permitted in overseas regulations and for the adoption of an overarching statement for amino acids similar to the European (EC No 953/2009) and US (21CFR172.320) regulations.

The December 2010 Consultation Paper included permissions for the addition of nineteen further forms of nutrients/related substances to FSMP which were approved as safe for addition to FSMP in overseas regulations (i.e. European PARNUTS, and Codex Advisory List for Infants and Young Children).

However, it was decided that forms of micronutrients that were not listed in these overseas regulations (i.e. not permitted overseas) should not be permitted in Standard 2.9.5.

Following this, submitters requested that chromium picolinate also be permitted for addition to FSMP. FSANZ subsequently reviewed the safety of adding this form of chromium to FSMP, and determined that it poses no health risk to consumers of FSMP.

6.7.1.2 Decision at Final Assessment

FSANZ reaffirmed the previous decisions and approved the permitted forms of particular substances as listed in Schedule 1 in Standard 2.9.5, for addition to FSMP, including chromium picolinate. This decision was made on the basis that permitted forms of nutrients in Australian and New Zealand FSMP regulations should harmonise where possible with overseas regulations.

Any other additional new forms required by the food industry will require an Application to FSANZ to amend the Code once Standard 2.9.5 is gazetted.

6.7.2. Minimum micronutrient composition of FSMP that are represented as being suitable for use as a sole source of nutrition, compared with the 2006 NRVs

6.7.2.1 Previous approach and submitter comments

In 2004, FSANZ proposed to adopt the minimum micronutrient limits in the European FSMP Directive, for FSMP represented as suitable for use as a sole source of nutrition.

An assessment undertaken when the project recommenced in early 2010 noted the potential for micronutrient intakes to be below the 2006 adult Nutrient Reference Values (NRVs), if the composition of this group of FSMP products was based on the European minimum limits. Despite this, stakeholders supported harmonising composition limits with the European regulations since nearly all FSMP is currently manufactured overseas and it is important to avoid barriers to trade so to maintain the supply of FSMP to Australia and New Zealand.

In the 2010 Consultation paper, FSANZ proposed to maintain the European minimum micronutrient composition limits. No specific risks were identified by stakeholders at that time although some stakeholders suggested that the minimum composition of FSMP should be guided by the 2006 NRVs and the potential risk of inadequate intakes further assessed.

In 2011, further assessment of potential risks of inadequate vitamin and mineral intakes was undertaken. The European minimum nutrient composition limits were used to estimate daily nutrient intakes at the lower and upper end of the estimated energy requirement (EER) range (for each adult age and gender group as outlined in the 2006 NRVs). These daily intake estimates were then compared with the 2006 estimated average requirements (EARs). To characterise the risk, nutrient composition information from product labels was used to create a second set of estimated daily intakes. This second set identified a potential risk of inadequate intake. It was concluded that further information on the use and manufacture of these products was required. This assessment is described in detail in SD1.

During consultation in 2011, stakeholders requested further assessment of the potential risk of inadequate vitamin and mineral intakes in children. An assessment of potential nutrient intakes and potential risk was conducted for all age and gender groups in the 2006 NRVs following the method outlined above for adults. Details of these assessments are in SD 1. During consultation in 2011, FSANZ obtained confirmation from industry that the proposed minimum micronutrient limits in the draft Standard were already being met. In addition, manufacturers noted that the basis for the declaration can depend on the source or location of production of FSMP as labelling requirements in the EU and USA differ. For most FSMPs, micronutrient declarations are based on average amounts across the shelf life of a product, with a small number of labels based on the minimum amount of a micronutrient that would be detected during the product's shelf life.

Health professionals clarified, that they used information on labels and supporting product documents to assess the nutritional adequacy of a product, and the management of potential inadequate micronutrient intakes when prescribing FSMP.

6.7.2.2 Decision at Final Assessment

The assessments concluded that the potential risk of inadequate micronutrient intakes in both children and adults was minimal as FSMPs are used under the supervision of health professionals and the nutritional status of the patient is closely monitored. Therefore, FSANZ maintained its previous decision to adopt the European requirements for the minimum composition of vitamins and minerals, to align with the European FSMP requirements.

6.7.3 Maximum micronutrient composition for FSMP that are represented as being suitable for use as a sole source of nutrition

6.7.3.1 Previous approach and submitter comment

In previous safety assessments undertaken in 2004 and 2010, FSANZ recommended that maximum limits were unnecessary for the majority of vitamins and minerals added to FSMP. However, for vitamins A, B_6, and D, selenium, iodine, zinc, calcium and manganese, potential safety risks were identified in the context of use of FSMP as a sole source of nutrition.

Thus, maximum limits were considered appropriate for these micronutrients. Setting such limits serves as a risk management tool to limit ongoing excessive exposure to these vitamins and minerals, rather than acting as a compositional 'cut-off' to what may be considered a safe or unsafe concentration.

The maximum limits proposed in 2010 were based on a mixture of the US Dietary Reference Intakes (United States Institute of Medicine, 2000a-c, 2001a, 2004), the European Union (Scientific Committee for Food), FAO/WHO Human Vitamin and Mineral Requirements (2001) and the upper levels of intake (ULs) in the 2006 NRVs. The selection of the appropriate level was based on an evaluation of the evidence base for each of these publications, rather than the levels used in European regulations. The proposed maximum limits were intended to relate solely to the use of the substances in FSMP, but were not intended for use as general upper levels for intake.

Submissions to the December 2010 Consultation Paper noted that the maximum vitamin and mineral limits proposed by FSANZ differed from the European maximum limits, with which most products on the market already comply. To avoid creating a potential trade barrier, FSANZ considered revising upwards the maximum limits to harmonise with European FSMP regulations.

FSANZ conducted an assessment of potential risk of excessive intake for the nine micronutrients shown in Table 2 below, as well as a comparison with 2006 Australian and New Zealand upper levels of intake (UL) for adults and children. The details of this assessment can be found in SD1. FSANZ considered the potential risk of intakes above the UL in both children and adults was minimal as FSMP are used under the supervision of health professionals and the nutritional status of the patient is closely monitored. The European maximum limits were considered acceptable for safety as they were developed with the intention of providing a vitamin or mineral intake above which there are no further identified nutritional benefits; and to minimise the risk of toxicity associated with the vitamin or mineral.

6.7.3.2 Decision at final assessment and rationale

FSANZ has amended Standard 2.9.5 to use the maximum vitamin and mineral limits from the European FSMP Directive (as shown in Table 2). Maximum limits are proposed to be raised for vitamins A and D, calcium and copper and decreased for the other five micronutrients (as shown in Table 2).

Table 2: Summary of amended the changes to the maximum micronutrient composition limits for FSMP suitable for use as a sole source of nutrition

Nutrient	Maximum composition limit (per MJ) proposed in 2010	Maximum composition limit (per MJ) from European FSMP Directive	Change from 2010 to 2011
Vitamins			
Vitamin A	345 µg	430 µg retinol equivalents[1]	↑
Vitamin B_6	2.9 mg	1.2 mg	↓
Vitamin D	5.7 µg	6.5 µg or 7.5 µg[3]	↑
Minerals			
Calcium	287 mg	420 mg or 600 mg[3]	↑
Zinc	4.6 mg	3.6 mg	↓
Iodine	115 µg	84 µg	↓
Selenium	46 µg	25 µg	↓
Manganese	1.32 mg	1.2 mg	↓
Copper	1.15 mg	1.25 mg	↑

Notes to table:
*Higher value is for children aged 1- 10 years

6.7.4 Micronutrient requirements for FSMP represented as a sole source of nutrition and variations from these requirements – and related labelling requirements

6.7.4.1 Previous approach and submitter feedback

In 2004, FSANZ proposed that FSMP represented as a sole source of nutrition must comply with minimum micronutrient limits, as well as prescribed maximum limits for micronutrients where there was a potential safety risk from excessive intake. The minimum limits were based on European FSMP requirements, and the maximum limits were based on FSANZ's safety assessment. FSMPs were permitted to vary from the minimum limits for sodium, potassium and phosphorus for particular medical reasons.

Consultations in 2010 indicated that stakeholders generally supported micronutrient compositional requirements for products that were represented for use as a sole source of nutrition, but called for more flexibility to enable product development for specific different medical conditions. Therefore, the draft Standard proposed in the 2010 Consultation Paper required that FSMP represented as being suitable as a sole source of nutrition meet the same list of minima and maxima originally proposed in 2004.

The draft Standard also permitted variations from the specified minima and maxima for a specific medical purpose (including a particular medical condition, disease or disorder). If a FSMP represented as suitable for use as a sole source of nutrition deviated from a specified limit, the FSMP was required to be labelled with a declaration to that effect. The declaration would inform health professionals that the composition of the FSMP had been modified in some way. As a result of these new provisions, the previous permission to vary the minimum limits for specific micronutrients (i.e. sodium, potassium, phosphorus) was deleted from the draft Standard.

Submitters on the 2010 Consultation Paper sought further clarification on how such a variation should be expressed on the label. Submitters also requested that labelling requirements be kept to a minimum especially where product information was available via manufacturer websites and documentation, and argued that labelling was not the primary mechanism for providing information to health professionals.

Further consultation in 2011 raised some additional issues. Submitters noted that current labelling on FSMP did not always include a description of the way in which the specified nutrients had been modified e.g. whether increased or decreased, although this information was normally provided in supporting product information. Including such a description on a label would require re-labelling which may not be financially justified for small volume products, and so may impact on the supply of these products.

Submitters also queried whether a product would be considered 'nutritionally complete' if a micronutrient had been eliminated from the composition to meet the needs of a particular medical condition.

FSANZ clarified that an FSMP could be a sole source of nutrition if it met the entire dietary needs of an individual in the context of his/her medical requirements e.g. a certain amino acid could be eliminated, but the product otherwise contained sufficient quantities of all other nutrients. Therefore for clarity, the term 'suitable for use as a sole source of nutrition' is used in Standard 2.9.5 and also throughout this Report.

6.7.4.2 Decision at Final Assessment

Standard 2.9.5 allows for manufacturers to vary the micronutrient composition of these FSMP from the specified limits for a specific medical purpose (including a particular medical condition, disease or disorder). However, if an FSMP represented as suitable for use as a sole source of nutrition is modified to vary from the prescribed compositional limits for micronutrients, its label must bear a statement indicating:

- the nutrient or nutrients that have been modified; and
- whether each modified nutrient has been increased, decreased or eliminated from the food (unless this information is provided in other supporting documentation).

In response to submitters' comments, this mandatory labelling requirement is less prescriptive than that proposed in 2010. Although a statement is required on the label indicating which nutrient(s) have been modified, the details of the modification(s) can be provided either on the label or in supporting documentation. Quantitative information on the variation is not required. Relative terms such as 'lower', 'reduced', 'higher', 'increased' can be used to describe the variation from the prescribed requirements. Also, there is no requirement to indicate the reference composition of the nutrient(s) from which the product composition was varied.

Qualitative information on the nutrient(s) variations from the prescribed requirements will therefore be available to health professionals either on the label or in supporting documentation. This approach appears to reflect the European FSMP labelling and current industry practice.

6.7.5 FOLFAPs – and related labelling requirements

6.7.5.1 Previous approach and submitter comments

In 2010, submitters expressed concern about the potential adverse health effects of the presence of FOLFAPs in FSMP. They noted that dietitians in Australia and New Zealand were advising consumers on a regular basis to limit their intake of FOLFAPs to manage food intolerance symptoms. Some submitters considered that consumers who use FSMP as a sole source of nutrition may be exposed to concentrated amounts of FOLFAPs, given particular FSMPs were 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).

Dietitians also noted that they experience difficulty identifying products containing FOLFAPs and requested that FOLFAP ingredients be more clearly stated on FSMP labels. However, some noted that the provision of information on FOLFAPs could be available either online or at the place of purchase, rather than on packaging.

In the 2010 Consultation Paper, the risk assessment noted the potential health risk from the presence of FOLFAPs in FSMP, although the magnitude of this risk was uncertain. FSANZ also noted that some existing generic labelling requirements in the Code would apply to FSMP which would require the presence of FOLFAP ingredients to be declared on the label. Standard 1.2.4 – Labelling of Ingredients, requires every ingredient added to a food to be listed on its label. It further 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. Thus FOLFAPs, when added to FSMP, would appear in the ingredient list. The EU and USA

have similar ingredient labelling requirements.

In addition, the Code contains provisions specifically for inulin-derived substances regulated under:

- 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

However, FSANZ noted that the term 'inulin-derived substance' does not encompass all of the fructose-based oligosaccharides included under the term FOLFAPs.

FSANZ did not propose any amendments to the revised draft Standard 2.9.5 in relation to FOLFAP ingredients in the December 2010 Consultation Paper.

In response to submitter comments, FSANZ proposed in 2011 to require FSMP to be labelled with an advisory statement to the effect that excess consumption of the food may have a laxative effect where an FSMP contains certain polyols or polydextrose above specified limits, (based on subclause 5(1) of Standard 1.2.3). This provision would provide further information for consumers and health professionals. The EU has similar requirements for such a statement.

Also, to further characterise the potential risk in this emerging area and to determine whether there was a need for additional regulatory response, FSANZ conducted a further assessment in 2011. This assessment concluded that the risk of adverse effects from FOLFAPs in FSMP is no greater than from the risk of adverse gastrointestinal symptoms from FOLFAPs present in the general food supply.

6.7.5.2 Decision at Final Assessment

FSANZ's assessment considered the normal physiological effects of dietary FOLFAPs and their potential adverse effects in healthy individuals, individuals with gastrointestinal disorders and, where possible, in consumers of FSMP. The assessment concluded that the available evidence demonstrates that FOLFAP consumption can induce adverse gastrointestinal effects including abdominal discomfort, bloating, cramps, flatulence, stomach rumbling, and diarrhoea. The evidence for these effects is well demonstrated in functional bowel disorders particularly irritable bowel syndrome (which is thought to incorporate small intestine bacterial overgrowth syndrome). Given the individual differences in carbohydrate digestion and tolerance to FOLFAPs, it is not possible to quantify a relationship between the FOLFAPs and adverse gastrointestinal symptoms.

The evidence for a role of FOLFAPs in adverse gastrointestinal effects in inflammatory bowel disease is limited. The use of FSMP in this patient group varies depending on the phase of disease (i.e. active or remission), with FSMP occasionally being used as a sole source of nutrition in active phases of the disease.

There is limited evidence demonstrating adverse gastrointestinal effects or adverse health effect from consumption of FOLFAPs in FSMP when used as partial dietary replacement. Evidence of the effects of FOLFAPS in enteral formula is mainly based on addition of fibres which incorporate FOLFAPs. Results from these are mixed, thus it is difficult to confirm the effects of FOLFAPs alone.

Therefore, other than the generic ingredient labelling requirements and the advisory statement outlined above (see Section 7.7.5.1), FSANZ has not made any further amendments to Standard 2.9.5 in relation to FOLFAP ingredients.

6.8 Additives and processing aids

6.8.1 Previous approach and submitter feedback

At Preliminary Final Assessment, FSANZ proposed to permit the use of food additives in FSMP by adding a specific entry for FSMP in Schedule 1 of Standard 1.3.1. This would enable the addition of food additives listed under Schedules 2, 3 and 4 of Standard 1.3.1 to FSMP. FSANZ's food technology assessment concluded that the food additives listed in Schedules 2, 3 and 4 were technologically justified and safe and suitable for use in FSMPs.

During 2010, the FSMP industry requested specific permission for additional food additives.

All of these are currently permitted for use in a range of other foods in Schedule 1 of Standard 1.3.1 or permitted as processing aids in Standard 1.3.3. FSANZ assessed the safety and suitability of these additional additives and in the December 2010 Consultation Paper, 11 additional food additive permissions for FSMP were recommended for inclusion in Schedule 1 of Standard 1.3.1. Maximum levels for the additional food additives were also established based on the risk assessment and the relevant international regulations to ensure harmonisation where possible.

Recognising that the use of colours in foods has come under increasing scrutiny in recent years and that food regulators and the food industry have investigated the merits of using alternative sources of colours to add to foods, FSANZ also proposed that Schedule 4 colours not be permitted in FSMP.

FSANZ proposed to apply clause 7 of Standard 1.3.1 – Carry-over of additives to FSMP. This provision permitted the addition of foods and ingredients to FSMPs that contain food additives.

FSANZ also proposed to apply the permissions for processing aids in Standard 1.3.3 to FSMP.

In submissions to the December 2010 Consultation Paper and in subsequent consultation, the FSMP industry indicated that additional permissions were required for colour additives as listed in Schedule 4 of Standard 1.3.1, the colours amaranth and annatto, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), phosphoric acid, sodium hydroxide and potassium hydroxide.

One submitter also noted that some of these substances were permitted as additives in EU and USA, but were not permitted in the Code as additives.

6.8.2 Decision at Final Assessment

The additive and processing aid permissions proposed in 2004 have been retained. In addition, FSANZ assessed requests from stakeholders for the addition of other foods additives to FSMP.

FSANZ noted that FSMP products have a history of consumption in Australia and New Zealand and that all the food additives requested by stakeholders have undergone previous safety assessments by FSANZ and international agencies with regard to their use in foods.

FSANZ also assessed the technological justification for the use of the requested food additives in FSMP.

On the basis of the food technology assessment, FSANZ has added 16 food additive permissions to Schedule 1 of Standard 1.3.1, in addition to the additives listed in Schedules 2, 3 and 4. FSANZ concluded these additives were safe for use in FSMP and that their use was technologically justified in FSMP.

A list of permitted food additives and their maximum levels of use are provided in Appendix 3 of the risk assessment (SD2).

6.9 Labelling

6.9.1 Previous approach and submitter feedback

In the Preliminary Final Assessment Report and in subsequent consultations in 2010 and 2011, FSANZ proposed that the generic labelling requirements in Part 1.2 – Labelling and Other Information Requirements of the Code would not all be applied to FSMP. Instead, certain generic labelling requirements (e.g. ingredient labelling and date marking) were selectively applied to FSMP. Some additional labelling requirements specific to FSMP (e.g. a statement to the effect that the food must be used under medical supervision) were also proposed. In addition, at consultations in 2011, FSANZ proposed not to apply other generic standards which contain certain labelling requirements, such as Standard 1.1A.2 – Transitional Standard on Health Claims and Standard 1.3.2 – Vitamins and Minerals.

A number of comments from stakeholders were received to the Preliminary Final Assessment and to the subsequent consultations in 2010 and 2011 on the proposed labelling requirements for FSMP.

Particular issues included:

- Allergen declarations (Section 3 of SD3)
- Gluten ‘free’ claims (Section 10 of SD3)
- Labelling of inner packages (Section 12 of SD3)
- Prescribed name (Section 6.3 of this Report)

FSANZ therefore reviewed all of the labelling requirements for FSMP since the Preliminary Final Assessment, considering relevant stakeholder comments. The labelling assessment is available at SD3. However, FSANZ’s review of some labelling requirements for FSMP which relate to composition issues are provided elsewhere in this Report, i.e. the variation from prescribed micronutrients and the labelling of FOLFAP ingredients (see Sections 6.7.4 and 6.7.5 respectively).

6.9.2 Decision at Final Assessment

The Standard applies certain generic labelling requirements currently contained in Part 1.2 of the Code to FSMP (e.g. allergen declarations, date marking etc.). These are included to protect the health and safety of users of FSMP and to provide health professionals and consumers with adequate information to make informed choices. Some additional labelling statements specific to FSMP also apply (e.g. statements about medical supervision, sole source of nutrition, intended age group etc.). These statements also provide useful information to health professionals and consumers and help to protect against inappropriate use.

As nearly all FSMP in Australia and New Zealand is imported, the labelling requirements that FSANZ has applied are, where possible, consistent with international requirements and/or with current industry practices. FSANZ has particularly sought to harmonise with EU requirements as the majority of FSMPs are imported from Europe. FSANZ also considered USA requirements as the USA is another source of imported FSMP, along with Codex requirements, where applicable.

As these are specialised foods essential for the dietary management of certain individuals, FSANZ has sought to find a balance between effectively informing FSMP consumers and health professionals, and minimising potential barriers to trade (e.g. re-labelling costs) that could potentially reduce the supply of some FSMP to Australia and New Zealand. The approach to only apply certain provisions from Part 1.2, was considered necessary to provide the appropriate balance.

The application of labelling requirements to FSMP, including specific mandatory statements, is in accordance with the Policy Guideline on the Intent of Part 2.9 (see Section 1.4), in particular, the following principle:

- *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.*

For instance, the requirement to label FSMP with directions for use and storage provides information for the safe use of FSMP.

Also, specific mandatory statements (e.g. statements on medical supervision, medical purpose, and intended age group) assist consumers and health professionals to understand the specific nature, intended population group, and intended special purpose of the food.

SD3 contains lists summarising the labelling provisions, including certain generic labelling requirements which will apply to FSMP in Standard 2.9.5, and the generic labelling provisions within the Code which will not apply to FSMP. Labelling requirements for inner packages of FSMP and transportation outers are also listed.

