# SUBMISSION

AUSTRALIAN
FOOD AND GROCERY
COUNCIL



Submission to

## Food Standards Australia New Zealand

in response to:

## Proposal P242 – Food for Special Medical Purposes: Draft Assessment Report

February 2003

Level 2, Salvation Army House • 2-4 Brisbane Avenue, Barton ACT 2600 • Locked Bag 1, Kingston ACT 2604
Telephone: (02) 6273 1466 • Facsimile: (02) 6273 1477 • www.afgc.org.au • ABN 23 068 732 883

# 1 EXECUTIVE SUMMARY

The Australian Food and Grocery Council (AFGC) makes this submission to Food Standards Australia New Zealand (FSANZ) in response to the Draft Assessment Report on Proposal P242 – *Foods for Special Medical Purposes.*

AFGC has one key objection to this draft assessment report.

**FSANZ has failed to demonstrate a market failure argument that would require regulatory intervention for foods for special medical purposes (FSMP).**

By their own admission there is no evidence of market failure in the production of FSMP and sales of FSMP are controlled by health professionals and through hospital tenders which based on any risk analysis would "*provide adequate information…to enable consumers to make an informed choice*" while "*protecting public health and safety*".

**The AFGC considers that:**

- **as there is no evidence of increased risk to public health and safety; and**
- **no need to invoke the power of the FSANZ Act to change the current access arrangements for FSMP**

**there is no purpose in changing the regulatory requirements for FSMP in Australia and New Zealand.**

**AFGC recommends maintaining the status quo as the least cost option for all parties in line with established COAG policy and the principle underpinning the Revision of the food standard code "*less prescriptive, where appropriate*".**

Notwithstanding this objection, should FSANZ pursue Option 2 and proceed to regulate FSMP, then **AFGC recommends that an industry consultative group be established to ensure the minimum effective regulation is developed at least cost to all parties.**

The AFGC **supports** FSANZ in broadening the definition of special purpose foods as per the Codex definition of foods for special dietary uses

**The AFGC recommends that advice be sought from the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC) through the Food Policy Unit for the appropriate policy principles that should be considered in developing standards for special purpose foods and, in particular, FSMP.**

The AFGC contends that if efficacy (a particular medical term) is an important principle for special purpose foods then the determination of this policy should be made by ANZFRMC before any standard for FSMP is determined.

The AFGC notes that no evidence is presented by FSANZ to support the statement concerning significant public health and safety risks or any evidence to support the statement of high rates of self-treatment for morbid obesity.

The AFGC considers that the evidence used by FSANZ to support restricting advertising of FSMP to the general public is inadequate.

**The AFGC recommends that advertising of FSMP should be permitted in both health professional publications and in lay organisations' self-help group publications.**

**The AFGC recommends that sound science be used for risk assessment in determining tolerable upper intake limits (TUIL) for vitamins and minerals contained in FSMP.**

**The AFGC recommends that no upper limits for micronutrients be prescribed, given**

- *the close medical/ health professional supervision available for persons requiring FSMP,*
- *the labelling requirement for "medical supervision", and*
- *the lack of appropriate risk assessed TUIL for micronutrients for persons requiring FSMP*

**The AFGC recommends however that, should sound science indicate a risk to health for a particular micronutrient in persons requiring FSMP, this be expressed as a maximum daily amount, rather than as a prescribed qty/100kJ, to allow for variation in daily energy requirements, especially in the elderly. This would be consistent with the approach to VLED.**

**The AFGC accepts** the FSANZ recommendation that VLED have a minimum daily amount set for the micronutrients

**The AFGC does not support regulation for generic labelling information on the label of FSMP.**

## 2 THE AUSTRALIAN FOOD AND GROCERY COUNCIL

The AFGC is the peak national organisation representing Australia's packaged food, drink and grocery products industry.

The membership of the AFGC comprises more than 185 companies, subsidiaries and associates which constitutes in the order of 80 per cent of the gross dollar value of the highly processed food, beverage and grocery products sectors (A list of members is included at *Appendix 1.*) The AFGC represents the nation's largest manufacturing sector. By any measure Australia's food, drink and grocery products industry is a substantial contributor to the economic and social welfare of all Australians. Effectively, the products of AFGC's member companies reach every Australian household.