7. Impact Analysis (ID 2544)

The Office of Best Practice Regulation (OBPR) decided that, given the small size and specialised nature of the market for these products, and the limited regulatory impact of the proposal, a regulation impact statement was not required. This advice was originally provided by OBPR's predecessor, the Office of Regulatory Review, on 16 June 2004. It was also confirmed by the OBPR on 5 November 2010.

The parties affected by this Proposal are:

- consumers with medical conditions including vulnerable groups such as the chronically ill and those with particular medical conditions who rely on FSMP as their sole source of nutrition
- consumers in general (i.e. unintended users)
- global manufacturers of FSMP

- Australian and New Zealand industry including importers of FSMP, retail outlets such as pharmacies, wholesale suppliers and distributors of FSMP, and a very small number of local FSMP manufacturers
- the Governments of New Zealand and Australia, including the states and territories, in particular enforcement agencies and government provided health services.

Approval of the Standard is unlikely to impact on consumers who use FSMP, as requirements for mandatory advisory labelling and restrictions on the sale and distribution of FSMP reflect the current system and are not expected to affect access to, or costs of, FSMP. Similarly, suppliers of FSMP such as pharmacies, wholesalers and distributors will not be disadvantaged.

In addition, the labelling requirements and restriction on sale of FSMP will act as a disincentive for the inappropriate positioning of products as FSMP to take advantage of fewer compositional controls.

There may be some costs to industry associated with some of the labelling requirements. However, this is likely to affect only a limited proportion of products given the flexible approach being applied to the composition and labelling requirements, which in general harmonise with EU requirements, US requirements or current industry practice where possible. Harmonisation also means that trade is not jeopardised for industry.

The new Standard will enable ongoing supply and distribution of FSMP and will meet the health and safety needs of consumers, particularly those who rely on these products for their sole source of nutrition.

With clear regulation, manufacturers will be able to continue to import and produce FSMP for the Australia New Zealand market. Health professionals will have sufficient information available by way of labels and supporting product information to make informed decisions about the best nutritional care of their patients. Also, a separate Standard specifically for FSMP will provide regulatory clarity for the state and territory enforcement agencies, DAFF Biosecurity and MAF New Zealand Biosecurity.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

FSANZ intends to develop relevant information to assist health professionals and the consumers of FSMP. This information is expected to include a fact sheet and general information on the FSANZ website and targeted communication with industry, government agencies, health professionals and affected consumers. FSANZ has also consulted with health professional representative organisations (e.g. pharmacists and dietitians) to develop professional guides and reference material on Standard 2.9.5.

Stakeholders and other interested parties who have provided comment on the Proposal through the course of this project will be notified of FSANZ's decision when the Forum has been notified of the decision and the Final Assessment Report is released.

9. Consultation

9.1 Public consultation

FSANZ undertook several rounds of public consultation to ensure ongoing input from key stakeholders and interested parties:

- an Initial Assessment Report in 2001
- a Draft Assessment Report, including a draft Standard, in 2002
- a Preliminary Final Assessment Report, including a draft Standard, in 2004
- a Consultation Paper in December 2010, including a draft Standard, when the project recommenced.

A summary of submissions received is at Attachment 3 and the issues raised are addressed in Section 6 above.

9.2 Targeted stakeholder consultation

Given the elapsed time since the Preliminary Final Assessment in 2004, FSANZ held targeted consultations in April-May 2010 to re-engage with key stakeholders. Teleconference meetings were held with industry representatives, health professionals and jurisdictions in both Australia and New Zealand. Their purpose was to gather up-to-date information on the FSMP market and products currently available. It also enabled stakeholders to indicate whether issues raised in 2004 were still relevant and to identify any new issues (see Attachment 3 for a list of key issues raised). Stakeholders provided additional comments by email or phone following these targeted meetings.

In addition, individual telephone discussions were held with key medical and nutritional experts specifically in relation to VLED products. These discussions informed FSANZ's decision to exclude VLEDs from the scope of Proposal P242 (see Section 2.1).

Stakeholders indicated general support for the regulatory approach proposed in 2004, but there was a range of views expressed on some aspects of the Standard.

9.3 Recent consultation

Discussions with stakeholders continued in mid- and late 2011 in response to the issues raised in 2010.

A consultation paper outlining the outstanding issues, FSANZ's proposed approach to issues raised previously, and a revised draft Standard 2.9.5 was provided in November 2011. In addition to meetings with manufacturers and distributors of FSMP, and health professionals, further information or clarity was provided via written comments, emails and telephone discussions (see Attachment 3).

In addition, consultation was undertaken with the New Zealand Pharmaceutical Society and several pharmacies in Australia and New Zealand to better understand the roles, responsibilities and training of pharmacist assistants. The development of professional guides and reference material on Standard 2.9.5 for pharmacists was also discussed. FSANZ also met with PHARMAC in New Zealand to discuss FSANZ's proposed approach to regulating FSMP.

Outcomes of this targeted consultation are reflected in Section 6 of this Report and have assisted FSANZ's final drafting of Standard 2.9.5.

10. 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 lodged a submission and this was addressed in the Preliminary Final Assessment Report (August 2004) and in the December 2010 Consultation Paper, with subsequent changes made to Standard 2.9.5.

CONCLUSION

11. Decision

Decision

To approve Standard 2.9.5 – Food for Special Medical Purposes, as amended after submissions were received.

To approve consequential variations to Standards 1.1.1, 1.1A.6, 1.2.1, 1.3.1 and 1.3.4, as amended after submissions were received.

11.1 Reasons for decision

FSANZ has approved Standard 2.9.5 which incorporates specific compositional and labelling requirements, including the mandatory labelling statement 'use under medical supervision'. These requirements are generally consistent with overseas regulations or current industry practice.

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

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

- The regulation of FSMP protects the health and safety of these consumers, particularly those who rely on FSMP as a sole source of nutrition.

- The setting of minimum and maximum requirements for vitamins and minerals in FSMP that are represented as being suitable for use as the sole source of nutrition ensures consumers nutritional needs are met and protects their health and safety. In addition, the permission to vary the nutrient composition for a specific medical condition ensures products can be manufactured to meet the particular needs of certain consumers of FSMP.

- Restricting the access to FSMP along with the requirement to label to the effect that the food must be used under medical supervision protects the health and safety of users of FSMP by promoting their access to medical or health professional advice on the use of these products.

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

During the development of the Standard several overarching issues were considered:

- **Harmonisation with overseas regulations**: nearly all FSMPs are imported from the EU or the USA; the majority come from EU. In order to limit impost on manufacturers and therefore ensure continued supply of these products to Australia and New Zealand, the compositional and labelling requirements in Standard 2.9.5 align primarily with EU, and the USA or current industry practice where possible. However, not all labelling requirements could easily be aligned, particularly the labelling requirements pertaining to gluten 'free' claims. This could require some re-labelling of certain imported products.

- **Composition**: the compositional requirements of FSMPs have been aligned with EU minimum and maximum levels for vitamins and minerals. Health professionals and manufacturers requested that formulation be allowed to vary from these requirements to meet the needs of certain medical conditions. Standard 2.9.5 therefore permits such variation but with an additional labelling requirement that indicates which nutrient levels have been varied. Details of the modification are required either on the label or in supporting product information. Also, permission for certain additives was requested by stakeholders. These additives have been assessed and permissions added.

- **Restriction on sale**: as compositional requirements have been made as flexible as possible, Standard 2.9.5 imposes a restriction on where and from whom FSMP can be sold. The restriction is designed to manage the potential risk of inappropriate use of these specialised products. Most stakeholders generally supported such a restriction. Distributers also play an important role in the sale of FSMP to consumers and are an important part of the supply chain. However, some stakeholders had concerns about how the Standard could both permit distributers to sell FSMP directly to consumers, as well as protect consumer health and safety.

  As no evidence has been identified that there is a problem with the current distribution system, Standard 2.9.5 permits distributers to continue to sell FSMP to consumers, but only under certain specified conditions.

- **Definition and prescribed name for FSMP**: a range of views on how best to define FSMP for regulatory and enforcement purposes was expressed by stakeholders. Some recommended a prescribed name to assist enforcement agencies to easily identify the products in the market place. A prescribed name is required in the EU but not in the USA where a range of terms are used on product labels. Although some jurisdictions are supportive of a prescribed name, FSANZ is not aware of specific problems associated with the absence of a prescribed name, as is the current situation. Therefore, to avoid additional impost on industry and the risk of the supply of certain products ceasing, Standard 2.9.5 does not require a prescribed name. Rather, the Standard provides a broad definition based on the purpose of these products, that they are intended to be used under medical supervision, and how they are represented. In addition, several mandatory labelling requirements, e.g. the 'medical supervision' statement, the true nature of the food, and the medical purpose, will also assist identification.

12. Implementation

Standard 2.9.5 will come into effect two years after gazettal. The two-year period is a transition period to allow manufacturers and importers of FSMP sufficient time to comply with the new Standard for FSMP.

Transitional Standard 1.1A.6 (applies only to New Zealand) will cease to have effect on the date of commencement of Standard 2.9.5, other than in relation to food formulated and represented as being for the dietary management of obesity i.e. it will continue to apply to foods formulated and represented for the dietary management of obesity in New Zealand. This will maintain the status quo for regulating VLED products manufactured in or imported into New Zealand (see clause 2 (3) of the schedule to the consequential variation to the Code in Attachment 1).

In conjunction with other agencies, FSANZ will keep under review the implementation of Standard 2.9.5 to identify any issues that may emerge, or further requirements that may be needed to ensure the safe and ongoing supply of FSMP to consumers.

13. References

Food and Agriculture Organization and World Health Organization (FAO/WHO) (2001) Human Vitamin and Mineral Requirements. Report of a joint FAO/WHO expert consultation Bangkok, Thailand, Geneva.

National Health and Medical Research Council (NHMRC) and the New Zealand Ministry of Health (MoH) (2006) Nutrient Reference Values for Australia and New Zealand. Commonwealth of Australia.

Scientific Committee on Food (2003) Opinions of the Scientific Committee on Food on tolerable upper intake levels of vitamins and minerals. http://europa.eu.int/comm/food/fs/sc/scf/out80_en.html

Gibson PR, Shepherd SJ (2010) Evidence-based dietary management of functional gastrointestinal symptoms: The FODMAP approach. Journal of Gastroenterology and Hepatology 25:252–258.

United States Institute of Medicine (2000a) Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline. National Academy Press, Washington DC.

United States Institute of Medicine (2000b) Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium and Carotenoids. National Academy Press, Washington DC.

United States Institute of Medicine (2000c) Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D and Fluoride. National Academy Press, Washington DC

United States Institute of Medicine (2001a) Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, Zinc. National Academy Press, Washington DC.

United States Institute of Medicine (2001b) Dietary Reference Intakes for energy, carbohydrate, fibre, fat, fatty acids, cholesterol, protein and amino acids. National Academy Press, Washington DC.

United States Institute of Medicine (2004) Dietary Reference Intakes: Water, Potassium, Sodium, Chloride, and Sulfate. National Academy Press, Washington DC.

Attachments

1. Variations to the *Australia New Zealand Food Standards Code*
2. Explanatory Statement – Standard 2.9.5
3. Summary of Submissions

Attachment 1 – Variations to the *Australia New Zealand Food Standards Code*

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

Standard 2.9.5 – Food for Special Medical Purposes

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences **two years from the date of gazettal** of the Standard**.**

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

STANDARD 2.9.5

FOOD FOR SPECIAL MEDICAL PURPOSES

Purpose

This Standard regulates the sale, composition and labelling of foods specially formulated for the dietary management of individuals with certain diseases, disorders or medical conditions. Food regulated by this Standard is intended to be used under medical supervision.

Because of the specialised nature and purpose of these foods, this Standard includes a restriction on the premises at which, and the persons by whom, food for special medical purposes may be sold to consumers.

Infant formula products as defined in Standard 2.9.1 of the Code and products formulated and represented as being for the dietary management of obesity or overweight are excluded from Standard 2.9.5, even though they might meet the requirements of this Standard.

Editorial note:

In accordance with usual practice, this Standard must be read in the context of the whole Code. This Standard both incorporates and exempts existing Standards in the Code, and also applies additional requirements specifically for food for special medical purposes. Where existing requirements have been incorporated, these are replicated in the Standard rather than cross referenced to the original Standard, for accuracy and ease of use.

Table of Provisions

Clauses

Division 1 – Preliminary

1 Definition of food for special medical purposes

(1) Subject to subclause (2), a food is a food for special medical purposes if the food is –

(a) specially formulated for the dietary management of individuals –

(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and
(ii) whose dietary management cannot be completely achieved without the use of the food; and

(b) intended to be used under medical supervision; and
(c) represented as being a food for special medical purposes or for the dietary management of a disease, disorder or medical condition.

(2) A food is not a food for special medical purposes if the food is –

(a) formulated and represented as being for the dietary management of obesity or overweight; or
(b) an infant formula product as defined in Standard 2.9.1.

Example:

An infant formula product specifically formulated to satisfy metabolic conditions (refer Subdivision 2 of Division 3 of Standard 2.9.1) is excluded from the definition of a food for special medical purposes, even if the infant formula product satisfies the requirements of paragraphs (1)(a),(b) and (c), and will not be regulated by Standard 2.9.5.

2 Other definitions

(1) In this Standard –

inner package, in relation to a food for special medical purposes, means an individual package of the food that –

(a) is contained and sold within another package that is labelled in accordance with Subdivision 2 of Division 4; and
(b) is not designed for individual sale, other than a sale by a responsible institution to a patient or resident of the responsible institution.

Example:

An example of an inner package is an individual sachet (or sachets) of a powdered food contained within a box that is fully labelled, being a box available for retail sale.

responsible institution means a hospital, hospice, aged care facility, disability facility, prison, boarding school or similar institution that is responsible for the welfare of its patients or residents and provides food to them.

(2) In this Standard, a reference to a **package** does not include a plate, cup, tray or other food container in or on which food for special medical purposes is served by a responsible institution to a patient or resident of the responsible institution, whether the plate, cup, tray or food container is uncovered, or is covered in whole or in part.

3 Application of other Standards

(1) The following do not apply to a food for special medical purposes –

(a) clause 9 of Standard 1.1.1;
(b) Standards 1.1A.2, 1.3.2 and 1.5.1;
(c) Standards 2.9.2, 2.9.3 and 2.9.4;
(d) Part 1.2 of this Code, subject to subparagraph 9(e) (iv), paragraph 12(a), clauses 13 and 16, and sub clauses 17(3), (4) and (5).

(2) Subclauses 6(3) and (4) of Standard 1.5.3 apply to a food for special medical purposes as if such food were subject to Standard 1.2.1.

4 Claims must not be therapeutic in nature

A claim in relation to a food for special medical purposes must not –

(a) refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or
(b) compare the food with a good that is –

(i) represented in any way to be for therapeutic use; or
(ii) likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason.

Division 2 – Sale of food for special medical purposes

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

(1) A food for special medical purposes must not be sold to a consumer, other than from or by –

(a) a medical practitioner or dietitian; or
(b) a medical practice, pharmacy or responsible institution; or
(c) a majority seller of that food for special medical purposes.

(2) In this clause, **medical practitioner** means a person registered or licensed as a medical practitioner under legislation in Australia or New Zealand, as the case requires, for the registration or licensing of medical practitioners.

(3) In this clause, a person is a **majority seller** of a food for special medical purposes during any [24] month period if –

(a) during the period, the person sold that food for special medical purposes to medical practitioners, dietitians, medical practices, pharmacies or responsible institutions; and
(b) the sales mentioned in paragraph (a) represent more than one half of the total quantity of that food for special medical purposes sold by the person during the period.

Division 3 – Composition

6 Permitted forms of particular substances

(1) All or any of the following substances may be added to a food for special medical purposes –

(a) a substance that is listed in Column 1 of Schedule 1 of this Standard if the substance is in one or more of the corresponding forms listed in Column 2 of that Schedule;
(b) a substance that is listed in Column 1 of Schedule 1 of Standard 2.9.1 if the substance is in one or more of the corresponding forms listed in Column 2 of that Schedule;
(c) any other substance regardless of its form, subject to the requirements of any Standard that applies to the substance or the food for special medical purposes.

(2) A provision in another Standard that limits the amount of a substance mentioned in paragraph (1)(a) or (b) that may be added to a food does not apply to a food for special medical purposes.

7 Compositional requirements for food represented as being suitable for use as a sole source of nutrition

(1) If a food for special medical purposes is represented as being suitable for use as a sole source of nutrition, the food must contain –

(a) not less than the minimum amount, as prescribed in Column 2 of Schedule 2, of each vitamin, mineral and electrolyte contained in Column 1 of that Schedule; and
(b) if applicable, not more than the maximum amount, as prescribed in Column 3 of Schedule 2, of each vitamin and mineral contained in Column 1 of that Schedule.

(2) However, the food is not required to comply with subclause (1) to the extent that –

(a) a variation from a maximum or minimum amount is required for a particular medical purpose; and
(b) the food is labelled in accordance with subclause 10(2).

Division 4 – Labelling
Subdivision 1 – Outline of requirements

8 Labelling and related requirements

(1) There must be a label on a package of food for special medical purposes.

(2) Subject to sub clauses (3) and (4), the label must comply with the requirements of Subdivision 2.

(3) The requirements of Subdivision 3 apply instead of Subdivision 2 if the package is an inner package.

(4) The requirements of Subdivision 4 apply instead of Subdivision 2 to transportation outer.

(5) To avoid doubt, this Division does not apply to a food for special medical purposes that is not in a package.

Subdivision 2 – General labelling requirements

9 Mandatory information

The label on a package of food for special medical purposes must include the following information –

(a) a name or a description of the food sufficient to indicate the true nature of the food;
(b) the lot identification of the food;
(c) directions for the use of the food or the storage of the food, or both, if the food is of such a nature to require directions for health or safety reasons;
(d) the minimum or average energy content expressed per given quantity of the food;
(e) the average quantity or minimum quantity, expressed per given quantity of the food, of –

(i) protein, fat and carbohydrate; and
(ii) any vitamin, mineral or electrolyte present in the food, if the vitamin, mineral or electrolyte has been added to the food; and
(iii) any substance present in the food, if that substance is listed under Column 1 of Schedule 1 and has been added to the food; and
(iv) subject to sub clauses 14(4) and 15(5) of this Standard, any other substance if a nutrition claim as defined in Standard 1.2.8 is made in relation to that substance.

10 Mandatory statements

(1) The label on a package of food for special medical purposes must include the following statements –

(a) a statement to the effect that the food must be used under medical supervision;
(b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food;
(c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated;
(d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose indicated in paragraph (c);
(e) if the food has been formulated for a specific age group—a statement to the effect that the food is intended for persons within the specified age group;
(f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition;
(g) the statements required by subclause (2) if the food is represented as being suitable for use as a sole source of nutrition;
(h) the advisory statements required by subclause (3);
(i) the warning statement required by subclause (4).

(2) For paragraph (1)(g), the required statements are –

(a) a statement to the effect that the food is not for parenteral use; and
(b) if the food has been modified to vary from the compositional requirements in Schedule 2 such that the content of one or more nutrients falls short of the prescribed minimum, or exceeds the prescribed maximum (if applicable), a statement indicating –

(i) the nutrient or nutrients which have been modified; and
(ii) whether each modified nutrient has been increased, decreased, or eliminated from the food.

(3) For paragraph (1)(h), the required advisory statements are –

(a) if the food contains bee pollen as an ingredient as defined in Standard 1.2.4—a statement to the effect that the food contains bee pollen which can cause severe allergic reactions; and
(b) if the food contains aspartame or aspartame-acesulphame salt—a statement to the effect that the food contains phenylalanine; and
(c) if the food contains guarana or extracts of guarana—a statement to the effect that the food contains caffeine; and

(d) if the food contains propolis as an ingredient as defined in Standard 1.2.4—a statement to the effect that the food contains propolis which can cause severe allergic reactions; and

(e) a statement to the effect that excess consumption of the food may have a laxative effect if the food contains –

(i) one or more of the substances listed in Table 1 to this paragraph, either singularly or in combination, at a level of or in excess of 10 g/100 g; or

(ii) one or more of the substances listed in Table 2 to this paragraph, either singularly or in combination, at a level of or in excess of 25 g/100 g; or

(iii) one or more of the substances listed in Table 1, in combination with one or more of the substances listed in Table 2, at a level of or in excess of 10 g/100 g.

Table 1 to paragraph

Substance
Lactitol
Maltitol
Maltitol syrup
Mannitol
Xylitol

Table 2 to paragraph

Substance
Erythritol
Isomalt
Polydextrose
Sorbitol

(4) If a food for special medical purposes contains royal jelly as an ingredient as defined in Standard 1.2.4, the following warning statement is required –

"This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases, fatalities, especially in asthma and allergy sufferers".

Editorial note:

The requirements of sub clauses 10(3) and (4) are based on relevant aspects of clauses 2, 3 and 5 of Standard 1.2.3.

(5) Despite paragraph (1)(g), the information mentioned in subparagraph (2)(b)(ii) is not required to be on the label if the information is provided in other documentation about the food for special medical purposes.

11 Mandatory declaration

(1) A declaration of the presence in a food for special medical purposes of any of the substances listed in the Table to this clause is required if the substance is present as –

(a) an ingredient; or

(b) an ingredient of a compound ingredient; or

(c) a food additive or component of a food additive; or

(d) a processing aid or component of a processing aid.

Table to subclause 11(1)

Added Sulphites in concentrations of 10 mg/kg or more
Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains
Crustacea and their products
Egg and egg products
Fish and fish products
Milk and milk products
Peanuts and peanut products
Sesame seeds and sesame seed products
Soybeans and soybean products
Tree nuts and tree nut products other than coconut from the fruit of the palm Cocos nucifera

(2) If a declaration in relation to a food for special medical purposes is required under subclause (1), the declaration must be included on the label on any package of the food.

Editorial note:

The requirement of clause 11 is based on clause 4 of Standard 1.2.3.

12 Labelling of ingredients

The label on a package of food for special medical purposes must comply with one of the following –

(a) Standard 1.2.4 of this Code;
(b) Article 6, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs;
(c) 21 CFR § 101.4.

13 Date marking of food

(1) A food for special medical purposes must comply with Standard 1.2.5.

(2) However, if a label on a package of food for special medical purposes is required to include a use-by date under Standard 1.2.5, the words 'Expiry Date', or words to similar effect, may be used instead of the words 'Use By', and Standard 1.2.5 applies to the food for special medical purposes as if any reference to a use-by date in that Standard were a reference to the 'Expiry Date', or the words to similar effect so used.

14 Lactose claims in relation to food for special medical purposes

(1) A claim to the effect that a food for special medical purposes is lactose free may be made if the food contains no detectable lactose.

(2) A claim to the effect that a food for special medical purposes is low lactose may be made if the food contains not more than 0.3 g of lactose per 100 g of the food.

(3) A claim to the effect that a food for special medical purposes is lactose reduced must be accompanied by a declaration of the proportion by which the lactose content of the food has been reduced.

(4) If a claim is made in relation to the lactose content of a food for special medical purposes, the label on the package of food must include the average quantity of the lactose and galactose in the food, expressed per given quantity of the food.

Editorial note:

The requirement of clause 14 is based on clause 15 of Standard 1.2.8.

15 Claims in relation to gluten content of food for special medical purposes

(1) A claim in relation to the gluten content of a food for special medical purposes is prohibited unless expressly permitted by this clause.

(2) A claim to the effect that a food for special medical purposes is gluten free may be made if the food contains –

(a) no detectable gluten; and
(b) no oats or oat products; and
(c) no cereals containing gluten that have been malted, or products of such cereals.

(3) A claim to the effect that a food for special medical purposes has a low gluten content may be made if the food contains no more than 20 mg gluten per 100 g of the food.

(4) A claim to the effect that a food for special medical purposes contains gluten or is high in gluten may be made.

(5) If a claim is made in relation to the gluten content of a food for special medical purposes, the label on the package of food must include the average quantity of the gluten in the food, expressed per given quantity of the food.

Editorial note:

The requirement of clause 15 is based on clause 16 of Standard 1.2.8.

16 Legibility requirements

The label on a package of food for special medical purposes must comply with Standard 1.2.9.

Subdivision 3 – Labelling requirements for inner packages

17 Labelling requirements for inner packages

(1) There must be a label on an inner package of food for special medical purposes.

(2) The label must include –

(a) a name or a description of the food sufficient to indicate the true nature of the food; and
(b) the lot identification of the food; and
(c) a declaration of the presence in the food of any of the substances listed in the Table to this paragraph if the substance is present as –

(i) an ingredient; or
(ii) an ingredient of a compound ingredient; or
(iii) a food additive or component of a food additive; or
(iv) a processing aid or component of a processing aid.

Table to paragraph

Added Sulphites in concentrations of 10 mg/kg or more
Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains
Crustacea and their products
Egg and egg products
Fish and fish products
Milk and milk products
Peanuts and peanut products
Sesame seeds and sesame seed products
Soybeans and soybean products
Tree nuts and tree nut products other than coconut from the fruit of the palm Cocos nucifera

(3) A food for special medical purposes contained in an inner package must comply with Standard 1.2.5, other than clause 6 of that Standard.

(4) However, if a label on an inner package of food for special medical purposes is required to include a use-by date under Standard 1.2.5, the words 'Expiry Date', or words to similar effect, may be used instead of the words 'Use By', and Standard 1.2.5 applies to the food for special medical purposes as if any reference to a use-by date in that Standard were a reference to the 'Expiry Date', or the words to similar effect so used.

(5) The label on an inner package of food for special medical purposes must comply with Standard 1.2.9.

(6) To avoid doubt, this clause continues to apply to the label on an inner package of food for special medical purposes even if a responsible institution subsequently supplies the inner package to a patient or resident of the responsible institution.

Editorial note:

The requirement of paragraph 17(2)(c) is based on the requirements of clause 4 of Standard 1.2.3.

Subdivision 4 – Information requirements for transportation outers

18 Information required on transportation outers

(1) If packages of food for special medical purposes are in a transportation outer, then there must be a label on the transportation outer that includes –

(a) a name or a description of the food sufficient to indicate the true nature of the food; and
(b) the lot identification of the food; and
(c) the name and business address in Australia or New Zealand of the supplier of the food, unless that information is provided in documentation accompanying the food for special medical purposes.

(2) However, a label on a transportation outer is not required if the information mentioned in paragraphs (1)(a), (b) and (c) is clearly discernible through the transportation outer on the labels on the packages within the transportation outer.

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	
Boron	Sodium borate
	Boric acid
Calcium	Calcium bisglycinate
	Calcium citrate malate
	Calcium malate
	Calcium L-pidolate
Chloride	Choline chloride
	Sodium chloride, iodised
	Hydrochloric acid
Chromium	Chromium chloride
	Chromium picolinate
	Chromium potassium sulphate
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

SCHEDULE 1 (continued)
Permitted forms of particular substances

Column 1	Column 2
Substances	**Permitted Form**
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
	L-carnitine
Carnitine	L-carnitine hydrochloride
	L-carnitine L-tartrate
	Choline
Choline	Choline bitartrate
	Choline chloride
	Choline citrate
	Choline hydrogen tartrate
	Inositol

SCHEDULE 1 (continued)
Permitted forms of particular substances

Column 1	Column 2
Substances	**Permitted Form**
Inositol	Adenosine 5′-monophosphate
Nucleotides	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 content of vitamins, minerals and electrolytes in food for special medical purposes represented as being suitable for use as a sole source of nutrition

Column 1	Column 2	Column 3
Nutrient	**Minimum Amount per MJ**	**Maximum Amount per MJ**
Vitamins		
Vitamin A	84 µg retinol equivalents[1]	430 µg retinol equivalents[1]
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	1.2 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	6.5 µg or 7.5 µg[3]
Vitamin E	1 mg alpha-tocopherol equivalents[4]	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 or 120 mg[3]	420 mg or 600 mg[3]
Magnesium	18 mg	No maximum set
Iron	1.2 mg	No maximum set
Phosphorus	72 mg	No maximum set
Zinc	1.2 mg	3.6 mg
Manganese	0.12 mg	1.2 mg
Copper	0.15 mg	1.25 mg
Iodine	15.5 µg	84 µg
Chromium	3 µg	No maximum set
Molybdenum	7 µg	No maximum set
Selenium	6 µg	25 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.

[3] The higher amount applies only to products intended for children aged one to ten years.

Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences **two years from the date of gazettal** of the Standard**.**

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) Variation.*

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

This variation commences on **two years from the date of gazettal of Standard 2.9.5.**

SCHEDULE

[1] ***Standard 1.1.1*** *is varied by –*

[1.1] *inserting in clause 2 the following definitions in alphabetical order –*

food for special medical purposes has the meaning given by Standard 2.9.5.

small package means a package with a surface area of less than 100 cm^2.

transportation outer means a container or wrapper which –

(a) encases packaged or unpackaged foods for the purpose of transportation and distribution; and
(b) is removed before the food is used or offered for retail sale, or is not taken away by the purchaser of the food.

[1.2] *omitting paragraph (e) from the definition of* **warning statement** *in clause 2, substituting –*

(e) sub clauses 3(3) and 3(4) of Standard 2.9.4; and
(f) subclause 10(4) of Standard 2.9.5.

[1.3] *inserting in alphabetical order in the* Table to clause 8 –

MJ	Megajoule

[2] ***Standard 1.1A.6*** *is varied by omitting subclause 2(3), substituting –*

(3) This Standard ceases to have effect on the date of commencement of Standard 2.9.5, other than in relation to food formulated and represented as being for the dietary management of obesity.

[3] ***Standard 1.2.1*** *is varied by omitting from clause 1 the definitions of* **small package** *and* **transportation outer**

[4] ***Standard 1.3.1*** *is varied by –*

[4.1] *omitting from* Schedule 1, *the heading to Item 13, substituting –*

13 SPECIAL PURPOSE FOODS

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

13.5 Food 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	
338	Phosphoric acid	GMP		Permitted for use as an acidity regulator

524	Sodium hydroxide	GMP		Permitted for use as an acidity regulator
525	Potassium hydroxide	GMP		Permitted for use as an acidity regulator
950	Acesulphame potassium	450	mg/kg	
954	Saccharin	200	mg/kg	
962	Aspartame-acesulphame salt	450	mg/kg	

13.5.1 Liquid food for special medical purposes*

123	Amaranth	30	mg/kg
160b	Annatto extracts	10	mg/kg

13.5.2 Food for special medical purposes other than liquids*

123	Amaranth	300	mg/kg
160b	Annatto extracts	25	mg/kg

[5] ***Standard 1.3.4*** *is varied by adding at the end of the* Schedule –

Specification 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):	
Selenomethionine	No less than 60% and no more than 85%
Other organic selenium compounds (including selenocysteine)	No more than 10%
Levels of inorganic selenium (% total extracted selenium)	No more than 1%

Attachment 2 – Explanatory Statements

Standard 2.9.5

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the Australia New Zealand Food Standards Code (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P242 to develop a Standard for food for special medical purposes (FSMP), being food that is specifically formulated for the dietary management of individuals with particular medical conditions and which is intended to be used under medical supervision.

The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard and a draft variation. This Explanatory Statement deals with the draft Standard.

Following consideration by COAG Legislative and Governance Forum on Food Regulation (the Forum), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sun setting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

There is currently no separate standard for FSMP within the Code with the result that FSMP is subject to generic (Chapter 1) food standards. However, the specially formulated nature and specialised use of FSMP often makes it difficult for these products to comply with the generic food standards.

FSMP is formulated for the dietary management of individuals with certain diseases, disorders or medical conditions. A FSMP is necessary when the dietary management of an individual cannot be completely or easily achieved with other dietary modification, including the use of other special purpose foods.

The purpose of Standard 2.9.5 is to protect the health and safety of FSMP consumers. This is achieved through three types of requirements as follows. Firstly, the Standard requires that FSMP which is represented as being suitable for use as an individual's as a sole source of nutrition contains certain vitamins, minerals and electrolytes in amounts necessary for human health.

The Standard allows for these amounts to be varied for particular medical conditions.

Secondly, the Standard contains a number of labelling requirements which are intended to ensure that health professionals are provided with enough information about a FSMP product to make appropriate decisions regarding its use by a consumer.

Finally, the Standard restricts the premises at which, and the persons by whom, FSMP may be sold directly to consumers. This restriction on the sale of FSMP is intended to promote consumers' access to medical or health professional advice about the appropriate use of the FSMP they are purchasing. It is also intended to prevent the sale of FSMP to unintended users, and to maintain the supply chain of FSMP to consumers.

Since almost all FSMP is imported from overseas, Standard 2.9.5 is, where possible, consistent with relevant international regulations to minimise any barriers to the supply of these products to Australia and New Zealand.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

The Authority's consideration of Proposal P242 has included four rounds of public consultation following assessments, the preparation of a draft Standard, a draft variation and associated reports. Public submissions were called for in 2001, 2002, 2004 and 2010. In addition, targeted consultation was undertaken in 2010 and 2011 after the project re-commenced with key stakeholder groups i.e. manufacturers, health professionals, jurisdictions and other interested parties.

The Office of Best Practice Regulation was also consulted and advised FSANZ that a Regulation Impact Statement was not required because the proposed Standard 2.9.5 was likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variations

Clause 1 defines a FSMP by reference to what it is formulated for, its intended use, and how the food is represented. This definition enables FSMP to be identified in the market place and distinguished from other foods. Subclause 1(2) clarifies that a food is not a FSMP if it is formulated and represented as being for the dietary management of obesity or overweight. The intention of this subclause is to ensure that Standard 2.9.5 does not apply to very low energy diet products. A food is also not a FSMP if the food is an infant formula product.

Clause 2 defines and clarifies other terms used in this Standard, including the definitions of inner package and responsible institution. It also clarifies the meaning of package where it appears in Standard 2.9.5.

Clause 3 provides for the application and exclusion of certain other Standards and provisions in the Code to FSMP, for example only some Standards in Part 1.2 of the Code apply to FSMP.

Clause 4 provides that a therapeutic claim must not be made about a FSMP.

Clause 5 prohibits the sale of FSMP to a consumer, unless the sale is from or by one of the persons or premises listed in the subclause (1). FSMP may be sold by medical practitioners and dietitians, and from medical practices, pharmacies and responsible institutions. An FSMP may also be sold to a consumer by a person who supplies that particular FSMP to any of the above listed persons or premises, provided that person sells more than half of that particular FSMP to those persons or premises during a 24-month period. The purpose of this provision is to ensure that bone fide distributors of FSMP, who are aware of the medical nature of these foods, are permitted to sell directly to consumers as is the current practice. The provision is intended to balance the need for consumers to be provided with adequate access to medical or health professional advice about the appropriate use of FSMP, with the need to ensure the supply chain remains open and that consumers are able to access FSMP through a distributor when appropriate.

Clause 6 contains a permission to add any substance listed in either Schedule 1 of Standard 2.9.5 or Schedule 1 of the infant formula Standard (Standard 2.9.1) to an FSMP, provided the substance is in the particular form specified in the relevant Schedule. Any provision in another Standard, that imposes a limit on the amount of one of the substances listed in either Schedule that can be added to a food, does not apply to FSMP.

However, if a substance is not listed in either of the Schedules, the substance may be added to an FSMP in any form, provided the addition of the substance complies with any other applicable Standard. For example, if a food additive is added to an FSMP, the additive must comply with Standard 1.3.1.

Clause 7 contains compositional requirements for FSMP that is represented as being suitable for use as an individual's sole source of nutrition. An FSMP that is represented in this way is required to contain at least the minimum specified level of the vitamins, minerals and electrolytes listed in Schedule 2 to the Standard. In the case of some of these listed nutrients, a maximum level is also imposed. However, subclause 7(2) allows the amount of a nutrient in an FSMP to exceed the prescribed maximum, or fall below the prescribed minimum, if a variation from the maximum or minimum is necessary for a particular medical purpose. If the amount of a particular nutrient falls outside its prescribed maximum or minimum level, the FSMP must be labelled in accordance with paragraph 10(2)(b). That is, the label must contain a statement indicating the nutrient or nutrients effected, and whether each nutrient has been increased, decreased, or eliminated from the food. However, subclause 10(5) provides that information on how the level of each nutrient has been varied (e.g. increased, decreased, or eliminated) is not required to be on the label, if the information is provided in other documentation about the FSMP.

Clause 8 requires a package of FSMP to have a label. Clause 8 also makes it clear that the requirements of Subdivision 2 of Division 4 of the Standard do not apply to a package which is an inner package (in which case Subdivision 3 applies to the package) or a transportation outer (in which case Subdivision 4 applies to the package).

Subdivision 2 of Division 4 (which contains clause 9 to 16 of the Standard) contains the general labelling requirements for packages of FSMP:

Clause 9 contains a list of information that must be included on the label on a package of FSMP.

Clause 10 contains a list of statements that must be declared on the label on a package of FSMP.

Some of the statements will not be applicable to all FSMPs and are only required where relevant. For example, if there are any precautions or contraindications associated with consumption of the FSMP, these must be declared on the label on the package of FSMP.

Clause 11 requires the presence of certain substances in an FSMP to be declared on the label on any package of the FSMP.

Clause 12 requires the label on a package of FSMP to contain a statement of ingredients that complies with either Standard 1.2.4, the relevant Directive of the European Parliament and Council, or the relevant provision in the United States Code of Federal Regulations.

Clause 13 requires FSMP to comply with date marking requirements in Standard 1.2.5. However, the words ‘Expiry Date’ or similar words may be used in place of the words ‘Use By’.

Clauses 14 and 15 set out the conditions that must be met if a claim about lactose or gluten is made about an FSMP. These conditions mirror the conditions that apply to claims made about the lactose or glucose content of regular food.

Clause 16 requires the label on a package of FSMP to meet the legibility requirements contained in Standard 1.2.9.

Subdivision 3 of Division 4 (or clause 17 of the Standard) requires inner package of FSMP to have a label, and specifies what the label must include.

Subdivision 4 of Division 4 (or clause 18 of the Standard) requires a transportation outer (defined in Standard 1.1.1 of the Code) that contains packages of FSMP to have a label which includes certain specified information. However, clause 18 makes it clear that the transportation outer is not required to have a label if the information specified is clearly discernible through the transportation outer on the labels on the packages inside.

Food Standards (Proposal P242 – Food for Special Medical Purposes – Consequential) variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the Australia New Zealand Food Standards Code (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P242 to develop a Standard for food for special medical purposes (FSMP), being food that is specifically formulated for the dietary management of individuals with particular medical conditions and which is intended to be used under medical supervision.

The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard and a draft variation. This Explanatory Statement deals with the draft variation.

Following consideration by COAG Legislative and Governance Forum on Food Regulation (the Forum), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sun setting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

This variation was prepared to complement new Standard 2.9.5 (Food for special medical purposes) by making necessary consequential changes to Standards 1.1.1, 1.1A.6, 1.2.1, 1.3.1 and 1.3.4 of the Code.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

The Authority's consideration of Proposal P242 has included four rounds of public consultation following assessments, the preparation of a draft Standard, a draft variation and associated reports. Public submissions were called for in 2001, 2002, 2004 and 2010. In addition, targeted consultation was undertaken in 2010 and 2011 after the project re-commenced with key stakeholder groups i.e. manufacturers, health professionals, jurisdictions and other interested parties.

The Office of Best Practice Regulation was also consulted and advised FSANZ that a Regulation Impact Statement was not required because the proposed Standard 2.9.5 was likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variations

Item 1 varies clause 2 of Standard 1.1.1 by applying the definitions of small package and transportation outer to the Code as a whole. Item 3 removes these definitions from Standard 1.2.1. Item 1 also varies clause 2 by referencing the definition of food for special medical purposes and by amending the definition of warning statement to include the prescribed warning statement in new Standard 2.9.5. Finally, Item 1 also varies Standard 1.1.1 by inserting the symbol MJ into the glossary of symbols and units at clause 8.

Item 2 varies Standard 1.1A.6 to ensure that Standard 1.1A.6 will not cease to have effect on the date of commencement of Standard 2.9.5 in relation to food formulated and represented as being for the dietary management of obesity. The purpose of this variation is to allow the continued regulation under Standard 1.1A.6 of very low energy diet products which are manufactured in, or imported into, New Zealand.

Item 4 varies Schedule 1 of Standard 1.3.1 to apply a number of food additive permissions to FSMP.

Item 5 varies the Schedule to Standard 1.3.4 by adding a specification for selenium-enriched yeast.

Attachment 3 – Summary of Submissions

Stakeholder Consultation

FSANZ commenced work on Proposal P242 – Food for Special Medical Purposes in 2001. Since that time, FSANZ has undertaken four rounds of public consultation, as well as three significant periods of targeted consultation to inform the development of Standard 2.9.5 – Food for Special Medical Purposes.

This Attachment provides a summary of comments and information received from stakeholders during each of the consultation periods. The following tables summarise:

1. Written comments from submitters on the Initial Assessment Report released for public consultation in October 2001.

2. Written comments from submitters on the Draft Assessment Report released for public consultation in December 2002.

3. Written comments from submitters on the Preliminary Final Assessment Report released for public consultation in August 2004.

4. Comments (written and verbal) provided by stakeholders during targeted consultation activities held in mid-2010.

5. Written comments from submitters on the Consultation Paper released for public consultation in December 2010.

6. Comments (written and verbal) provided by stakeholders during targeted consultation activities held in mid- and late-2011.

1. Summary of submissions to the Initial Assessment Report

List of Submitters

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

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

- Tatua Nutritionals (TN)

Summary of comments

Preferred Regulatory Option

Option	Submitters Supporting Option	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text	
		Supported	**Not Supported**
1. Status Quo			Those submitters that discussed Option 1 mentioned that: • FSMP must be lawful foods [FCG] • this option is no longer acceptable [NCWA] • no legal recognition of FSMP would result in regulatory ambiguity and enforcement problems [TN].
2. Recognition in Volume 2 with minimal regulatory control.	ANZENMA KM, TN (Total = 3)	• Support for this option was provided mostly by industry, including FSMP manufacturers. • Support for minimal regulatory control was provided because: - To date there has been no evidence of market failure in the production of FSMP [ANZENMA]. - Detailed regulations are not necessary as sales of FSMP are controlled by health professionals and hospital tenders [KM, ANZENMA].	Comments opposing Option 2 were received from the National Council of Women Australia. It was stated that Option 2 would rely solely on definitions that could easily be misinterpreted.