The industry has an annual turnover in excess of $54 billion and employs 165,000 people — almost one in five of the nation's manufacturing workforce. Of all Australians working in the industry, half are based in rural and regional Australia. And the processed food sector sources more than 90 per cent of its ingredients from Australian agriculture.

The AFGC's agenda for business growth centres on public and industry policy for a socio-economic environment conducive to international competitiveness, investment, innovation, employment growth and profitability.

The AFGC's mandate in representing member companies is to ensure a cohesive and credible voice for the industry, to advance policies and manage issues relevant to the industry and to promote the sector and the virtues of its products, enabling member companies to grow their businesses.

The Council advocates business matters, public policy and consumer-related issues on behalf of a dynamic and rapidly changing industry operating in an increasing globalised economy. As global economic and trade developments continue to test the competitiveness of Australian industry, trans-national businesses are under increasing pressure to justify Australia as a strategic location for corporate production, irrespective of whether they are Australian or foreign owned. In an increasingly globalised economy, companies' ability to internationalise their operations is as significant as their ability to trade globally.

Increased trade, rationalisation and consolidation of businesses, increased concentration of ownership among both manufacturers and retailers, intensified competition and a dynamic, increasingly complex and demanding consumer are features of the industry across the globe. Moreover, the growing global middle-class of consumers is more sophisticated and discerning, driving innovation and differentiation of products and services.

The AFGC is working with governments in taking a proactive, even tactical approach to public policy to enable businesses to tackle the threats and grasp the dual opportunities of globalisation and changing consumer demands.

# 3 GENERAL COMMENTS ON THE PROPOSAL

To meet government policy objectives, the Council of Australian Governments' (COAG) policy principles require regulatory measures to:

- *impose the minimum regulatory burden on the community – consumer, industry and government;*
- *be derived from transparent and accountable consultative processes;*
- *be founded on sound science when addressing technical concerns – for example, public health, environmental protection, etc.; and*
- *be justified following rigorous, and preferably quantitative, cost-benefit, or cost-effectiveness analyses, detailed comprehensively in a regulatory impact statement.*

Government policy therefore is for minimum effective regulation, a policy that is fully endorsed by the AFGC. Regulation should be imposed only to ensure that minimum necessary regulations are maintained and detailed standards imposed only where necessary to correct market failure.

In its draft concept paper, "Revised Structure of the Food Standards Code", the, then, National Food Authority stated, "the Code should be structured so that it is:

- *easy to use;*
- *easy to understand;*
- *easy to interpret;*
- *free of inconsistencies; and*
- *less prescriptive where appropriate".*

The Authority also stated:

> *The Authority will use standards which are prescriptive enough to meet the objectives set out in Section 10 of the ANZFA Act but flexible enough to allow innovation in the food industry.*

The Section 10 objectives are:

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

In addition to these objectives, in developing food regulatory measures ANZFA must also have regard to:

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

**The AFGC endorses the objectives of FSANZ in the protection of public health and safety and endorses the use of adequate labelling information to permit informed choice by consumers and their carers.**

## 3.1 Policy objectives of FSANZ

The AFGC considers that FSANZ has not demonstrated any market failure in current methods by which FSMP are offered for sale in Australia and New Zealand and that the sole

purpose of the regulatory option proposed is to harmonise food regulations in Australia and New Zealand.

The AFGC notes that in developing and varying standards FSANZ must also have regard to (among other things):

- *the promotion of consistency between domestic and international food standards; and*
- *the need for standard to be based on risk analysis using the best available scientific evidence.*

**The AFGC considers that FSANZ has not given appropriate consideration to either of these principles.**

FSANZ also states that one of the specific objectives for proposal P242 is to:

*protect public health and safety particularly by ensuring the safe and appropriate use of FSMP.*

The AFGC notes that FSMP are "*principally formulated food products used under the supervision of medical or other health professionals for the dietary management of individuals (including children) with either ongoing chronic medical or disability conditions or during acute phases of illness, injury or disease states*".