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

Regulatory Considerations

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

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

Definition and Scope of FSMPs

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

Composition of FSMP

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Inclusion of compositional requirements	• Several submitters representing consumers, health professionals and government agencies indicated that compositional requirements were necessary for any FSMP standard [AMA, FCG, NCWA, QH]. - FSMP should have product-type specific compositional requirements [NCWA, QH]. - All FSMP should be able to meet a set of compositional requirements. If a product (imported or otherwise) cannot meet compositional requirements of a medical condition, then it should not be suitable for use in the treatment of that condition [NCWA]. - Due to the dependence of patients on FSMP, there is a risk to public health and safety. FSMP should therefore have compositional requirements to minimise this risk [QH]. - The Fonterra Co-operative Group indicated that they supported maximum requirements only for safety reasons. • Industry groups were the most outspoken opponents to the inclusion of any compositional requirements for FSMP, although comments against compositional requirements were provided from other sectors [ANZENMA, ASMI, KM, TN]. - FSMP are already formulated to meet European or United States compositional requirements that are internationally recognised standards. Creating separate compositional requirements that differ from these countries will prevent many non-compliant products from being imported into Australia [ANZENMA, ASMI, KM]. - The provision of FSMP through healthcare settings and/or under health professional supervision minimises the risks associated with their composition [ANZENMA, ASMI, KM]. - No evidence exists to date of the health and safety needs of the target population being compromised through the composition of FSMP [ANZENMA, ASMI]. - The wide range of FSMP will create difficulties in detailing compositional requirements that cover all products. A generic permission for the incorporation of vitamins, minerals and other components into FSMP may be more appropriate [TN].
Addition of more nutritive and other substances	• Comments were received from all sectors in support of the permission for the addition of “non-standard” nutritive substances to FSMP. All comments indicated that these substances should only be permitted on the basis of scientific investigations into their efficacy and safety [DAA, KM, NCWA, QH, TN]. • Some of these comments also indicated that the definition of a “nutritive substance” should be clarified. - **Ms K McIlroy** suggested that the definition should include the requirement of ‘an added health benefit’ or ‘improved outcome’. - **Tatua Nutritionals** stated that the current definition in Volume 2 should be expanded to cover essential fatty acids, substances containing ACE inhibitory peptides / anti-thrombotic peptides, or substances that play a role in oral health. - **Fonterra Co-operative Group** mentioned that lactic acid bacteria may be beneficial but are not defined as a nutritive substance. • The **NCWA** suggested that a schedule similar to those used for vitamins and minerals could also be provided for nutritive substances and an upper limit established for their use. • The **TGA** commented that there is the potential for some substances added to FSMP (e.g. selenium) to be included within the *Australian Standard for the Uniform Scheduling of Drugs and Poisons*. A clear regulatory approach on this issue is therefore required.

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text

Distribution and Access to FSMPs

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

Labelling of FSMP

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

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

Additional comments made in submissions

Genetic modification / food irradiation

- The NCWA indicated that it did not consider biological substances derived from genetic modification to be safe. They would not, therefore, support any permission for the addition of nutritive substances to FSMP that are produced by this method.
- The DAA stated that FSMP should indicate on leaflets and brochures as whether they are a genetically modified or irradiated food as consumers are entitled to this information.

Microbiological requirements

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

Comments on issues outside the scope of P242

Infant formula

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

Cholesterol-lowering products and phytosterol-containing margarines

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

Meal replacements

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

2. Summary of submissions to the Draft Assessment Report

List of Submitters

A public consultation period occurred from the 18 December 2002 to 24 March 2003 for the Draft Assessment of Proposal P242. During this period, 17 separate submissions were received by FSANZ. A list of the submitters that provided comment on the Draft Assessment Report is provided below.

- Australasian Society of Inborn Errors of Metabolism - Dietitians Group (ASIEM)
- Australian Food and Grocery Council (AFGC)
- Australia New Zealand Enteral Nutrition Manufacturers Association (two submissions provided) (ANZENMA)
- Australian Self-Medication Industry Inc. (late submission) (ASMI)
- BioActive Technologies (BT)
- Dietitians Association of Australia (DAA)
- Food Technology Association of Victoria Inc. (FTAV)
- European Commission, Enterprise Directorate-General (EC)
- Ms Kay Gibbons, Clinical Dietitian (KG)
- Nestlé Australia Ltd. (NA)
- New Zealand Dietetic Association (NZDA)
- New Zealand Food Safety Authority (NZFSA)
- Novartis Consumer Health Australasia Pty. Ltd. (NCHA)
- Nu Skin Enterprises Australia Inc. (NSEA)
- ORFAM Pty Ltd. (ORFAM)
- South Australian Department of Human Services (SADHS)

Summary of comments

Preferred Regulatory Option

Option	Submitters Supporting Option	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text	
		Supported	**Not Supported**
1 – Maintain Status Quo	AFGC, ASMI, FTAV, KG	• FSANZ has not demonstrated any market failure with the currently unregulated usage of FSMP, or that FSMP are unsafe/inappropriate [AFGC, KG]. • The current labelling of FSMP is sufficient to meet the provision of adequate information to consumers without further regulation [AFGC]. • Products are not currently developed without regard to best practice and are utilised under the supervision of health professionals. This provides a level of nutritional 'insurance' [KG]. • If FSMP are to be regulated, then it should be as therapeutic goods and not as foods [FTAV].	• Option 1 is not an option as it leaves in place the delays and continuing negative impact on government and industry. [NSEA].
2 – Regulation by a discreet standard in the FSC	ANZENMA, NA, NZFSA, ORFAM, SADHS.	• A discreet standard should be placed in the FSC that only sanctions FSMP as foods, rather than the format proposed at Draft Assessment [ANZENMA]. • The **NZFSA** supports the development of a discreet standard in principle, but not one that is overly prescriptive. It is important that FSMP products are not withdrawn from the domestic market. •	• In the absence of evidence for a safety risk with the current access to FSMP, there is no purpose in changing the regulatory requirements for FSMP in Australia or New Zealand [AFGC]. • Arguments raised in the impact analysis supporting Option 2 are largely hypothetical [KG]. • Option 2 may limit the product range available in Australia, or result in companies withdrawing from the market. This is of particular concern for items with a limited sale [KG, AFGC]. •

Other Comments on the Proposed Regulatory Options:

- **NSEA** states that FSMP should not be recognised as being available for general consumption. The application of general food standards is therefore inappropriate.

- **NSEA** supports a different option (named Option 3) that would amend relevant food standards to ensure that these standards do not apply to FSMP. This would eliminate the regulatory uncertainty surrounding the importation of FSMP.
- Although supportive of Option 2 in principle, the **NZDA** recommended that a further assessment should be made of the costs to industry and the consumer before any regulations are implemented.

Regulatory Considerations

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Costs and Benefits Associated with Option 2	In the impact analysis the AFGC considers that FSANZ overstates the benefits and understates the restriction associated with Option 2. <u>Costs:</u> • There will be a cost to industry to comply with Option 2 that will inevitably result in increased costs for consumers [AFGC, KG, NZDA, ORFAM]. • Although supportive of Option 2 in principle, the ANZENMA has indicated that 95% of FSMP will be non-compliant with the proposed standard. • It was estimated that the costs associated with Option 2 could result in a 20% price increase for products manufactured by ORFAM. • The compositional requirements would result in a business impact of $250000 for Nestlé, as its FSMP products would no longer be supplied to the Australian market. <u>Benefits:</u> • If Option 2 only sanctions FSMP as legitimate foods without other requirements, then it would remove importation concerns and contribute to the ongoing investment in local research and development [ANZENMA]. • Benefits for Option 2 include standardised labelling, and the potential for the adoption of an existing code in its entirety [KG].
Safety	• Several industry and health professional submitters did not agree with the view that FSMP are unsafe and pose a risk to the general public [AFGC, ANZENMA, DAA, NA, NZDA]. - There has been no evidence demonstrating safety concerns with the current unregulated environment for FSMP [ANZENMA, DAA, NA], or of non-compliance with the basic requirement of a food being safe under the Food Acts of Australia and New Zealand [NA]. - FSMP are supervised by health professionals in their use and therefore pose a lesser risk to the public than other foods [AFGC, ANZENMA, NZDA]. - FSMP need to meet strict overseas regulations that contribute to the protection of public health and safety in domestic markets [AFGC, ANZENMA, NZDA]. - Consumers are unlikely to be aware that FSMP are unregulated, and would consider these products to be safe [NA].
Regulation of VLED	• The **SADHS** stated that there are different risks between FSMP and VLED. Therefore, it was recommended that VLED be included as a separate category in Part 2.9 of the *Food Standards Code*.

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
	• **NCHA** was concerned that regulations for VLED have evolved from one region of the world only, e.g. the European Union (EU); and may limit product innovation.

Objectives and Principles for Proposal P242

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
The Objectives of the Proposal	• **Ms Kay Gibbons** agreed with the objectives of P242 as provided at Draft Assessment. • The AFGC supported the objectives of protecting public health and safety, and the use of adequate labelling information to permit informed choice by consumers and their carers. However, it stated that: - no regard has been given to 'consistency between domestic and international food standards' and ' the need for a standard to be based on risk analysis using the best available scientific evidence' as stated in the FSANZ Act; and - supply issues for FSMP have not been fully considered, that is, the majority of FSMP are imported in small and infrequent quantities. It is therefore recommended that another objective should be provided - *'to not jeopardise supply of FSMP needed in small quantities on an infrequent basis'*. • The **NZDA** stated that the objectives of FSANZ in P242 are unclear when the current use of FSMP has not been established as unsafe or inappropriate.
Underlying Regulatory Principles	• The **AFGC** states that the underpinning regulatory principles for special-purpose foods are in effect policy principles, and therefore should be referred to the Australia New Zealand Food Regulation Ministerial Council.

Definitions Provided at Draft Assessment

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
The definition of special purpose foods	• The **AFGC** supported the categorisation of FSMP as special-purpose foods. However, it was suggested that the associated need *'to provide appropriate regulatory measures to mitigate the risk to the target group from inappropriate consumption'* should relate to 'inappropriate composition' instead of 'inappropriate consumption'. Support was also given for the proposed definition of 'special-purpose foods'.
The definition of protein	• **Nestlé** stated that the definition for protein, and the prescribed method of analysis for protein (Schedule 4) were inappropriate. • It is unclear whether this definition only applies to minimum protein levels in VLED [ANZENMA]
The definition of FSMP	• Support for the definition of FSMP was given by health professional and industry submitters [ANZENMA, DAA, NA, NZDA]. Although supported, several submitters proposed minor changes to the wording: - Expansion of 'medical supervision' to include supervision by dietitians [DAA, NZDA]. - 'for use solely under medical supervision' to 'should be used under medical supervision' [ANZENMA]. - 'impaired capacity to take, digest, absorb or metabolise' to 'impaired capacity to take, digest, absorb, metabolise or excrete' [ANZENMA] - 'cannot be achieved solely' to 'may not be achieved solely' [ANZENMA]. • The SADHS commented that the proposed definition of FSMP excludes patients who use VLED. These patients do not have a 'limited or impaired capacity to take absorb or metabolise ordinary foodstuffs', and obesity can be managed by modification of the normal diet.
The definition of VLED	• **ANZENMA** recommended that the definition of VLED be clarified further, as these products could be used as a supplement and thus result in a daily energy intake greater than 3350 kJ. It was suggested that the upper energy limit for VLED be removed from compositional provisions and placed into the definition of VLED.

Access and Availability of FSMP

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
The distribution and access of FSMP	• Several health professional / industry submitters supported the decision to maintain current distribution and access practices for FSMP [ANZENMA, KG, NA, NZDA, ORFAM]. - FSMP should be available for purchase from pharmacies and hospitals, through health professionals (including retail pharmacists) [DAA, NZDA], or direct from the manufacturer / medical distributor [DAA]. - The warning 'use under medical supervision' is an adequate risk management strategy [KG]. • **BioActive Technologies** stated that a proportion of food products that could be classified as FSMP are not provided through healthcare settings. Examples provided were low energy weight management products and formulated high fibre foods for bulk forming laxative applications. It was suggested that these products should be covered by formulated beverages regulations.
The availability of FSMP	• As a large proportion of the FSMP market is imported, the proposed labelling / compositional changes will impact on the availability of FSMP [ANZENMA, ASIEM, DAA, SADHS]. - Availability would be affected by price increases or removal of products from the market due to the impact of re-labelling / reformulation. This would restrict access to FSMP [AFGC, ANZENMA, SADHS]. - Any reduction in the availability of FSMP for patients with inborn errors of metabolism will have serious medical consequences [ASIEM]. -

Advertising

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Restriction on advertising	• Some submissions from the health professional sector supported a restriction on advertising [KG, NZDA]. - VLED should be treated separately for advertising [DAA, NZDA]. - Limited advertising of VLED may be applicable where a wide range of other similar foods exists on the market (e.g. meal replacements). The content of such advertising would need to be monitored [KG]. - Access to information on FSMP should be restricted to health professionals [NZDA]. • Comments against the restriction on advertising were received from industry submitters [AFGC, ANZENMA, BT, NA, ORFAM]. - The restriction is not warranted, as there is no evidence of market failure or public health and safety risks associated with the use of FSMP [AFGC, NA]. The AFGC considers that a restriction on advertising to health professionals only would not meet the needs of users of FSMP e.g. Self-help groups

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
	- The **AFGC** stated that no evidence was provided in support of the public health and safety risks or high rates of self-treatment for morbid obesity associated with VLED. It was further mentioned that what evidence exists indicates that the morbidly obese are not likely to undertake self-treatment. - Public health and safety may actually be adversely affected by preventing advertising to consumers, as consumer access to health professionals is decreasing [ANZENMA]. - Many weight loss products are more readily abused through self-treatment than VLED, yet are still permitted to advertise [ORFAM]. - There are various industry codes of practice that could apply to advertising of FSMP [ANZENMA] e.g. Medicines Australia, Australian Self-Medication Industry, and New Zealand Advertising Authority.
The term 'health professional publication'	• **Ms Kay Gibbons** provided support for the term 'health professional publications'. • Several submitters indicated that the expression 'health professional publications' was too narrow [AFGC, ANZENMA, ASMI, DAA, NA, NZDA, ORFAM]. It was recommended that this expression be expanded to include: - patient support groups, and disease specific consumer groups [AFGC, ANZENMA, ASMI, NA]; - conferences, educational forums and meetings, direct mail campaigns, emails and websites [ANZENMA, DAA, NZDA]; - trade exhibitions [ANZENMA, NZDA]; and - product information and leaflets [DAA]. • Clarification should be to be given to the disciplines covered by 'health professionals' [ASMI, NZDA, ORFAM]. Both **ANZENMA** and **ASMI** recommended the use of the definition for health professionals as stated under Part 2, Division 1(4) of the Australian *Therapeutic Goods Regulations 1990**.

* These regulations list health professionals as: medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, dietitians, scientists working in medical laboratories, and nurses.

Composition of FSMP

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Risk Assessment for proposed composition	• Nutrient ranges should be based on practice and the best available evidence [AFGC, KG]. • The mixture of EU and United States Institute of Medicine (IOM) values to set maximum limits is an ad hoc process to risk assessment and is therefore incorrect [AFGC]. • Two submitters questioned the compositional requirements when no safety issues had been identified [NZDA, NZFSA], although in principle, NZFSA supported the risk-based approach to composition.
Impact of proposed composition	• Submissions from industry and health professional sectors indicated that the compositional requirements proposed at Draft Assessment would have adverse effects on the current range of FSMP [ANZENMA, ASMI, KG, NA, NCHA, NZDA, ORFAM]. - The proposed compositional requirements would increase the price of FSMP, limit product choice and result in a restriction / absence of supply of FSMP [ASMI, KG, NA, NZDA]. - The proposed composition would disrupt supply of current State and Federal Government Tenders [ANZENMA]. - The proposed compositional requirements would result in the two FSMP produced by Nestlé being withdrawn from the Australian and New Zealand markets. - Novartis indicated that its product range would be seriously affected if FSMP regulations do not allow both US and European compositions. - ORFAM indicated that the compositional requirements proposed at Draft Assessment would result in the reformulation of its VLED products. It was stated that this will pose no technical difficulty, however a cost will be incurred.
Minimum limits for vitamins and minerals	• Several submitters from across all sectors supported the minimum limits (that apply only to nutritionally complete FSMP) proposed at Draft Assessment [AFGC, ANZENMA, NZDA, NZFSA]. - Nutritionally complete FSMP need to be nutritionally adequate for use as the sole source of nutrition [DAA, NZDA]. Agreed that minimum quantities of micronutrients are required per daily quantity to meet recommended intakes [AFGC]. - Some of the minimums requirements are of concern to **ANZENMA**, and a further review of these provisions is required. - **Nestlé'**s products will be non-compliant with the minimum levels for niacin, vitamin B_{12}, folate, and magnesium.
Maximum limits for vitamins and minerals	• Concern was raised over the maximum limits provided at Draft Assessment by a number of submitters representing all sectors [AFGC, ANZENMA, ASMI, DAA, KG, NA, NZDA, NZFSA]. The following concerns were raised: - The majority of FSMP will be unable to comply with the proposed maximum limits [ANZENMA, DAA, KG, NZDA], resulting in reduced availability and/or increased prices [DAA]; - The maximum limits do not take into account the situation where a patient's health status may result in nutritional requirements exceeding normal limits [AFGC, ANZENMA]. - Maximum limits should be established only where a risk from daily intakes of FSMP has been identified [AFGC, NZFSA]; - No maximums should be prescribed as medical supervision is provided with the use of FSMP [AFGC]. - The **DAA** is unaware of clinical evidence indicating that excess intake beyond the proposed maximum limits has a deleterious effect on any patient group;

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
	- The composition of FSMP is constantly improving, and maximum limits will impede such progress [NZDA]; and - It is unclear as to how composition is to be harmonised with EC directives when the proposed maximums prevent this [NZDA]. - The adult intake of 8700 kJ / day used to calculate requirements is inappropriate, as patient requirements in some situations may be as low as 6000 kJ / day. Therefore, requirements should be expressed as a daily amount similar to VLED requirements [AFGC]. - Given medical supervision, there is no justification for maximum limits except where there is sufficient evidence of adverse health effects [ANZENMA]. • Of the submitters commenting on maximum limits, three indicated that they did not support any introduction of maximum limits for FSMP [AFGC, ANZENMA, NZDA]. - Comment received from **ANZENMA** questions the use given that the US upper limits have not been generated for application to FSMP. . • **Nestlé** indicated that its FSMP products would be non-compliant with the maximum limit for vitamin A, while **Ms Kay Gibbons** indicated that consideration of current products against the proposed maximums indicate that the amount by which a nutrient falls outside the range is minor, and does not generally constitute a variation of multiple times the acceptable limit.
Non - nutritionally complete FSMP	• Several health professional submitters indicated that nutritionally incomplete FSMP could experience problems with compositional requirements (maximum limits) expressed as a proportion of energy content. Where energy is not a major nutrient supplemented in a FSMP, then it is impossible to comply with the maximum limits [ASIEM, DAA, NSEA, NZDA]. This is of particular significance for low-volume FSMP for rare genetic disorders [ASIEM].
VLED	• Support was received for the additional compositional requirements for VLED from several industry and health professional submitters [ANZENMA, KG]. • Although supported, the composition of VLED should also include permissions for vitamin K, chromium, and fluoride additions as allowed for nutritionally complete non-VLED [ANZENMA]. Also questions the maximum limits for certain nutrients: - vitamin E, as it is eligible for listing in complementary medicines without a maximum; - niacin, as nicotinamide is not significantly toxic and the consequence of excess nicotinic acid intake is mild flushing; and - magnesium, as it is not restricted for complementary medicines or dietary supplements - VLED should be required to provide the recommended daily allowances of minerals, vitamins, trace elements, and fatty acids in a dose/serve [DAA]. - VLED should have a minimum daily amount set for micronutrients [AFGC]. • **Ms Kay Gibbons** considers that macronutrient requirements are important for VLED, but do not need to be mandated, as there is an inconsistency in prescribing macronutrient requirements for VLED and not for nutritionally complete non-VLED FSMP.
Certain medical conditions	• Two submissions were received recommending that the permission for FSMP to deviate from sodium and potassium levels be extended to all prescribed compositional requirements. Such deviations should only occur where they are necessary for the intended use of a FSMP, and can be justified through scientific evidence [ANZENMA, EC]. - The **ANZENMA** indicated that this permission would be consistent with European regulations.

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
	• **Ms Kay Gibbons** mentioned that it is unclear as to whether the permission to vary from sodium and potassium requirements for certain medical conditions applies to FSMP for non-specific use.
Schedule of permitted forms	• **Ms Kay Gibbons** supports the permitted forms of nutrients / additives proposed at Draft Assessment. • The **ANZENMA** requested consideration be given to permitting other forms of nutrients that are permitted elsewhere (e.g. Standard 1.1.1, Standard 2.9.1, Listable medicines) • Flexibility should be given in FSMP regulations to accommodate new ingredients or the extension of use for approved substances in response to scientific advances in the dietary management of medical conditions [DAA, NZDA].
Other general comments on composition	• **Ms Kay Gibbons** recommended the adoption of the EU minimum and maximum compositional requirements as an alternative to the proposed compositional requirements for FSMP. The rationale for a decision not to prescribe macronutrient content for nutritionally complete non-VLED but for micronutrients is unclear . • **ANZENMA** supports the use of the Codex general principle on the composition of FSMP. • **NSEA** stated that the expression of minimum and maximum micronutrient requirements per 100 kJ was unsuitable as the measure depends as much on the energy content of the product as the micronutrient content. Therefore it is recommended that Schedule 2 of draft Standard 2.9.5 be changed to use the RDIs / ESADDIs as the basis for establishing vitamin and mineral compositional requirements.

Labelling of FSMP

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Impact of proposed labelling	• Submitters from all sectors expressed concern that the proposed labelling requirements may have a negative impact on industry and consumers [AFGC, ANZENMA, ASIEM, ASMI, DAA, NCHA, NZDA, NZFSA]. - FSANZ should use performance-based principles to establish labelling requirements on FSMP suitable to the needs of health professionals and consumers [ASMI]. - Manufacturers will need to make significant and onerous changes to the labels of imported FSMP to comply with the proposed draft standard [ASIEM, DAA]. - Labelling requirements will increase the cost of 90% of FSMP for consumers due to the cost of compliance for industry, reduce the range of general and specialised FSMP in Australia and New Zealand, and impede product innovation [NZDA]. - Even though generic labelling requirements are important for general-purpose foods, **NZFSA** questions the impact of the proposed labelling requirements on a small and highly specialised market.
Provision of labelling information on supporting product literature	• Submissions from both industry and health professionals were received advocating the use of supporting product literature (e.g. pamphlets and brochures provided to health care professionals) as a means of providing domestic labelling information not mandated by overseas regulations [AFGC, ANZENMA, ASMI, DAA, NCHA]. - Reference was given to the provision of local supplier details on this material [AFGC, ANZENMA]. - **ASMI** stated that supporting literature is able to provide the risk management of a label, as similar distribution techniques for FSMP are used in Australia for pharmacist only and prescription only therapeutic goods.
Application of generic labelling requirements	• Industry cannot meet the labelling requirements proposed at Draft Assessment. If generic labelling statements are applied to FSMP, a large percentage of FSMP will fail to comply [ANZENMA]. Problems include local supplier details, allergy labelling, labelling of ingredients, characterising ingredients and directions for use and storage. • The provision of domestic supplier details is adequately met by product supporting literature [AFGC]. • The primary package 'case or carton' could display the local supplier details as very few products are sold as individual units [ANZENMA].
Date marking	• **ANZENMA** requested that consideration be given to the use of overseas date marking requirements such as 'EXP', 'best before', or words to the effect of 'use by'.
Declaration of nutrition information – general comments	• **ANZENMA** recommended that FSANZ accept global practice in respect to nutrition information statements. • **AFGC** supports the provision of nutrition information consistent with Codex requirements, even if it is in a non-domestic format. • **Nestlé** stated that expressing nutrition information as prepared for consumption (Clause 7(4)) may not be relevant for all products e.g. thickeners.
Declaration of nutrition	• Comments by health professional and industry submitters indicated that the requirement to label with the number of serves

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
information – number of serves and serving size	and the serving size was inappropriate [AFGC, ANZENMA, DAA, NA]. The following arguments were provided: - Inconsistent with EU and USA requirements where most products are sourced [ANZENMA]. - A number of FSMP – particularly enteral formula – need to be delivered in continuous amounts over time [AFGC, ANZENMA], or in volumes specific to certain medical conditions [ANZENMA, DAA]. - Codex STAN 180-1991 allows this requirement to be voluntary under Clause 4.5.6 (using the statement 'if applicable'), and infant formula regulations in the FSC set a precedent for not providing nutrition information per serve [NA]. - Comments by health professional and industry submitters indicated that the requirement to label with the number of serves and the serving size was inappropriate • **The ANZENMA requested**: - replacement of 'average' with 'average or minimum' in clause 7; and - use of other values besides per 100 g or 100 mL.
Mandatory advisory statement – *'use under medical supervision'*	• The wording of an advisory statement 'use under medical supervision' should include supervision by a dietitian [NZDA, SADHS]. - It was further stated by **SADHS** that if the inclusion of dietetic supervision would result in the removal of products from the market, then the use of a non-prescribed advisory statement would be supported. • Several industry submissions did not support the inclusion of 'important notice' before an advisory statement on medical supervision [AFGC, ANZENMA, NA]. Such a requirement: - is not provided in Codex, US or Canadian regulations [ANZENMA, NA]; - is unnecessary as generic legibility requirements in the FSC are sufficient, and industry would need to over-stick labels (at a cost) to meet this requirement [AFGC]; and - suggests that FSMP have a greater risk than actually exists [ANZENMA]. • The **AFGC** did not support regulation of labelling 'use under medical supervision', stating that it is an unnecessary as all products currently on the market label with this statement.
Mandatory warning and advisory statements for VLED	• The **NZDA** supports the labelling of 'may not be suitable for pregnant, nursing or lactating women or by infants, children, adolescents or the elderly' on VLED. • **ANZENMA** and **ORFAM** did not support the statement 'may not be suitable for pregnant, nursing or lactating women or by infants, children, adolescents or the elderly' on VLED. It was mentioned that: - members of these population groups can be obese, and if a VLED were to be recommended by a health professional to these people, then labelling would create anxiety and confusion [ANZENMA]; and - VLED are used under medical supervision, and this advice should be routinely provided to the patient [ORFAM]. • ORFAM did not support the statements 'it is important to maintain an adequate daily fluid intake while using the product' as

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
	VLED are used under medical supervision, and this advice should be routinely provided to the patient. • ORFAM does not object to the requirement to label with the warning 'for the dietary management of obesity', although this requirement is considered unnecessary.
Mandatory advisory statement – *not for parenteral use*	• Submissions from the **DAA** and the **NZDA** supported the labelling of 'not for parenteral use' for oral and enteral products to prevent inappropriate use. • The **ANZENMA** does not support the statement 'not for parenteral use', as the European Union provides voluntary regulation for this statement using the words 'where appropriate FSMP are to include…'. **ANZENMA** requests that 'where appropriate' be included in domestic regulations.
Mandatory advisory statement – *intended / not intended as the sole source of nutrition*	• The **ANZENMA** does not support the statement 'intended / not intended as the sole source of nutrition', as the European Union provides voluntary regulation for this statement using the words 'where appropriate FSMP are to include…'. ANZENMA requests that 'where appropriate' be included in domestic regulations.
Mandatory advisory statement – *the product poses a health hazard when consumed by persons who do not have a disease, disorder or medical condition for which the product is intended*	• Submitters from industry and health professional sectors commented that the requirement to label a FSMP as a 'health hazard' is inappropriate [AFGC, ANZENMA, DAA, NA]. - FSMP do not pose a health risk to healthy individuals, as they are composed of normal nutritional ingredients. Furthermore, the use of these products occurs under medical supervision [AFGC, ANZENMA]. - The requirement to label with a 'health hazard' statement is suited to VLED only. It was suggested that a statement regarding use in certain conditions was more suitable for FSMP [DAA]. - The labelling of a FSMP as a 'health hazard' may not always be a true statement, as all family members can use foods that are provided for people with medical conditions. Therefore, this statement would breach the Trade Practices Act [NA].
Additional labelling requirements – *advising of any necessary precautions, side-effects, contraindications and potential interactions with drugs, in consuming the food*	• Support was received from health professional submitters for the labelling of known side effects, contraindications, and product-drug interactions where known [ASIEM, DAA, NZDA]. - Information on the side effects for some ingredients / nutrients is necessary for certain health conditions. An example provided was the labelling of 'low lactose' products and the method of removing lactose – if lactose has been split into its glucose and galactose components, then patients with galactosaemia are at a health risk from consuming such a product [ASIEM, DAA]. - The **NZDA** stated that this information should not be a mandatory requirement as adverse effects are dependent on dietary patterns and associated use of medications. • Several industry submissions were not supportive of the requirement to label with known side effects, contraindications, and product-drug interactions [AFGC, ANZENMA, NA]. - The large volume of information required would be impractical to include on the label of FSMP [AFGC, ANZENMA, NA]. - It is the responsibility of the supervising medical professionals and drug manufacturers to provide information on drug-nutrient interactions and contraindications [ANZENMA, NA].

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
	- Labelling with the statement 'use under medical supervision' is sufficient to meet these risks [AFGC]. - This requirement is voluntary under Codex STAN 180-1991 [NA].
Additional labelling requirements – daily quantity for VLED	• Several submitters indicated that the labelling of a recommended daily quantity for VLED established by the manufacturer is inappropriate, as: - the dosage and concentration is the responsibility of the supervising health professional [NZDA, ORFAM]. - VLED can sometimes be used in smaller supplemental quantities. It was suggested that this requirement be related to 'when the product is intended as the sole source of nutrition' [ANZENMA].
Additional labelling requirements – reference to disease states	• Support was received for the ability to label with a reference to the condition disease or disorder for which a food for special medical purposes has been designed [AFGC, ANZENMA, ASMI, SADHS]. - The **ASMI** does not consider the context of labelling a FSMP with disease states or conditions for nutritive purposes to be a contravention of the prohibition on health claims. It was also stated that claiming on FSMP labels could be captured under a proposed Trans-Tasman arrangement for the pre-market clearance of advertisements containing therapeutic claims **. • The **SADHS** mentioned that it did not support the permission extending to VLED. It was stated that because VLED are available via pharmacies / supermarkets, such labelling would result in self-diagnosis.

** - This arrangement has been proposed for both foods and medicines under Recommendation 12 of the 'Report of a Review of Advertising Therapeutic Products in Australia and New Zealand', for which a copy can be obtained from http://www.tga.health.gov.au/docs/html/advrev.htm.

Additional comments

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Transition and Stock-in-Trade Periods	• Several industry submitters recommended an extension to the transition period from 2 years to 4 years to accommodate current tenders which are in place, and any reformulation of FSMP; and an extension to the stock-in-trade period from 12 months to 2 years, as the majority of FSMP have a long shelf life [AFGC, ANZENMA, NA]. • **ORFAM** indicated that the two-year transition period was reasonable.
Micro-biological requirements	• The NZDA supported the proposed microbiological requirements provided at Draft Assessment given the higher at risk status of the target consumer.
Application of standards requiring pre-market clearance	• **BioActive Technologies** supports the application of pre-market clearance standards. • The **NZDA** commented that information on genetic modification and irradiation should be placed on the label of a FSMP.
Errors in draft variations	• Amendment [2](f) should refer to Clause 8 instead of Clause 9 [NA]. • Amendments [7] and [8] refer to Volume 2 when there is no longer a Volume 1 [NA].

Comments made outside the scope of P242

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Classification of FSMP as therapeutic goods	• The **FTVA** stated that if regulation of FSMP is required, then these products should be regulated under the TGA Act. FSMP are aligned more closely with therapeutic purposes than food products.
Importation and re-exportation of foods	• NSEA commented that current food standards legislation precludes the importation into Australia for re-export of foods that are non-compliant with domestic food standards. Such foods are classified 'failing foods' as defined by Clause 3(1) of the Australian Imported Food Control Act 1992, even though such products are not distributed for sale in Australia. - It was suggested that the Imported Food Control Act should be amended, or alternatively, the FSC amended to reflect that standards apply to foods only consumed in the domestic market.

Issue	Comments Names of submitters providing comments are abbreviated in square brackets [ ] unless stated in bolded text
Over-the-counter products	• BioActive Technologies has submitted the following three comments: - Some foods sold over-the-counter could be classified as FSMP (examples given were the company's range of weight management foods and high-fibre foods for laxative purposes). It was recommended that these products be covered by Formulated Beverage regulations. - FSMP like products traditionally sold over the counter or by direct sales should remain free to advertise and promote directly to the public. - Over-the-counter products are not purchased by 'at risk' or vulnerable individuals, as opposed to FSMP used by patients under constant medical supervision. Therefore, the manufacture of over-the-counter FSMP should not be required at microbiological standards greater than those for Food-Type Dietary Supplements.
Definition of Novel Foods	• BioActive Technologies stated that the current definition of 'novel foods' was too restrictive and would require the evaluation of ingredients that would otherwise be accepted with the use of a broader definition.

3. Submitter comments to the Preliminary Final Assessment Report

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 – maintain *status quo* i.e. no specific regulation of FSMP in the Code; and
- Option 2 – regulation by a discrete standards in the Code incorporating specific compositional and labelling requirements, which are in general, consistent with relevant overseas regulations, in addition to the application of an overarching risk management framework consisting of mandatory advisory labelling for use under medical supervision, and restriction on the sale and advertising of FSMP.

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 FSMP 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 FSMP 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.
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).

Submitter	Comments
	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; and • 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; and • 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); and • 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 FSMP (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

Submitter	Comments
	phosphorus to satisfy particular medical conditions) reflect EU specifications. ***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 FSMP 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 FSMP. 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*** Supports 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*** Concerned that some FSMP 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.

Submitter	Comments
Fonterra Cooperative Group	**Supports Option 2** No additional comments.
Food Liaison	***Food Additives*** Comments that 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. ***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.
Food Technology Association of Victoria Inc (FTAV) (now the Food Technology Association of Australasia)	**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**

Submitter	Comments
	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 FSMP.
New South Wales (NSW) Food Authority	**Supports Option 2** No additional comments.
New Zealand Food Safety Authority (NZFSA) (now MAF)	**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 FSMP (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 FSMP however notes the access to information through electronic media e.g. websites.
Novartis Consumer Health	***Permitted Forms*** Provides safety data on seeking permission for use of chromium acetate, as a source of chromium in FSMP. Currently uses this form in FSMP 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.

Submitter	Comments
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 FSMP that low protein baked products e.g. biscuits. Recommends that FSMP 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

Submitter	Comments
	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). ***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 FSMP 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 FSMP 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.

Submitter	Comments
Superior Health Care	***Restriction on sale and distribution*** Is a distributor for at-home products including FSMP. 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 FSMP 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 FSMP 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.

4. Targeted stakeholder consultation – mid-2010

In mid- 2010, FSANZ undertook targeted consultation to re-engage with key stakeholders given the lapse in time since the last public consultation in 2004 for the Preliminary Final Assessment Report.

Teleconference meetings were held with industry representatives, health professionals and jurisdictions in both Australia and New Zealand. The purpose of these meetings was to gather up-to-date information on the FSMP market and products currently available. It also enabled stakeholders to indicate whether issues raised in 2004 were still relevant and to identify any new issues.

Stakeholders provided additional comments by written submission, email and/or telephone following these meetings. In addition, individual telephone discussions were held with key medical and nutritional experts specifically in relation to VLED products. FSANZ representatives also met with the Therapeutic Goods Agency in Australia and Medsafe in New Zealand to discuss FSMP and the food/medicine interface.

A summary of information, by issue and stakeholder group, as gathered through the above consultation activities is provided in the following table.

Key issue / Stakeholder group	**Comments**
Very low energy diet (VLED) products ***FSANZ raised a number of issues with stakeholders relating to the current VLED market, use of VLED products, differentiation of VLED products from other formulated weight loss foods, and access and advertising of VLED products.***	
Industry	*Current VLED market* Noted that the range of VLEDs has increased since 2004 to include soups, bars etc. The range and volume of weight loss products, including VLEDs, manufactured in Australia is increasing with some products being exported to the United Kingdom, Ireland and India. *Differentiation of VLED products from other formulated weight loss foods* Noted confusion between formulated meal replacements and VLED products, and the resulting problems for the enforcement of these products.

Key issue / Stakeholder group	Comments
	Use of VLED products Rarely used as a sole source of nutrition for more than 2-3 weeks, and compliance is generally poor unless the consumer is hospitalised. VLED programs include support for consumers and training for pharmacists and pharmacy assistants. Support for a minimum age of 18 years for use of VLED products and BMI of greater than 27, unless on medical recommendation.
Jurisdictions	*Differentiation of VLED products from other formulated weight loss foods* General agreement that consumers are not able to differentiate between VLED products and formulated meal replacements; consider it is highly likely that consumers use VLED products as meal replacements. Acknowledged that enforcement of these products is difficult. Questioned whether VLED products and meal replacements could be placed in the same standard; with the same criteria applied to all weight loss products. *Use of VLED products* Except for one reported case, jurisdictions were not aware of any problems or complaints associated with the use of VLED products or other formulated food products. *Access and advertising of VLED products* Generally supportive of the proposed restrictions on access to VLED products. Concern raised that VLED products can be promoted and sold by unskilled pharmacy assistants and therefore may be purchased and used by consumers with no medical supervision. Suggested consideration of non-regulatory options to manage the positioning of VLED products within the pharmacy setting. Raised concern about the relationship of VLED products to S2 and S3 medications in relation to advertising of these products. Suggested use of a so-called “complaints committee” to oversee advertising content. Acknowledged that the internet was a source of VLED products and individuals can access them easily through this means.
Health Professionals	*Use of VLED products* Reported wide variation in the use of VLED products, ranging from over-the-counter unsupervised use through to preparation for bariatric surgery under medical supervision. Noted that consumers commonly use VLED products as meal replacements, and that these products are frequently used in conjunction with other foods. Agreed that exiting evidence on VLED products suggest they are most effective when used in combination with a lifestyle education program.

Key issue / Stakeholder group	Comments
	Considered the use of VLED products and weight loss meal replacements had increased since 2004, but were not aware of any quality evidence on usage by consumers. Reported on observed adverse effects from the use of VLED products without medical supervision, including loss of lean body mass, micronutrient imbalances and rebound weight gain. *Differentiation of VLED products from other formulated weight loss foods* Considered it unlikely that consumers are able to differentiate between VLED products and other formulated weight loss foods. Noted that unsupervised/non-prescribed meal replacements and VLED products are being used interchangeably. This can be hazardous for vulnerable groups such as children and the elderly. Suggested that formulated meal replacements and VLED products should be regulated under one standard in the Code. *Access and advertising of VLED products* General concern about the ease with which VLED products can be purchased from pharmacies and via the internet. Agreed that VLED products are frequently used without medical supervision. Commented that consumers are now more likely to purchase VLED products over the internet, though the proportion of online sales is unknown. Expressed concern over the lack of internet regulation and the risk of misuse when VLED products are purchased by this means. Considered that pharmacists have a 'duty of care' to clients and ultimate responsibility for products sold in their pharmacies. Noted that there is a process in place for the sale of VLED products in pharmacies; assistants are usually trained to ask a series of questions and high risk individuals are referred to the pharmacist. However, there is no standardised requirement to record sales of VLED products in pharmacies.
Current FSMP market ***FSANZ asked stakeholders if the range of FSMP products (excluding VLED products) and their sources had changed since 2004.***	
Industry	Noted that the range of FSMP products available includes enteral feeds, oral supplements and sip feeds, and that the range is increasing for specific purposes (e.g. wound healing and home enteral nutrition). Stated that the majority of enteral feeds and oral supplements are imported from Europe and the USA. One manufacturer reported that growth within its Australian business in the last three years indicates an increase in local demand for FSMP.
Jurisdictions	Information not gathered on this issue.