**The AFGC considers that FSANZ has not demonstrated that current usage is either unsafe or inappropriate in the supply of FSMP within Australia and New Zealand.**

FSANZ also proposes another specific objective for P242 is to:

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

**The AFGC considers that current information on labels and in other forms for FSMP, which are supplied on recommendation from medical or other health professionals, currently enables the safe and effective use of FSMP without further regulation.**

The AFGC further considers that in determining its specific objectives FSANZ has not taken sufficient notice of supply issues within Australia and New Zealand. Many of these products are needed in small quantities on an infrequent basis and any excessive regulation with respect to labelling provisions is likely to lead to their removal from supply within Australia and New Zealand.

Indeed, FSANZ indicates (p. 5), "*There is minimal local manufacturer of FSMP as it is estimated that 99% of products are imported mainly from the European Union and the United States of America. On a world scale the Australian and New Zealand markets are comparatively small*".

**The AFGC recommends that a further specific objective is required for proposal P242, that it:**

- **not jeopardise supply of FSMP needed in small quantities on an infrequent basis.**

## 3.2 Special purpose foods – policy principles

The AFGC agrees that FSMP fall within the category of special purpose foods in that they are not intended for consumption by the general population and in most instances are designed for specific diseases or disorders and designated as such.

As one of its reasons for pursuing regulation of FSMP in section of 5.1 (p. 13) FSANZ comments, "*the regulation of special purpose foods allows for formulations that ensure an appropriate and*

*adequate nutrient content and in general the greater the food to overall intake the greater the need to provide appropriate regulatory measures to mitigate the risk to the target group from inappropriate consumption".*

**The AFGC considers that while this may be true for currently defined special purpose foods, FSMP are:**

- **intended for consumption only after medical or other health professional advice; and**
- **the need for appropriate regulatory measures to mitigate risk for target groups should relate to inappropriate composition rather than consumption.**

The AFGC **supports** FSANZ in broadening the definition of special purpose foods as per the Codex definition of foods for special dietary uses.

In proposing this definition, FSANZ states (p. 14 para. 2), *"The purpose of this commentary is to explicitly acknowledge the underpinning* ***regulatory principles*** *for special purpose foods that consider not only the primary objective of safety but also effectiveness. Efficacy is an important principle for special purpose foods as they (are) relied upon in meeting the particular nutritional requirements of the intended at risk target groups".*

**The AFGC considers that regulatory principles are, in effect, policy principles and as such are no longer the responsibility of FSANZ under the new institutional arrangements.**

**The AFGC recommends that advice be sought from the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC) through the Food Policy Unit for the appropriate policy principles that should be considered in developing standards for special purpose foods and, in particular, FSMP.**

**The AFGC contends that if efficacy (a particular medical term) is an important principle for special purpose foods then the determination of this policy should be made by ANZFRMC before any standard for FSMP is determined.**

# 4 SPECIFIC COMMENTS ON THE PROPOSAL

## Section 5.3 – Distribution and access

FSANZ notes (p. 15) that in both Australia and New Zealand individuals requiring access to FSMP generally obtain this *"through health care institutions or either from pharmacies or directly from suppliers"* and notes that in Australia consumers can *"obtain most FSMP without prescription although generally this occurs under some level of health professional supervision".*

FSANZ acknowledges that, *"there appears little evidence to suggest that there are problems and an increased risk to public health and safety from the current unrestricted access to FSMP".*

**The AFGC contends that in the absence of evidence to suggest there are problems under the current unrestricted access to FSMP, there is no market failure requiring a regulatory solution.**

FSANZ further acknowledges this in stating that, *"given the apparently successful operation of the current system there is no need to invoke the power of the FSANZ Act and change the current access arrangements for FSMP".*

**The AFGC considers that:**

- **as there is no evidence of increased risk to public health and safety; and**
- **no need to invoke the power of the FSANZ Act to change the current access arrangements for FSMP**

**there is no purpose in changing the regulatory requirements for FSMP in Australia and New Zealand.**

FSANZ asserts that, *"as a means of deterring inappropriate use of FSMP the mandatory advisory labelling of products as for "use under medical supervision" is considered an appropriate risk management strategy".*

Products currently on the market as FSMP all contain a statement to the effect "use under medical supervision", rendering unnecessary the need for this particular risk management strategy to be regulated.