Key issue / Stakeholder group	Comments
Health Professionals	Information not gathered on this issue.
Composition – minimum and maximum requirements for micronutrients of nutritionally complete FSMP (other than VLEDs)	
Industry	Support for compositional requirements to align with European regulations rather than USA regulations, which are less specific. Also, support for requirements to align with CODEX STAN 180-1991. General support for aligning minimum requirements for micronutrients with European regulations for vitamins A and D, calcium, selenium and copper. Minimum requirements for calcium and molybdenum still a concern for some manufacturers. Noted that some medical conditions require composition outside the proposed range, and therefore more flexibility is required to formulate products for special medical conditions. Requested more generic requirements to accommodate future innovation; noting the European regulations which permit blanket exemptions from compositional requirements according to disease conditions. Noted that it would be difficult, or impossible, to provide an exhaustive list of medical conditions that require products with a formulation outside the proposed compositional limits.
Jurisdictions	Information was not gathered from jurisdictions on this issue.
Health Professionals	Many health professionals noted the need for some flexibility in compositional requirements for FSMP designed for certain medical conditions. Provided examples of medical conditions that may require product formulations outside of the proposed minimum and maximum limits, including renal disease, liver disease and conditions requiring ketogenic diets.
Composition – permitted forms of substances added to FSMP	
Industry	Supported updating the schedule of permitted substances in draft Standard 2.9.5 in accordance with the updated PARNUTS directive and US GRAS list.
Jurisdictions	Information not gathered on this issue.
Health Professionals	Information not gathered on this issue.
Composition – food additives and processing aids in FSMP	

Key issue / Stakeholder group	Comments
Industry	Support for the provisions in Standard 1.3.1 to apply to FSMP, as well as additives deemed safe for use in FSMP by international authorities (i.e. CODEX, EU and USA FDA).
Jurisdictions	Information not gathered on this issue.
Health Professionals	Information not gathered on this issue.
Proposed restriction on the sale and advertising of FSMP (other than VLED)	
Industry	General view that there is no evidence of market failure. Some stakeholders commented that Australian consumers were adequately protected by the *Trade Practices Act*, and therefore further advertising restrictions are not required for FSMP. Some industry stakeholders proposed allowing direct advertising of oral FSMP supplements to consumers and sale in supermarkets. Noted increasing malnutrition in the community setting (outside hospital) due to the ageing population, and therefore a need to provide information to consumers regarding appropriate products. Noted that consumers purchase FSMP via the internet without access to medical supervision. Suggested a pragmatic approach as sales via online pharmacies are increasing and these sales currently fill the supply gap for remote areas.
Jurisdictions	Agreed with the proposed restriction on the sale of FSMP. General agreement that FSMP (other than VLED products) are not advertised inappropriately.
Health Professionals	General support for restrictions on the sale and advertising of FSMP. Some representatives commented that restrictions on advertising would be of little value due to the advertising of FSMP products to consumers on the internet. Noted that FSMP products are accessed through PBS, PHARMAC, wholesalers, pharmacies and internet pharmacies. It was also noted that some pharmaceutical companies in New Zealand sell directly to consumers. One representative suggested use of a disclaimer page on websites to protect consumers.
Labelling – allergens	
Industry	Support for an exemption from allergen labelling for imported products. Noted that labelling requirements that are not consistent with overseas regulations would have significant implications for industry and consumers. The cost of over-labelling may not be justified given the small Australia/New Zealand market and may result in reduced local supply of FSMP.

Key issue / Stakeholder group	Comments
Jurisdictions	Questioned the rationale for the proposed exemption for FSMP from allergen labelling.
Health Professionals	General concern regarding the proposed exemption from allergen labelling, as this requirement would help to protect public health and safety. Noted that allergen labelling on FSMP would benefit consumers and health professionals, especially as obscure ingredients can be difficult to identify as potential allergens. Though one representative considered that the absence of labelling on FSMP is inconsequential because they are used under medical supervision and the doctor/dietitian must know the composition to advise the use of the product. A key stakeholder recommended internationally standardised allergen declarations for FSMP. Notes use by food industry of the Voluntary Incidental Trace Allergen Labelling (VITAL) system, which appears to be assisting food allergic consumers to make informed choices. Recommended allergen labelling on individual FSMP bottles and packets to reduce consumer risk, and would like the listing to extend to FOLFAP ingredients.

5. Submissions on the Consultation Paper 2010

In December 2010, FSANZ released a Consultation Paper for public comment. The Consultation Paper proposed a number of questions for comment by submitters, specifically:

Q1	Will the recommended level of 200 mg/kg of saccharin in FSMP pose any problems for current formulations of FSMP products imported into Australia?
Q2	Is there a justified technological need for the addition of Schedule 4 colours to FSMP?
Q3	Are FSMPs used in the management of FBDs and/or IBD (including during hospitalisation)?
Q4	What is the prevalence of FBDs and/or IBD in consumers of FSMPs?
Q5	Do FOLFAPs exacerbate FBDs and/or IBD in consumers of FSMPs that are used in the management of these conditions.
Q6	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.
Q7	Will the revised restriction on the sale of FSMP result in any difficulties in the sale of, or access to FSMPs.
Q8	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?
Q9	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?
Q10	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?

FSANZ received 18 submissions in response to the Consultation Paper during the public consultation period of 15 December 2010 to 9 February 2011. A summary of submitter comments is provided in the following table.

Submitter	Comments
Industry	
Abbott Nutrition Australia / New Zealand *Kelly Snowden*	***Q1 Recommended level of saccharin*** Agrees with the recommended level of 200 mg/kg of saccharin for use in FSMP products and does not see any potential problems for current formulations of FSMP imported into Australia. ***Q2 Schedule 4 colours*** Notes the importance of harmonisation with international regulations given the small size of the FSMP market in Australia and New Zealand. Considers that Schedule 4 colours should be part of this harmonisation, specifically permissions should be aligned with EU Directive 94/36/EC. Abbott currently uses two Schedule 4 colours (Sunset Yellow and Allura Red) in a variety of oral nutrition support supplements. Notes that these colours are heat stable and have excellent stability over the shelf life of the product. ***Q3 Use of FSMP in management of FBDs and/or IBD*** States that FSMP are used in the dietary management of FBDs and/or IBD. Specifically there is a role for the provision of specific fibre ingredients, particularly short-chain fructooligosaccharides (scFOS), in patients with gastrointestinal discomfort. The mechanism is thought to be prebiotic in origin. Provides scientific evidence to support the utility and function of fermentable oligosaccharides, in particular scFOS, in consumers of FSMP and those with IBD. ***Q5 FOLFAPs and FBDs and/or IBD*** Considers that grouping FOLFAP ingredients together under one acronym in relation to gastrointestinal intolerance is inappropriate because they elicit distinct physiologic responses. Considers that for individuals using FSMP to manage FBDs and/or IBD, FOLFAP ingredients (including polyols, lactose, fructose and fermentable oligosaccharides) may exacerbate gastrointestinal symptoms if consumed at levels exceeding the tolerable level. ***Q6 & 7 Restriction on the sale of FSMP*** Does not agree with a restriction on sale for all FSMP products given that some products are available for purchase over the internet. Provides examples of online pharmacies where FSMP can be purchased with little or no medical advice and limited access to product information. Agrees there should be a mechanism for provision of health professional advice with use of specialised FSMP. However, notes that in practice this is minimal even when FSMP are purchased from pharmacies and labelled “use only

Submitter	Comments
	under medical supervision". Considers that a distinction should be made between products specifically formulated for disease states and oral nutrition support supplements. The restriction on sale should only apply to specialised FSMP whereas oral nutrition support supplements should be made available more freely, including in supermarkets to facilitate ease of access for consumers. Notes that in most international markets oral nutrition support supplements can be purchased from supermarkets and advertised directly to consumers. ***Q8 Inner package labelling*** States that most Abbott Nutrition products available in Australia and New Zealand are sold as cartons or cases (not as individual units), and therefore inner package labels currently contain the following information: • product name and intended use; • nutrition information panel and ingredients list; • instructions for use and storage; • best before or use-by date; • batch number; and • a statement to the effect that the product is a FSMP and should be used under medical supervision. Allergen information is included in the ingredients list and in most cases is highlighted in bold. Additional supporting information is available to health professionals and consumers where limitations on packaging size and format size arise. Notes that given Australia and New Zealand are a small part of the global FSMP market, any further labelling requirements or restrictions would result in a cost increase or potentially withdrawal of the product(s) from the market. ***Q9 Identification of FOLFAP content*** Considers that current FSMP labels provide sufficient information (ingredients list, nutrition information and/or claims) to determine the content of FSMP products, including the levels of FOLFAPs. ***Q10 Supporting material regarding FOLFAP content*** Notes that supporting material provides additional descriptive information for the nutrient and ingredient composition of FSMP. ***Additional comments*** *Chromium picolinate* Requests that chromium picolinate is permitted as a source of chromium with no set maximum limit for use in FSMP. Provides information to support the request, including data on safety and efficacy, and relevant international regulations. *Variation from the minimum / maximum micronutrient levels* Considers there is a need for flexibility in the macro- and micro-nutrient content of FSMP to meet the nutritional needs of

Submitter	Comments
	patients with specific diseases or conditions. Recommends that the micronutrient minima and maxima are aligned with Codex STAN 180-1991.
Australian Food and Grocery Council *Kim Leighton*	***Q5 FOLFAPs and FBDs and/or IBD*** Considers that although FOLFAP ingredients may be problematic for some people who consume FSMP this should not be grounds for restricting their use for the benefit of the wider population. Considers there is limited clinical evidence to support a link between FOLFAPs and bowel symptoms, and that other factors may increase susceptibility too (e.g. stress and immune factors). Recommends consistency with international regulations in regard to the use of FOLFAPs in FSMP. ***Q8 Inner package labelling*** Recommends that mandatory labelling requirements for FSMP, especially inner packaging, are kept to a minimum. Essential information relating to date marking, allergen content and other relevant health and safety information should be mandated, while external packaging should provide the general information prescribed in Standard 2.9.5. ***Additional comments*** *Restriction on advertising* Supports a limit on advertising and promotion of FSMP provided it does not restrict the ability of companies to provide information to health professionals who are supervising consumers of FSMP. *Permitted nutrients and related substances* Supports the permission for 19 new forms of nutrients / related substances and 11 food additives to be added to FSMP, and recommends that permissions are aligned as closely as possible with EU and USA regulations. *Labelling – variation from the minimum / maximum* States that labelling is not the primary mechanism for providing information on which health professionals use to make a decision as to whether a product is suitable for a consumer. Recommends that additional labelling requirements for nutritionally complete products that vary from micronutrient requirements are kept to a minimum, especially if detailed information for health professionals is provided elsewhere, such as the internet.
Complementary Healthcare Council (CHC) *Kristy Tomas*	***Q6 & 7 Restriction on the sale of FSMP*** Supports a restriction on sale of FSMP to outlets where a health care professional is present. Recommends that the definition of health care professional align with that defined in the *Therapeutic Goods Act 1989*, which includes herbalists, naturopaths etc. Subsequently, Clause 4 of draft Standard 2.9.5 would also need to be expanded to include health food stores, naturopath clinics etc.

Submitter	Comments
	Additional comments *Draft Standard 2.9.5* Suggests that the model for listed 'practitioner only' complementary medicines be used as a basis for the FSMP standard. Suggests amendments to the definition of health care professional and Clause 4 as mentioned above. *Health claims* Strongly supports that any health claims for FSMP be supported by appropriate evidence.
Food Technology Association of Australia (FTAA) *Rob Richards*	***Q2 Schedule 4 colours*** Recommends that Schedule 4 colours be permitted for addition to FSMP as Schedule 3 colours will be permitted and it would also be consistent with permissions in other categories, such as meal replacements. Notes that colours are added to food to enhance the appearance and make the food appealing, which is an important factor for consumers of FSMP. ***Additional comments*** Accepts the reasons for removing VLED products from Standard 2.9.5 though is concerned about the resulting delay in the development of a standard for these products.
Nestlé Australia Ltd and Nestlé Nutrition *S. Rajczyk*	***Q1 Recommended level of saccharin*** States that the recommended level of saccharin will not pose problems for Nestlé FSMP products currently imported into Australia as they contain less than 200 mg/kg of saccharin. ***Q3 Use of FSMP in management of FBDs and/or IBD*** Notes that FSMP are used in the nutritional management of IBD, including during hospitalisation. For example, exclusive enteral nutrition is a first-line treatment for active Crohn's disease in children and adolescents; provides references to support efficacy in the induction of remission, together with other nutritional and inflammatory benefits. Notes that FSMP are more commonly used for the management of secondary problems relating to FBDs, such as malnutrition. ***Q5 FOLFAPs and FBDs and/or IBD*** Advises that many people with acute illness such as gastrointestinal inflammation may be temporarily intolerant to lactose and fructose, which could result in diarrhoea, abdominal pain and potentially malabsorption. Notes that most nutritional

Submitter	Comments
	products designed to treat those with IBD are either lactose free or low lactose, though are not necessarily low or devoid in fructose. States the use of FOS can benefit individuals with IBD and FBDs, especially if used when the disease is not in the acute phase. States that FOS may be used to treat diarrhoea. ***Q6 & 7 Restriction on the sale of FSMP*** Considers the revised restriction on sale accurately reflects current sale and access arrangements. Considers the revised restriction on sale will not result in any difficulties in the sale of, or access to FSMP. ***Q8 Inner package labelling*** Agrees with the proposal for labelling of inner packages. Nestlé currently labels inner FSMP packages with: • product name • product description • allergen information • lot code • date coding • net weight statement • directions for use • manufacturer's name. ***Q9 Identification of FOLFAP content*** Considers that the ingredient list provides sufficient information for health professionals to identify whether the product contains FOLFAP ingredients. All added fructose, lactose, inulin, FOS and GOS ingredients are stated in the ingredient list of Nestlé products. In addition, supporting information is provided to health care professionals by field operators and is also available on a website. Health care professionals can access a full list of Nestle products that do not contain FOLFAP ingredients. Considers that the combination of these measures provides sufficient information to the health care professionals and consumers that require it. ***Additional comments*** *Permitted nutrients and related substances* Proposes the following additional additives are approved for use in FSMP: • Phosphoric acid, potassium hydroxide and sodium hydroxide as acidity regulators, as per EU and US regulations; in addition to their current permissions as processing aids in Standard 1.3.3. • Annatto (160b) and Amaranth (123) as permitted colours at levels of GMP under Schedule 1 of Standard 1.3.1, as per EU and US regulations.

Submitter	Comments
	Draft Standard 2.9.5 Requests an editorial note is inserted in the Standard to clarify the definition of, and the sections that apply to 'nutritionally incomplete FSMP' or 'specialised supplemental formulas or foods'. *Variation from the minimum / maximum* Requests that the proposed maximum amounts for vitamin A, vitamin D, calcium and copper are aligned with EU regulations to reduce regulatory burden, as this would avoid the need for nutritionally complete products imported from the EU to be relabelled to explain the nature of the variation. Requests that FSANZ gives guidance as to the acceptable wording of the variation statement for nutritionally complete FSMP that have been modified to vary from the prescribed compositional requirements. Questions if the statement needs to include a numerical figure or if a description of the difference is enough. *Allergen labelling* Considers the allergen declaration requirements in Standard 1.2.3 do not harmonise with the EU. Ingredients derived from allergenic substances (e.g. glucose from wheat) must be declared, yet the EU is exempt from labelling certain highly refined ingredients. These inconsistencies will create the need for separate labels and will therefore restrict the availability of some products. Requests that allergen labelling requirements for FSMP align with EU and US requirements..
Nutricia *Melanie McPherson*	***Q1 Recommended level of saccharin*** The recommended level of 200 mg/kg of saccharin does not pose any problems for Nutricia products. ***Q2 Schedule 4 colours*** Does not use Schedule 4 colours in FSMP based on market feedback and consumer expectations, rather than a lack of technological justification. Supports permission for Schedule 4 colours in FSMP as: • colours enhance consumer perception of flavourings added to FSMP; • Schedule 4 colours are in general more stable to heat, oxygen and pH changes than Schedule 3 colours; and • Schedule 4 colours are considerably cheaper than schedule 3 colours. ***Q5 FOLFAPs and FBDs and/or IBDs*** Considers that grouping of FOLFAP ingredients is problematic and that this approach misrepresents the true nature of these compounds and their individual behaviour in the gastrointestinal tract. Provides scientific references for evidence that indicates inulin-like fructans (oligofructose and inulin) may be safe for individuals with inflammatory disease of the gut, including IBD. Notes that some FSMP containing inulin-like fructans for use in individuals with IBD and other inflammatory gut

Submitter	Comments
	conditions are available in the USA. ***Q6 & 7 Restriction on the sale of FSMP*** Does not consider the revised restriction on sale of FSMP will cause any difficulties in the sale of, or access to FSMP. ***Q8 Inner package labelling*** Aims to always include the following information on inner packaging: • product name • statement describing the medical purpose of the product • statement 'use under medical supervision' • appropriate warnings and contraindications • allergens • content (ml or g) • best before date. ***Q9 Identification of FOLFAP content*** Considers there is currently sufficient information on product ingredient lists and NIPs to identify FOLFAP content. ***Q10 Supporting material regarding FOLFAP content*** Nutricia uses its website to convey product information to consumers who must click on a button to qualify that information obtained through the website does not replace advice from a qualified health professional and that medical advice should be sought before consuming Nutricia products. Nutricia also has a clinical care line for customer enquiries. Overall, considers that these information channels provide an adequate alternative to label information. ***Additional comments*** *Permitted nutrients and related substances* Supports the addition of the 19 new forms of nutrients / related substances that have been added to the permitted forms list. Recommends that the permitted sources of micronutrients and amino acids be extended to capture source materials used in FSMP currently imported into Australia and to align with international regulations. Requests an explanation for why no minimum or maximum amount for fluoride is listed in Schedule 2, and suggests referring to the NHMRC Dietary Guidelines for an appropriate maximum level. *Labelling – variation from the minimum / maximum* Does not support the labelling requirement for nutritionally complete FSMP that deviate from the compositional minima and maxima to state each of the micronutrients that have been changed and to describe the change.

Submitter	Comments
	Notes that such a requirement would have an impact on trade as it is inconsistent with some international regulations, and that health professionals are more likely to refer to product compendia provided by suppliers than product labels for information. *Restriction on advertising* Supports removing the restriction on advertising. *Legibility* Supports the proposed legibility requirement. *Sole source of nutrition* Supports removing the statement "the product is intended/not intended as a sole source of nutrition." *Not for parenteral use* Supports the requirement to include the label statement 'not for parenteral use', whether the product is nutritionally complete or not. *Date marking* Supports the proposal to include date marking for FSMP and to allow flexibility in the format. *Allergen labelling* Supports allergen labelling and alignment with overseas requirements. *Lactose and gluten claims* Does not support the applicability of general labelling provisions to FSMP, which provide that 'free' means 'no presence of'. Considers that provisions for 'free from' claims for FSMP should be clinically relevant to the target population and have a sound basis in science. Requests that FSANZ consider additional provisions to allow for a level equivalent to clinically insignificant amounts.
Wyeth *Michelle Farnfield*	***Q6 & 7 Restriction on the sale of FSMP*** Believes the proposed restriction on sale is overly prescriptive and considers it unnecessary when some over-the-counter medicines are available at supermarkets and convenience stores. ***Additional comments*** *Permitted nutrients and related substances* Supports the addition of the 19 new forms of nutrients / related substances that have been added to the permitted forms listed in overseas regulations, and further supports the addition of further substances that have emerged since 2004.

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	Restriction on advertising Supports removing the restriction on advertising. Believes this is in line with Proposal P242 and FSANZ Act objectives that relate to the provision of sufficient information to health professionals and consumers to make informed choices. *Labelling requirements* Supports harmonising labelling requirements with international regulations, wherever possible, to reduce costs and burden to industry.
Jurisdictions	
Ministry of Agriculture and Forestry (MAF), New Zealand *Jenny Reid*	***Q2 Schedule 4 colours*** Supports the addition of Schedule 4 colours to FSMP, stating the technological need for these colours is no different to those in Schedule 3 and that there is no reason to treat FSMP differently to other foods in this case. Considers that food additive permissions that ensure the continued supply of FSMP in New Zealand are critical for those groups of individuals who rely on these products. ***Q6 & 7 Restriction on the sale of FSMP*** Notes that New Zealand dietitians (along with medical practitioners) can independently prescribe FSMP once they have completed the 'Dietitians Prescribers' training course. **Additional comments** *Restriction on advertising* Supports the proposal to remove the restriction on advertising of FSMP. Disagrees that the removal of the prohibition harmonises with Codex STAN 180-1991. Considers that the Codex preference is for these products not to be directly advertised to the general public, though notes that this requirement is voluntary. *Labelling* Supports labelling requirements that ensure the continued supply of FSMP in NZ. *Draft Standard 2.9.5* Seeks clarification on the term 'nursing home'. Suggests the use of 'residential care facility' to capture live-in care facilities, as this would be consistent with other New Zealand legislation. Notes that 'medical supervision' appears to be fundamental to the characterisation of FSMP products but that this intent is not realised in the draft Standard. Suggests that the purpose statement and labelling provisions be amended to reflect that these products, while freely available from restricted premises, should bear statements that they only be used on the advice of a medical practitioner or dietitian as per clause 4(b) of the draft Standard.