## Section 5.3.2 – Advertising of FSMP

FSANZ states that it is *"aware of **regulations** that restrict the advertising of FSMP including VLED to the general public."*

The AFGC notes that the reference is to a **single** country's regulation and not to **regulations** (Canadian Food and Drug Regulations 1954).

FSANZ further (p. 15) states that, *"FSANZ is unaware that the FSMP industry is unethically advertising products to the general public".*

The AFGC **agrees** with this statement and further asserts that it **confirms the lack of market failure** in FSMP that would lead to the requirement for regulation.

FSANZ continues (p. 16), *"There are however **significant public health and safety risks** associated with the unsupervised and inappropriate use of FSMP by consumers particularly for VLED given the increasing rates of morbid obesity and high rates of self treatment".*

**The AFGC notes that no evidence is presented by FSANZ to support the statement concerning significant public health and safety risks or any evidence to support the statement of high rates of self-treatment for morbid obesity.**

The AFGC notes that the statement (p. 14) contradicts that in Section 5.3 (p. 15): *"to date there appears little evidence to suggest that there are problems and an increase risk to public health and safety from the current unrestricted access to FSMP".*

The AFGC considers that what evidence there is suggests the morbidly obese are likely to seek treatment under medical supervision rather than through self-treatment. The NHMRC *Draft Clinical Guidelines for Weight Control and Management of Obesity in Adults*, states in its evidence-based recommendation relating to morbid obesity, that *"Surgery is the most effective treatment for morbid obesity..."*.

**The AFGC considers that the evidence used by FSANZ to support restricting advertising of FSMP to the general public is inadequate.**

Notwithstanding this, the AFGC considers that restriction to health professional publications alone would not meet the needs of users of FSMP for many of the rare disorders for which these FSMP are intended. Self-help groups and their newsletters are an appropriate means of communication to both sufferers and carers of those with these conditions.

While not supporting the restriction on advertising to the general public on the basis of the lack of evidence put forward to indicate market failure, **the AFGC recommends that advertising of FSMP should be permitted in both health professional publications and in lay organisations' self-help group publications.**

## Section 5.4 – Composition of FSMP

The AFGC supports and endorses the Codex general principle for FSMP which requires that, *"formulation be based on sound medial and nutritional principles and that their use be demonstrated by scientific evidence to be safe and effective in meeting the nutritional requirements of the person for whom they are intended".*

**The AFGC rejects** the FSANZ view that maximum levels are necessary for all FSMP because *"the highly formulated nature of FSMP presents a risk of excessive vitamin and mineral additions".*

**The AFGC recommends that sound science be used for risk assessment in determining tolerable upper intake limits (TUIL) for vitamins and minerals contained in FSMP.**

Where a product is nutritionally complete and constitutes the sole source of nutrition, then the AFGC **agrees** that minimum quantities of micronutrients are required per daily quantity to meet recommended intakes. Maxima, however, should be set only where there is evidence of risk to health of the daily levels of intake. In determining these levels, several countries (USA, EU and UK) have in recent years updated their risk assessments for TUIL of vitamins and minerals.

The AFGC **recommends** FSANZ considers the evidence supporting these limits as in some cases they are based on "guidance" and not sound science, while in others, the evidence for toxicity is drawn from intake other than from the food matrix of the micronutrient (supplement use). While the latter may represent a best guess for potential risk, the effect from food based intake may well differ and this should be considered in the risk assessment.

However, since medical foods are intended for exclusive or partial feeding of persons with limited or impaired capacity to take, digest, metabolise or absorb ordinary food or certain nutrients, it may be that their special requirement might exceed "normality", requiring micronutrients in excess of the proposed ranges. Equally, the proposed maxima are based on TUIL determined from a "healthy population". rendering the risk assessment process suspect when applied to persons requiring medical foods.

**The AFGC recommends that no upper limits for micronutrients be prescribed, given**

- **the close medical/health professional supervision available for persons requiring FSMP;**
- **the labelling requirement for "medical supervision"; and**
- **the lack of appropriate risk assessed TUIL for micronutrients for persons requiring FSMP.**

In determining daily quantity, FSANZ has currently assumed an adult intake of 8700kJ to determine the nutrient/100kJ (Table 2, Attachment 2). There are many situations in the elderly populations where daily intakes for enteral feeds fall below 8700kJ. In some cases where the person is bedridden the requirement may be as low as 6000kJ.

**The AFGC recommends that, should sound science indicate a risk to health for a particular micronutrient, this be expressed as a maximum daily amount, rather than as a prescribed qty/100kJ, to allow for variation in daily energy requirements, especially in the elderly. This would be consistent with the approach to VLED.**

In determining the maximum values for micronutrients FSANZ **incorrectly** states (p. 47) that EU maxima should not be used as these are based on *"minimum values X 3"*. Reference to the actual EU data used shows this to be incorrect. In any event, recent revisions provide further information on the derivation of the maxima. FSANZ has used a mixture of EU derived and IOM derived data to fill Table 2 maxima values.

**The AFGC considers this ad hoc approach to risk assessment is incorrect. FSANZ's statutory requirement is to ensure regulatory measures be based on risk analysis using the best available scientific evidence.**

For example, no maxima are set for Thiamin, Riboflavin, B12, Biotin, Pantothenic acid by the EU, based on no clearly defined adverse effects, with the USA adopting a similar approach based on the available science. In some cases where daily maxima are set, these are based on evidence derived from supplement use.

For example, niacin has separate values (EU) for nicotinic acid and nicotinamide, and the side effect (flushing) is based on bolus supplement consumption. Similarly, magnesium intake is based on supplement use (USA) and the side effect of diarrhoea.

**The AFGC accepts the FSANZ recommendation that VLED have a minimum daily amount set for the micronutrients..**

## Section 5.5 – Labelling of FSMP

FSANZ states that, *"due to the current methods of distribution the use of supporting product literature as a means of providing information required by generic labelling standards is not considered a suitable alternative to labelling"*.

The AFGC considers the current methods of distribution, which are either through health care services of pharmacies on the advice of pharmacists or other health care professionals, demonstrate that supporting product literature is an appropriate means of providing information for the ultimate consumer of these products.

**The AFGC does not support regulation for generic labelling information on the label of FSMP.**

In some instances FSMP are required for extremely limited numbers of individuals within Australia and the costs required for a special label run or over-stickering by manufacturers of these products in Europe or the USA could result in the **unavailability of these products for use in Australia**.

## Section 5.5.3 additional labelling : specific FSMP other than VLED

FSANZ proposes that, *"the label contain a statement that the product poses a health hazard when consumed by individuals who do not have the disease disorder or medical condition for which the product is intended"*.

**The AFGC considers that in general most FSMP, composed as they are of normal nutritional ingredients such as vitamins and minerals, macronutrients, amino acids, etc., would not of themselves pose a health hazard when consumed by individuals who do not have the disease.**

In any event, inclusion of the mandatory advisory statement that these products should be *"used only under medical supervision"* (or words to that effect) would provide adequate risk management when combined with their availability through pharmacies or other health agencies where health professional advice is available.

FSANZ further proposes that the label *"contain information about known side effects contraindications and product drug interactions"*.

**The AFGC considers this is an impractical requirement since the list of potential drug interactions for ingredients found in FSMP is likely to be extremely long.**

Medicines, whether supplied over the counter or on prescription, are not required on their label to provide information about nutrient interactions with particular medicines but, rather, make available consumer medicine information leaflets summarising this information. For the majority of medicines this document can be 1,000–2,000 words long.

For risk management purposes regarding product drug interactions the **AFGC considers that information supplied with the medicine and the labelling provision for FSMP *"to be used only under medical supervision"* (or words to that effect) adequately covers the issue**.

## Section 5.5.2 – Specific labelling requirements for all FSMP

FSANZ proposes a *"declaration of a nutrition information statement including number of servings per package and serving size"*.