Submitter	Comments
	Requests clarity on the meaning of the term 'information' as used in the proposed labelling 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'*. Considers the term to be too broad and that its use may require enforcement agencies to themselves determine the amount of information necessary on the label. Concerned that the current definition of FSMP may not exclude all VLED and requests further information on how VLEDs will be excluded from Standard 2.9.5. Seeks clarification on the meaning of the term 'ordinary food', as used in clause 1(a) of the draft Standard. *New Zealand Medicines Act 1981* Notes the relationship between the restrictions on claims of therapeutic purpose in the New Zealand Medicines Act 1981 and the requirement in the clause 6(3)(b) of the draft Standard for the label on a FSMP to include a statement indicating the medical purpose of the product. The Medicines Acts 1981 applies to all 'related products', including foods. Due to the crossover, notes it is likely that the Medicines (Related Products (Exempted Foods)) Regulation 2003 will need to be amended to exempt foods that comply with Standard 2.9.5. This would be able to occur after Standard 2.9.5 is gazetted and therefore the transition period needs to account for this process. Notes that the Medicines (Related Products (Exempted Foods)) Regulation 2003 will also need to be amended when the Health Claims standard is gazetted. MAF's preference is for both amendments to be made at once, rather than on two separate occasions. *Transition period* Requests clarification on whether a two-year or four-year transition period is being proposed for New Zealand, in relation to the application of Standard 1.1A.6. *VLED products* Notes that VLED products available in New Zealand are currently regulated under Standard 1.1A.6. Seeks clarity on how it is proposed that these products will be regulated if Standard 1.1A.6 is repealed, and in the absence of a new standard specifically for VLEDs.
NSW Food Authority *Edward Jansson*	***Q6 & 7 Restriction on the sale of FSMP*** Does not support sale of FSMP by manufacturers or distributors. Believes that the restriction on the sale of FSMP does not align with the Policy Guideline on the Intent of Part 2.9 – Special Purpose Foods; it makes a mockery of the labelling requirement 'use only under medical supervision'; and it will allow less reputable businesses to start marketing and selling FSMP. ***Additional comments*** *Draft Standard 2.9.5* Does not support the proposed draft Standard. Believes it does not adequately protect consumers and ensure consumers

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	have sufficient information. Also considers that the sale and consumption of FSMP have not been sufficiently scoped. Concerned that changes relating to advertising, sale and mandatory advisory statements may result in FSMP being marketed and sold by non-health professionals with inadequate advice given to consumers. *Permitted nutrients and related substances* Does not support the automatic inclusion of substances permitted for use in infant formula in FSMP. Considers that an assessment of the appropriateness of the substance in FSMP should be undertaken. *Restriction on advertising* Does not support removing the restriction on advertising to allow direct advertising of FSMP to consumers. Considers that the proposed variation does not align with Codex STAN 180-1991; that removal of VLED products from the scope of Proposal P242 does not lessen the risk to consumers; future FSMP products may challenge the proposed regulatory approach regarding advertising; and FSMP are designed for use under medical supervision. *Labelling* Does not support removal of the statement 'the product is intended/not intended as the sole source of nutrition'. Considers the statement ensures proper usage of FSMP by health professionals and patients.
Queensland Health *Tenille Fort*	***Q1 Recommended level of saccharin*** Unaware of any adult or paediatric FSMP that contain saccharin, or reasons for its use in these products. ***Q2 Schedule 4 colours*** Not aware of any technological need for the addition of Schedule 4 colours to FSMP. ***Q3 Use of FSMP in the management of FBDs and/or IBD*** Aware that prebiotics may be used in the management of FBDs and/or IBD, but this is not routine. ***Q4 Prevalence of FBDs and/or IBD in consumers of FSMP*** Not aware of any data on the prevalence of FBDs and/or IBD in consumers of FSMP, but estimates that it is likely to be similar to the general population. ***Q5 FOLFAPs and FBDs and/or IBDs*** Prefers the use of FODMAPs rather than FOLFAPs to avoid confusion. Not aware of any data on exacerbation of FBDs and/or IBDs as a result of FOLFAPs in FSMP. Considers that tolerance to FOLFAPs will vary between individuals, but may be more problematic for individuals consuming FSMP as the sole source of nutrition. ***Q6 & 7 Restriction on the sale of FSMP***

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	Concerned that Clause 4(c) in draft Standard 2.9.5 broadens access to FSMP beyond current sale practice, and requests clarification on whether the revised wording would allow sale of FSMP from supermarkets. Supports sale of FSMP from non-government organisations (e.g. Queensland Nutrition Australia) that employ dietitians and have the capacity to provide professional advice and support. Considers that the sale of FSMP by companies/ organisations that do not provide medical or dietetic advice will place consumers of FSMP at a public health safety risk. Notes that most FSMP manufacturers offer support to consumers through access to qualified dietitians. Recommends that only distributors that offer dietetic support from a qualified dietitian be able to sell directly to consumers to more adequately protect the health and safety of FSMP consumers. Is not aware of any difficulties in the sale of or access to FSMP that would arise from the revised restrictions on the sale. ***Q8 Inner package labelling*** Does not support the proposal to exempt inner packages of FSMP not for individual sale from all labelling requirements. Considers that inner package labelling is required if the outer packaging is discarded before it reaches the end-user (e.g. health professional or consumer), which often happens in the hospital setting. In this case supporting information may not be sufficient as hospital staff cannot always access this information quickly and reliably. Recommends that inner package labels display the following information: • name of food • manufacturer/importer • ingredients • allergens • date marking • medical purpose • whether suitable for a particular age group • contraindications • whether nutritionally complete • instructions for use (when appropriate). ***Q9 Identification of FOLFAP content*** Notes that consultation with Queensland dietitians indicates there is insufficient information on FOLFAP ingredients in FSMP. Therefore, supports consideration of how to accurately display this information for health professionals and consumers. Notes that FOLFAPs will not be listed on the label if they are part of a compound ingredient and the amount of the ingredient in a product is less than 5%. Recommends consideration of the effects of exposure to FOLFAPs from such products for some individuals, especially those using complete dietary supplements.

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	Q10 Supporting material regarding FOLFAP content Considers that information provided by manufacturers in supporting material is a useful adjunct to ingredients listing, but may not be sufficient or appropriate to provide information on the potential health and safety risks from the presence of FOLFAPs in FSMP in all circumstances. ***Additional comments*** *Labelling requirements* Supports the requirement for a statement on the medical purpose of the product, including any conditions, diseases or disorders for which the product has been specifically formulated. Suggests that powdered FSMP products are labelled with the number of serves per package to allow consumers to compare liquid and powdered forms to choose the most convenient and economical product. Does not support removal of the statement 'the product is intended/not intended as the sole source of nutrition'. This assumes dietitians and other health professionals are familiar with all FSMP on the market. This information needs to be available where there is an absence of dietitians, e.g. in some aged-care and disability services and in rural and remote areas. *VLED products* Supports removal of VLED products from the scope of Proposal P242. *Permitted nutrients and related substances* Requests the rationale for extending the list of permitted substances in FSMP to include those listed in Standard 2.9.1. *Restriction on advertising* Does not support removal of the restriction on advertising to allow direct advertising of FSMP to consumers. States FSMP are not suitable for the general population and that there is a risk that consumers will self-diagnose and self-manage their conditions. Considers this has the potential to cause harm, for example, through drug-nutrient interactions. Considers that the statement 'use only under medical supervision' does not sufficiently protect consumers from inappropriate use. *Allergen labelling* Does not support exemption on allergen labelling as information on the presence of allergens is important for the safe and appropriate use of FSMP.

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	Legibility Supports the application of Standard 1.2.9 – Legibility Requirements to FSMP in the draft Standard. *Date marking* Supports flexibility with the format of date marking to account for different international date marking requirements. *Lactose and gluten claims* Supports the proposal to apply clauses 15 and 16 of Standard 1.2.8 – Nutrition Information Requirements to lactose and gluten claims for FSMP.
South Australia Health *Joanne Cammans*	***Q1 Recommended level of saccharin*** Is not aware that the recommended level of 200 mg/kg saccharin would pose any problem for current formulations of FSMP. ***Q2 Schedule 4 colours*** Is not aware of a technological need to add Schedule 4 colours to FSMP. ***Q3 Use of FSMP in the management of FBDs and/or IBD*** FSMP can be used in the treatment of FBDs and/or IBD, or as nutritional support for malnourished patients with these conditions. ***Q5 FOLFAPs and FBDs and/or IBDs*** Anecdotal feedback from dietitians working in the disability sector is that the prevalence of FBDs and/or IBD in the disabled population is unknown and often goes undiagnosed. Loose bowels and abdominal distension is often experienced by disabled patients on enteral nutrition products and does not always resolve with change in feed type, volume or rate, and it is possible that FOLFAPs may play a role in this. ***Q6 & 7 Restriction on the sale of FSMP*** Supports the proposed restriction on the sale of FSMP though suggests the following adaptions to the Standard: • For FSMP sold in pharmacies, that the advice and sale should only be performed by the pharmacist and not general pharmacy staff. • 'Distributors' should be replaced with 'distributors of medical products'. • To require a prescription from a doctor or dietitian for patients purchasing FSMP directly from manufacturers, to help ensure patient safety. Feedback from South Australian dietitians suggests the revised wording does not accurately reflect current sale and access arrangements, as doctors and dietitians do not currently sell FSMP.

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	Q8 Inner package labelling Does not support exemption of labelling requirements on inner packages, especially in regard to allergen labelling and warning and advisory statements. Considers that many health professionals will not have access to the outer packaging and will therefore have limited or no access to nutrition information. ***Q9 Identification of FOLFAP content*** Feedback from South Australian dietitians indicates there is insufficient information on labels to determine FOLFAP content in FSMP. Notes research by Monash University showing that some FSMP contain high levels of FOLFAPs, often higher than that stated in the product information. Recommends that information in FSMP nutrition information panels, including FOLFAPs, be determined by laboratory analysis to ensure maximum accuracy. ***Additional comments*** *Consistency with international regulations* Acknowledges that most FSMP are manufactured overseas and therefore considers it is essential that composition and labelling requirements set out in Standard 2.9.5 do not impair availability of FSMP in Australia and New Zealand. *Permitted nutrients and related substances* Supports the addition of new nutrients/related substances based on scientific risk assessment. Considers permissions should harmonise with overseas regulations wherever possible. Does not support the automatic inclusion of substances permitted for use in infant formula in FSMP. *Restriction on advertising* Acknowledges that much of the concern relating to advertising was originally due to the inclusion of VLED products. However, considers removing the restriction on advertising to allow free advertising to consumers would not adequately protect public health and safety. *Labelling – mandatory advisory statements* Does not support removal of the mandatory advisory statement 'the product is intended/not intended as the sole source of nutrition'. Requiring this statement will minimise inappropriate use by health professionals, support staff and consumers who may lack expert knowledge on the nutrient profile of FSMP. Notes the requirement for a statement "describing the properties or characteristics which make the product appropriate for the condition, disease or disorder." However, considers that there needs to be an independent assessment of the

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	evidence by an independent authoritative body before such statements are made to avoid health professionals and consumers from being misled as to the benefits and uses of products.
The Department of Health and Human Services, Tasmania *Judy Seal*	***Q6 & 7 Restriction on the sale of FSMP*** Supports restriction on the sale of FSMP. Considers this helps to ensure individuals receive professional advice and therefore protects public health and safety. However, recommends further consideration of the term 'distributor' to ensure consumers receive professional advice with the purchase of FSMP. ***Q8 Inner package labelling*** Does not support removal of the requirement to label inner packages of FSMP. Refers to the Policy Guideline on Intent of Part 2.9 – Special Purpose Foods, which states the need for adequate information including labelling to assist consumers. Notes that in Tasmania, FSMP are frequently provided to patients as individual items. Labelling on inner packages allows health professionals/consumers to check the product before consumption, which is particularly important for allergens. Also, no information on inner packages may lead to consumers receiving the incorrect product. ***Additional comments*** *VLED products* Supports removal of VLED products from Proposal P242. *Restriction on advertising* Acknowledges the rationale for removing advertising restrictions though considers that direct advertising to consumers may lead to potential adverse outcomes. Recommends a commitment to monitoring the impact on usage of FSMP if the restriction on advertising is lifted. *Labelling requirements* Supports proposal to apply allergen declaration requirements (Clause 4 of Standard 1.2.3), legibility requirements (Standard 1.2.9), date marking requirements and lactose and gluten free claims. *Labelling – mandatory advisory statements* Concerned about removal of the mandatory advisory statement 'the product is intended/not intended as the sole source of nutrition' for the following reasons: • It cannot be guaranteed that individuals will receive advice from appropriately trained health professionals, which may result in FSMP being used inappropriately. • With the potential growth in FSMP and increasing demands on health professionals, it is unrealistic for health professionals to have a thorough knowledge of all products on the market. • The statement provides a safety net to ensure health professionals are aware that some products should not be used

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	as the sole source of nutrition and would therefore protect the consumer.
Department of Health Victoria **(and the departments of Primary Industries and Business and Innovation)** *Fiona Jones*	***Q1 Recommended level of saccharin*** Is not aware that the recommended level of 200 mg/kg saccharin will pose any problem for current formulations of FSMP. ***Q2 Schedule 4 colours*** Is not aware of a technological need to add Schedule 4 colours to FSMP. ***Q3 Use of FSMP in the management of FBDs and/or IBD*** Notes that FSMP are not commonly used to specifically treat FBDs and/or IBD, however they are often used in these patients groups where nutritional needs are unable to be met through food alone. ***Q4 Prevalence of FBDs and/or IBD in consumers of FSMP*** Provides information from the Monash University Eastern Health Clinical School on the prevalence of FBD in the general population: • 1 in 7 have irritable bowel syndrome • 1 in 100 have coeliac disease • 1 in 200 have irritable bowel disease Considers the prevalence of FBD in users of FSMP would be similar to levels in the general population. However, temporal bowel disorders can occur (e.g. during and following gastroenteritis or with antibiotic use) and for this reason, the prevalence of FBDs in FSMP consumers is likely to be higher than the general population. ***Q5 FOLFAPs and FBDs and/or IBDs*** Notes there is limited research that specifically investigates the effect of FOLFAPs in FSMP on individuals with FBD. However, notes that it is generally recognised that poorly absorbed substances such as lactose are problematic for users of FSMP, and for this reason most FSMP are lactose free. Notes recent research at Monash University indicates that some FSMP have very high levels of FOLFAPs, often at levels that cause symptoms in individuals without FBDs. Notes bowel issues such as bloating and diarrhoea are common in users of FSMP and there is increasing discourse among health professionals about the role of FOLFAPs. ***Q6 & 7 Restriction on the sale of FSMP*** Considers the revised wording of the draft Standard 2.9.5 unintentionally broadens sales restrictions of FSMP beyond current sales practice. Considers current access to FSMP via pharmacies, hospitals, aged-care facilities, dietitians, from certain wholesalers and from manufacturers (where individuals have a prescription from a medical practitioner or dietitian), is appropriate and

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	allows for medical or dietetic supervision. Requests that the term 'distributor of a manufacturer of foods for special medical purposes' is clarified in the draft Standard, as it does not adequately protect the restriction on access to these products. Requests that 'nursing home' is more clearly defined, stating a nursing home is specifically a high level aged care facility, yet individuals in low level care may also access FSMP. Considers the inclusion of 'medical practitioner' is questionable as while doctors prescribe FSMP they do not sell them, and this situation is unlikely to change. Considers it unnecessary to include medical practitioners in the permissions given access to FSMP though pharmacies. ***Q8 Inner package labelling*** Does not support exemption of inner packages of FSMP from labelling requirements. Notes that feedback from some tertiary hospitals, smaller hospitals and healthcare facilities indicates FSMP are delivered to ward level without outer packaging. The proposed exemption could result in vital information being unavailable to health professionals, in particular medical and nursing staff who are not familiar with the nutritional characteristics of FSMP. Considers inner packages should contain the following information: ingredients, nutrition information, allergen labelling, date marking, the medical purpose of the product, the target group, whether the products is complete and in what quantity. ***Q9 Identification of FOLFAP content*** Notes that feedback from dietitians is that there is insufficient information on the FOLFAP content of FSMP, and that patient care could be maximised if this information was made available either on product labels or manufacturer websites. Notes that research by Monash University shows that labelling of FOLFAP content in FSMP can be inaccurate if levels are determined using the ingredients list rather than standardised laboratory analysis. Recommends that any labelling requirements for FOLFAP content are based on laboratory analysis rather than ingredient lists. ***Additional comments*** *Draft Standard 2.9.5* Requests that the purpose of the Standard clearly sets out the policy purpose; what it aims to achieve rather than a description of what is included in the Standard (example provided). Considers it imperative that the definition of FSMP is sufficiently clear to exclude those foods which are positioned as complementary medicinal foods, or which make unsubstantiated claims about treating diseases (example provided). Considers that the definition of 'transportation outer' should be provided in Standard 1.1.1 (and apply across the Code) rather than in Standard 2.9.5 to avoid confusion and to be consistent with good drafting practice.

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	Permitted nutrients and related substances Supports inclusion of all substances currently listed in the EU regulations for FSMP, as relevant noting that the EU regulations cover a wider range of FSMP products than the proposed draft Standard for Australia and New Zealand. This will ensure compliance of all current products on the Australian market. Does not support extending the permitted substances to include those listed in Standard 2.9.1 – Infant Formula Products, as considers that no rationale has been given for doing so. *Composition – minima and maxima* Supports setting minimum and some maximum compositional requirements for those FSMP represented as nutritionally complete, especially as these products are often used for extended periods of time. Concerned about the adoption of the EU minima and maxima for the following reasons: • The European requirements are based on the normal population requirements of males over the age of 18 years. Considers that Australian values of population requirements should be equally appropriate. • The minima and maxima should be based on current evidence, noting that the NRVs for Australia and New Zealand were published more recently (in 2006) than the European requirements (published in 1992). • Many of the proposed minimum levels are below the 2006 RDIs for adult males over 18 years, which may have implications on the nutritional status of individuals using FSMP as the sole source of nutrition over extended periods of time. Requests further information on whether FSMP on the market in Australia and New Zealand meet the local RDIs. If so, considers that the trade implications of using the Australia and New Zealand RDIs would be negligible. Considers it appropriate that variations for specific nutrients for products aimed at children aged between one and ten years are considered. *Variation from the minima and maxima* Supports exemption of products designed for specific medical conditions from the compositional minima and maxima, and also supports the associated labelling requirements. *Restriction on advertising* Considers there is no clear rationale for removing the restriction on advertising of FSMP, given that these products are not appropriate for use by the general population and the restrictions would be consistent with current practice. Concerned that removing the restriction may result in more individuals accessing FSMP through pharmacies or other outlets and using them inappropriately without medical or dietetic supervision. Likens the situation to that of toddler milk and sports foods which are often used inappropriately. Considers that if the restriction on advertising is lifted there should be a commitment to review the use and access to

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	FSMP in 3-5 years to determine whether there has been an increase in inappropriate use. *Allergen labelling* Agree with the decision to apply to FSMP the allergen declaration requirements in clause 4 of Standard 1.2.3. *Legibility* Support applying Standard 1.2.9 on legibility requirements to FSMP. *Sole source of nutrition* Do not support the removal the mandatory advisory statement "the product is intended/not intended as the sole source of nutrition". In addition to this statement, recommends that labels of nutritionally complete FSMP must also state the volume of the product required to meet population requirements, for the following reasons: • Dietitians cannot be familiar with every FSMP product given the large number of products available. • Access to this information via manufacturer websites is not available in all clinical situations. • Other health professionals who manage patients on FSMP are generally not familiar with the nutritional composition of FSMP or where information on FSMP can be sourced. • To assist health professionals to ensure that individuals are consuming sufficient quantities of FSMP to meet their nutritional requirements, or whether certain nutrients need to be individually monitored. *Date marking* Agrees that date marking requirements listed in Standard 1.2.5 should be applied to FSMP, while allowing some flexibility to account for overseas date marking requirements. *Lactose and gluten claims* Supports applying the lactose and gluten claim requirements outlined in clauses 15 and 16 of Standard 1.2.8 to FSMP.
Health Professionals	
Anaphylaxis Australia Inc. (AAI) *Maria Said*	***Additional comments*** *Allergen labelling* Supports allergen labelling on FSMP. Does not support the exemption proposed for allergen labelling on inner packages for the following reasons: • A precautionary approach should be adopted and in the absence of evidence the existing requirement (in accordance with Standard 1.2.3) should remain. • Despite increasing awareness of food allergy among health professionals, a knowledge gap still exists. Attempts to alert, remind and assist health professionals to provide safe food free of allergens should be supported through food

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	standards. • In the hospital setting, the potential for error is greater with a formulated product in a bag compared with a plated meal where food allergens are more visible. • The likelihood of food allergens being present in FSMP is high. • Manufacturers currently list food allergens on inner packages therefore maintaining the requirement will not pose an additional burden to industry.
Coeliac Society of Australia (CSA) *Graham Price*	***Q8 Inner package labelling*** Does not support the exemption proposed for allergen labelling on inner packages, as there is no convincing rationale and the exemption would place consumers at an increased public health and safety risk. ***Additional comments*** *Allergen labelling* Supports the application of the allergen declaration requirements in clause 4 of Standard 1.2.3 to FSMP, which would include declaration of cereals containing gluten and their products as well as other allergens. *Lactose and gluten claims* Notes that it has repeatedly sought a tolerance of 20 mg/kg for gluten-free claims. Acknowledges that it is a complex matter but requests that FSANZ take a more proactive role to seek changes to the ACCC legislation to permit gluten-free claims on foods containing up to 20 mg/kg gluten in line with the EU.
Dietitians Association of Australia *Bree Murray*	***Q3 Use of FSMP in the management of FBDs and/or IBD*** Notes that FSMP are used in the management of FBDs and IBD, either as a form of treatment or to provide nutritional support for individuals who cannot meet their nutritional requirements through a normal diet. Temporary functional bowel disorders can occur in individuals consuming FSMP. Careful selection of FSMP is necessary during these periods e.g. avoid those containing lactose. ***Q4 Prevalence of FBDs and/or IBD in consumers of FSMP*** Considers it is difficult to determine prevalence of FBDs and IBD in consumers of FSMP. Outlines three different patient groups with FBD: 1. Patients with IBD that require sole use of FSMP for resolution of inflammatory symptoms. 2. Patients with various bowel disorders who do not usually consume FSMP to manage their symptoms but require FSMP for other medical reasons. 3. Patients who regularly use FSMP and acquire a temporary FBD e.g. due to gastroenteritis or medication. States the estimated prevalence of inflammatory bowel disease is at 1 in 200 and of irritable bowel syndrome is 1 in 7.

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	Q5 FOLFAPs and FBDs and/or IBD Considers the use of the term FOLFAPs is confusing and unnecessary. Notes anecdotal evidence that FSMP that contain FOLFAPs cause adverse reactions though very little research is available. FSMP intolerance is common in hospital patients, particularly in those on enteral feeds, which has implications for recovery and can extend hospital length-of-stay. States that it is well established that FOLFAPs such as lactose exacerbate FBDs, but there is limited evidence on other FOLFAPs. Notes analyses undertaken by Monash University indicates that some FSMP contain over five times the FOLFAPs found in a typical diet. States that FOLFAPs can have a laxative effect and therefore it is feasible that high doses of FOLFAPs will increase the risk of bowel symptoms, even in those without underlying bowel disorders. Furthermore, a retrospective study (reference provided) found that the FOLFAP content of enteral formulas was the only factor independently associated with the development of diarrhoea. ***Q6 & 7 Restriction on the sale of FSMP*** Supports the proposed restriction on the sale of FSMP and considers it is likely to broaden rather than restrict sale, or access to, FSMP. Notes that FSMP are currently available through hospitals, care facilities, pharmacies, dietitians, manufacturers of FSMP (with a prescription) and some medical wholesalers. Recommends that pharmacists are directly involved in the sale of FSMP through pharmacies to enable screening of consumers. Concerned about the phrase “distributor of a manufacturer”, as this could refer to any business that purchases FSMP from a manufacturer, such as health food shops, gyms and online companies, where medical or dietetic supervision is unavailable. Suggests providing a definition for ‘medical wholesaler’ to prevent inappropriate sale of FSMP. ***Q8 Inner package labelling*** Considers that removing the requirement to label inner packages is a significant safety issue, given that outer packaging is often discarded before reaching the end user. Recommends that individual FSMP packages list: ingredients, nutrition information, whether a product is nutritionally complete, allergy information, what the product is intended for, target age groups and use-by dates. ***Q9 Identification of FOLFAP content*** Considers that there is currently insufficient information on ingredient lists and nutrition information panels (NIP) to identify FOLFAP ingredients in FSMP.

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	Notes it would be useful to have total FOLFAP content on the NIP. ***Q10 Supporting material regarding FOLFAP content*** Considers that supporting material on FOLFAP content is a useful alternative to information on the ingredients list or NIP but that the content would need to be determined by standardised laboratory analysis. ***Additional comments*** *Draft Standard 2.9.5* Concerned that the current definition of FSMP may allow some products to inappropriately position themselves as FSMP and make unsubstantiated health claims. *Restriction on advertising* Does not support removing advertising restrictions for FSMP. *Labelling – sole source of nutrition* Supports use of the phrase "the product is intended/not intended as the sole source of nutrition." Disagrees that health professionals do not require this information because they are familiar with FSMP, noting that they are not always familiar with the intricate details of FSMP. This also applies to other health professionals who monitor patients on FSMP. Recommends information on the use of FSMP as the sole source of nutrition should be included on outer and inner packages. Recommends that for nutritionally complete FSMP, the label should state the volume of FSMP required to be nutritionally complete for a specified reference e.g. EU reference of male 18 years and over, 2000 kcal/day. Also recommends that information on NRVs/RDIs is readily available so health practitioners can determine the volume of FSMP required to meet nutritional requirements.
Dietitians NZ *Jan Milne*	***Additional comments*** *Labelling – mandatory advisory statement* Recommends that the mandatory advisory statement 'use under medical supervision' is expanded to 'use under medical or dietetic supervision'. This would recognise the ability for New Zealand registered dietitians to prescribe PHARMAC subsidised special foods and related products, including FSMP.
Department of Nutrition and Dietetics, Westmead Hospital *Susan Thompson*	***Q6 & 7 Restriction on the sale of FSMP*** Considers the revised restriction on the sale of FSMP reflects current sale and access arrangements for FSMP in Australia and would not appear to present any difficulties in the sale or access to FSMP. ***Q8 Inner package labelling***

Submitter	Comments
	Concerned about the proposed exemption of inner packages of FSMP from all labelling requirements. States that the inner packet should be labelled with the following: • name of the product • weight of product • batch number • expiry date Notes that for patients with inborn errors of metabolism, who may use several FSMP for dietary management, there is potential for products to be confused if inner packages are not labelled, and this could have serious clinical repercussions. ***Q9 Identification of FOLFAP content*** Notes that they would tend to rely on information from the manufacturer about FOLFAP content, rather than labelling. ***Additional comments*** *Restriction on advertising* States that the removal of the restriction on advertising of FSMP is in line with current advertising on company websites. *Permitted nutrients and related substances* Considers the range of allowed nutrients/related substances and additives appears appropriate. *Composition – minima and maxima* Generally supports the approach for minima and maxima for FSMP represented as nutritionally complete, but raises two issues: 1. Concerned that creating an Australian standard that differs from North American and European standards could potentially restrict availability. In particular for those products used in small quantities in Australasia but that are essential for the management of rare conditions. Believes there is potential for manufacturers to pull out of the Australasian market if compliance is unnecessarily difficult. 2. Questions whether the proposed minima and maxima have been modelled for various age groups (e.g. do they provide adequate intake for young children as well as adults?).

6. Targeted stakeholder consultation – mid- and late-2011

In mid- and late-2011, FSANZ undertook further targeted consultation with stakeholders in response to issues raised in 2010. A discussion paper outlining the outstanding issues, FSANZ's proposed approach to issues raised previously, and a revised draft Standard 2.9.5 was provided to key stakeholders in November 2011. In addition to meetings with manufacturers, distributors of FSMP, health professionals and jurisdictions, further information or clarification was provided to FSANZ via emails and telephone discussions.

A summary of information, by issue, gathered through this targeted consultation in 2011 is provided in the following table.

Key issue / Stakeholder group	Comments
Regulatory approach ***FSANZ's preferred approach is to regulate FSMP products by a discrete Standard in Part 2.9 – Special Purpose Food of the Code, incorporating specific compositional and labelling requirements. A draft of Standard 2.9.5 was provided to key stakeholders in late-2011.***	
Industry	Support the development of Standard 2.9.5 to regulate FSMP. Emphasise the need for composition and labelling requirements to be consistent with overseas regulations wherever possible.
Jurisdictions	Support the development of Standard 2.9.5 to regulate FSMP. However, one jurisdiction considered that parts of the draft Standard were not enforceable and therefore did not support the progression of Proposal P242 until it was amended accordingly.
Health Professionals	Support the development of Standard 2.9.5 to regulate FSMP.
Definition of FSMP in draft Standard 2.9.5 ***In late-2011 the proposed definition of FSMP focussed on how these products are represented at the point of sale to allow FSMP to be distinguished from other foods.***	
Industry	The majority of industry stakeholders supported the proposed definition of FSMP.

Key issue / Stakeholder group	Comments
Jurisdictions	Some jurisdictions considered that the definition should include reference to the purpose and use of FSMP, rather than representation alone. Specifically, it was considered that reference to the use of these products under medical supervision should be included in the definition. Sought clarification on the clause in the definition that excludes foods represented as formulated for the dietary management of obesity. Recommended that formulated products for the dietary management of overweight, as well as obesity, should be captured. Considered that further clarification was needed in the definition with regard to the exclusion of infant formula products from Standard 2.9.5.
Health Professionals	Generally agreed with the proposed definition. Sought clarification of the term 'medical purposes'. FSANZ noted at the relevant meeting that this term is used broadly to reflect overseas labelling requirements and to help identify products represented as an FSMP. It was noted that in New Zealand, certain dietitians are permitted to prescribe FSMP. New Zealand dietetic representatives suggested this be noted in Standard 2.9.5.
Use of a prescribed name	
Industry	It was noted that the EU regulations require a prescribed name but the USA regulations do not. Some manufacturers were opposed to FSMP becoming a prescribed name, noting that it could have significant implications for relabelling cost and the supply of FSMP in Australia and New Zealand.
Jurisdictions	Three jurisdictions recommended that a prescribed name be required for FSMP to assist enforcement authorities identify FSMP products. To reduce costs to industry, one jurisdiction suggested that the prescribed name used could be permitted to differ depending on the place of export and the respective regulation.
Health Professionals	Not comments on this issue.
Restriction on the sale of FSMP ***FSANZ proposed a restriction on the sale of FSMP direct to consumers to protect public health and safety. Stakeholders were advised that the intent of the new wording was to balance the need to maintain the supply chain and link a sale of FSMP to medical (health professional) advice/supervision.***	
Industry	Most industry stakeholders disagreed with the proposed restriction on the sale of FSMP, particularly relating to the

Key issue / Stakeholder group	Comments
	requirement for a written request (i.e. in order for distributors to sell directly to consumers). Some stakeholders requested further details regarding the requirements of a written request, including the length of time a written request would be valid, and questioned whether this approach was enforceable. Others preferred a more flexible approach and suggested the words 'authorised' advice or request, which could include verbal, written or email requests. Some considered that there should be a distinction between the generic oral nutrition supplement type products and disease specific FSMP, and that only disease specific FSMP should require a written request or access to medical supervision or advice. Suggested that the list of those who can sell FSMP be expanded to include: accredited practising dietitian, practice nurse, nurse practitioner, domiciliary nurse, speech pathologist and other suitably qualified healthcare professionals. Also suggested the addition of 'general practice clinics' to the list of facilities that are permitted to sell FSMP. Distributors noted that the supply of FSMP directly to consumers is only a small part of their businesses. They also advised that the large majority of their consumers are under medical supervision and are often part of an established referral system. If no referral is received, some distributors contact a dietitian or doctor to validate the consumer's request. Overall, considered that the costs to implement a written referral system to capture the few sales made without a formal written referral is not warranted, given that there is no evidence of risk to health using the current system.
Jurisdictions	The majority of jurisdictions supported a restriction on the sale of FSMP, as they considered it reflected existing practices and did not create significant further restrictions. Jurisdictions sought clarification of the legal requirements of a written request, such as the time period in which a written request would be valid, who would validate the referrer and how this approach would work for phone rather than written orders for FSMP products. Suggested the term 'valid', 'legitimate' or 'current' written request be used in the drafting or words of similar intent. Some considered the draft requirement for a written request was vague and would not be enforceable as it was. Noted that a requirement for a written request could increase costs for distributors, and suggested FSANZ check with industry regarding the feasibility and costs of the proposed approach. Sought clarification regarding how sales over the internet could be managed.
Health Professionals	Generally supported the restriction on the sale of FSMP. Considered that the list of practitioners authorised to sell FSMP in the draft Standard should be expanded, for example to include practice nurses, to reflect current practice. Some health professionals expressed concern about the additional impost for them of the requirement to give a written request when the current system seemed to be efficient and effective. Considered that the requirement for a written request should be broadened to enable verbal requests for the provision of FSMP direct to consumers.
Restriction on advertising of FSMP to the general public	

Key issue / Stakeholder group	Comments
FSANZ proposed to remove the restriction on advertising of FSMP to the general public as it would be difficult to enforce due to the inability to control who receives information on FSMP, especially via the internet.	
Industry	Support for the removal of restrictions on advertising of FSMP to the general public.
Jurisdictions	Some jurisdictions considered that there was no reason why advertising to the general public should not be restricted. The majority of jurisdictions said that they could support the removal of a restriction on advertising provided the restriction on sale of FSMP was tightened further.
Health Professionals	No comments on this issue.
Exclusion of very low energy diet (VLED) products from Standard 2.9.5	
Industry	No further comments were made regarding VLED.
Jurisdictions	Supported the exclusion of VLED products from Standard 2.9.5. Recommended that Standard 2.9.5 exclude weight loss products for the dietary management of overweight, as well as obesity.
Health Professionals	One health professional noted their support to exclude VLED products from the Standard. Other health professionals did not comment on this issue.
Transition period for Standard 2.9.5 ***FSANZ advised stakeholders that there would be a two-year transition period from the date of gazettal of the new Standard.***	
Industry	No issues were raised relating to the proposed transition period.
Jurisdictions	One jurisdiction noted that the transition period may need to be reconsidered if foods captured in Standard 2.9.5 need to be exempted from the *New Zealand Medicines Act.*
Health Professionals	Not comments made on this issue.
Labelling requirements – inner packages ***FSANZ proposed that inner packages (not designed for individual sale) should be exempt from labelling requirements.***	
Industry	Provided examples of packages not designed for individual sale, including sachets packaged in an outer carton, some bottled products sold in multipacks, and some ready to hang FSMP.

Key issue / Stakeholder group	Comments
	Industry supported inclusion of name of food, lot ID, expiry date on inner packages to ensure traceability. Two of the three main manufacturers also supported the inclusion of allergen labelling. One expressed concern regarding allergen labelling of inner packages of imported products, as the EU provides some exemptions from allergen labelling that the Code does not. They requested that allergen labelling requirements for FSMP be aligned with EU requirements. Stated that full labelling requirements, including allergens, would require imported products to be relabelled with a sticker on inner packages (due to the small volume and large variety of products sold in Australia and New Zealand).
Jurisdictions	General support for the proposed labelling requirements for inner packages plus inclusion of lot ID and expiry date to assist identification and potential recalls in situations where the inner package becomes separated from the outer box. One jurisdiction considered that requirements for inner package labelling should be consistent with overseas regulations to ensure continuity of product supply and to avoid the need for relabelling. Noted that the EU does not mandate inner package labelling but that the information is often supplied.
Health Professionals	Supported the proposed labelling requirements for inner packages (name of food and allergens) noting that a lot ID is already provided. An expiry date was considered important.
Labelling requirements – nutrition and health claims Standards ***FSANZ proposed that Standards 1.3.2, 1.1A.2 and 1.2.7 (when gazetted) of the Code would not apply to FSMP.***	
Industry	Agreed that the nutrition and health claim Standards in the Code should not apply to FSMP. Noted that manufacturers would need to keep appropriate substantiating evidence for any nutrition and health claims made in relation to products, and requested clarification on the process to follow.
Jurisdictions	Generally supported the approach not to apply health claims requirements to Standard 2.9.5 provided the restriction on sale of FSMP is maintained. One jurisdiction supported the exemption if the definition was expanded (to include reference to the need for medical supervision), and supported by a prescribed name. One jurisdiction noted that Standard 1.3.2 already exempts Part 2.9 standards in the purpose statement.
Health Professionals	Supported the proposed exemptions for health claims and noted that there is information available to assist health professionals to make a clinical judgement.
Labelling requirements – therapeutic claims ***FSANZ sought comment on whether therapeutic claims should be prohibited or not, noting the requirement in draft Standard 2.9.5 to state the***	

Key issue / Stakeholder group	Comments
medical purpose of FSMP.	
Industry	Considered that therapeutic claims should not be prohibited. One manufacturer noted that claims are currently limited to the disease state or condition for which the product is intended. Another manufacturer noted that its products do not currently indicate any therapeutic claims on labels.
Jurisdictions	Jurisdictions had mixed views on whether therapeutic claims should be prohibited or not. The majority noted the requirement for FSMP to state the medical purpose of the product on the label, and considered this appropriate. One jurisdiction considered it difficult to justify the need for therapeutic claims on FSMP as access to these products will be restricted for consumers and the medical/nutritional purpose of the product will be stated on the label. One jurisdiction supported the use of therapeutic claims as it may assist in indicating the true nature of the product and to communicate the specific indications for use.
Health Professionals	Few comments received on this issue from health professionals. One health professional noted that claims on current FSMP appear to be quite restricted in the countries where they are manufactured and fall short of being considered a therapeutic claim.
Labelling requirements – warning and advisory statements	
Industry	Few comments made by industry on this issue. One manufacturer stated it had no objection to the advisory and warning statements regarding polyols and dextrose.
Jurisdictions	Support the approach to apply Standard 1.2.3 requirements for mandatory warning and advisory statements to FSMP.
Health Professionals	No comments were provided on this issue.
Labelling requirements – FSMP not in a package and transportation outers containing FSMP	
Industry	Few comments made by industry on this issue. One manufacturer supported the labelling exemption for FSMP not in a package and the proposed labelling requirements for transportation outers.
Jurisdictions	One supported that we maintain consistency with US and EU so there would be no need for relabelling. One stated that transportation outers are generally discarded, so need name and address on package label for traceability/recall.

Key issue / Stakeholder group	Comments
	One supported only requiring the name of food, lot ID and name and address of supplier on transportation outers or in accompanying FSMP documentation (unless visible through the transportation outer).
Health Professionals	No comments were provided on this issue.
Composition – minimum and maximum levels ***FSANZ proposed that EU minimum and maximum levels would be adopted for FSMP that are a sole source of nutrition.***	
Industry	Noted that most declarations for vitamins and minerals in the nutrition information panel are based on average amounts, though a small number of products declare the minimum amount. This reflects different labelling tolerances in the USA (minimum values) and the EU (average values). These values are determined through calculation and/or analytical methods.
Jurisdictions	General support for the approach to align with EU compositional requirements. One jurisdiction requested clarification on the risk of inadequate intake of some micronutrients when products are used as the sole source of nutrition. One jurisdiction queried the compositional suitability of FSMP for young children and adolescents. They also sought examples of medical conditions that would necessitate the need for a variation from these compositional requirements, and questioned whether an 'expressed permission' or 'approval' would be necessary for a company to deviate from these requirements.
Health Professionals	Supported the flexibility in compositional requirements to permit manufacturers to deviate from minimum levels for FSMP for specific disease conditions. Noted that patients may use FSMP products as a sole source of nutrition, or as supplemental nutrition, for periods from a few months to 10 to 20 years, or possibly for life in some cases.
Composition – permitted substances	
Industry	It was noted that some substances in the EU and USA are classed as additives rather than processing aids (e.g. phosphoric acid and sodium hydroxide). Further information is required to determine whether these substances can be declared on the label as processing aids in Australia and New Zealand when they are not approved. Requested that chromium picolinate be permitted as a form of chromium in Schedule 1 of Standard 2.9.5.
Jurisdictions	No comments were provided on this issue.
Health Professionals	No comments were provided on this issue.

Key issue / Stakeholder group	Comments
Additional comments – labelling	
Industry	*Listing contraindications and precautions* One manufacturer was unclear as to what specific contraindications and precautions would be required to be listed outside of the advisory statements already required/suggested.
	Variation statement One manufacturer anticipated difficulty with the requirement to indicate on the label the nutrient that has been modified to vary from the compositional requirements and how it has been modified. This would impact mainly on those imported products with labels that are relevant to many markets. Due to the smaller volumes for Australia and NZ, it would be difficult to obtain dedicated labels to comply with this requirement, especially for products coming from USA.
	Gluten free claims Two manufacturers raised points about the proposed requirement: The current Standard does not specify the method of analysis to be used in making the 'no detectable' determination. Problems arise for manufacturers in identifying validated tests and determining the appropriate method of analysis. Compliance issues arise due to testing using different newer test kits. There is no agreement within the food sector about the limit of detection Considered that the criteria needed for determining a "gluten free" limit for food regulation includes that: • it protects a majority of individuals with coeliac disease, whilst ensuring that they can still access a nutritious and varied diet, and • it is achievable by the food industry under normal conditions of GMP, and • there are validated methods of analysis, widely available to the food sectors, that are able to reliably and reproducibly detect gluten at the prescribed level in all relevant food matrices Proposed that because there is a drive internationally to establish a threshold for gluten at <20 ppm that we align with this view locally. However understanding the potential complexity in progressing this, proposed that alternatively there could be an exemption granted from the 'nil detected' criteria in the ANZFSC for this special category of medical foods. Reference provided - Regulation EC No 41-2009 on gluten labelling.

Key issue / Stakeholder group	Comments
Jurisdictions	*Gluten free claims* One Jurisdiction suggested Standard 2.9.5 be silent on the requirements for 'gluten-free' as the meaning under the Code and ACCC/NZ fair trading laws means free of any detectable gluten. Considered the Clause is a problem as the Code was not updated when Codex changed from 200 ppm to 20 ppm for gluten free. Also EU and Codex use an extra category of 'very low gluten'. Queried whether FSANZ plans to review the Code for 'low gluten'?
	Standard 2.9.5 One Jurisdiction raised broad concerns about how the Standard accommodated the exemptions from, or flexibility to Part 1.2. This was considered to be cumbersome and inconsistent with other drafting and with the previous move away from vertical standards.
	Supplier name and address One Jurisdiction was concerned that the name and address of the distributor in Australia is not required. This was considered problematic for enforcement as a first step in recalls would be to contact the distributor. They recommended this be explored further.
Labelling – impact of requirements	
Jurisdictions	One Jurisdiction commented that the costs of relabeling for one or more elements are much the same, therefore the addition of a prescribed name should not be at any additional cost.
Industry	Several manufacturers provided market information on the likely impacts of relabelling, for FSANZ's information.