**The AFGC contends that for FSMP used for tube feeding, serving size is a meaningless designation since the product is delivered continuously over time.**

## Section 7 – Impact analysis 7.2.1: Option 1, maintain status quo

The AFGC **agrees** with FSANZ that under this option *"the regulatory requirements of the exporting market overseas ie European Union or the United States of America where the vast majority of products are imported from will continue to provide adequate health and safety protection for the Australian and New Zealand population".*

The AFGC **disagrees** with the assertion that *"some consumers may perceive the lack of specific domestic regulations as poor assurance of the protection of health and safety for consumers who are mostly vulnerable population groups."*

The AFGC **questions** how consumers would know there was a lack of specific domestic regulations and **disagrees** with the implication that the protection afforded by the regulatory requirements in the European Union or the United States of America are likely to contribute to poor assurance of the protection of public health and safety in Australia.

## Section 7.2.2 – Option 2, Regulation by discrete standard in the Code

FSANZ asserts that this option provides consumers with *"continued access to and greater assurance of safe quality products".*

The AFGC contends that FSANZ has not shown that the current system provides lesser assurances of safe quality products for sale within Australia and New Zealand, or that evidence of market failure has been demonstrated.

The AFGC **agrees** with FSANZ that the labelling provisions contained within Option 2 will inhibit trade and prevent consumers with medical conditions from accessing products that benefit their dietary management.

The likely effect on the supply of FSMP to consumers with rare diseases is that they will **become unavailable for sale within Australia and available only to consumers by personal import.**

**The AFGC considers that this alone provides for considerable cost to consumers of these types of products.**

The AFGC **agrees** with FSANZ in that the required labelling changes and/or reformulation necessary due to changes to vitamins and minerals content of FSMP will lead to increased cost to industry, especially for brands produced in low volumes.

FSANZ states that, *"in some cases this may mean that products may be withdrawn from the local market as reformulation and relabelling would be seen by industry as* ***unprofitable****".*

The AFGC **disagrees** with the term **unprofitable** as a reason for withdrawing supply. For many FSMP required for rare diseases, the margin is small. In any event, industry would see reformulation and relabelling specifically for the Australian market as uneconomic rather than unprofitable in that the necessary costs required to achieve this could not be passed on to the consumer or the health care system.

The AFGC **welcomes** the opportunity to further consult with FSANZ on the issue of anticipated costs associated with Option 2.

## Section 10 – Conclusion and recommendation

The AFGC considers that FSANZ **overstates** the benefits and **understates** the restrictions on industry likely to occur should Option 2 be developed further.

The AFGC further considers that the sole benefit of Option 2 is to allow for the harmonisation of regulations for FSMP between Australia and New Zealand and that the other benefits listed are not relevant **given the lack of evidence presented by FSANZ for market failure requiring regulatory action.**

## Section 11 – Implementation and review

Notwithstanding AFGC opposition to regulatory Option 2, should such a regulation for FSMP occur then, given the nature of the products, the AFGC **recommends** that a transition period of four years should apply with a minimum of two years stock in trade following expiration of the transition period.

## Attachment 2 Proposal P242 – FSMP Compositional Assessment

The AFGC **agrees** with the use of the Codex standard for FSMP that relates to composition – that is, *"formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated by scientific evidence to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended".*

The AFGC **agrees** that for nutritionally complete FSMP, including VLED, there is a need to establish minimum levels of essential nutrients to manage the risks for these types of FSMP.

The AFGC **agrees** that maximum limits may be required for some FSMP, **"where this is based on sound science and appropriate risk assessment".**

However, since medical foods are intended for exclusive or partial feeding of persons with limited or impaired capacity to take, digest, metabolise or absorb ordinary food or certain nutrients, it may be that their special requirement might exceed "normality", requiring micronutrients in excess of the proposed ranges. Equally, the proposed maxima are based on TUIL determined from a "healthy population". rendering the risk assessment process suspect when applied to persons requiring medical foods.

**The AFGC recommends that no upper limits be prescribed, given**

- **the close medical/health professional supervision available for persons requiring FSMP;**
- **the labelling requirement for "medical supervision"; and**
- **the lack of appropriate risk assessed TUIL for micronutrients for persons requiring FSMP.**

## Attachment 3 Proposal P242 – FSMP Labelling Assessment

The AFGC considers that current labelling requirements provide adequate information to consumers for informed choice in that:

- they have an advisory statement on medical/health professional supervision; and
- they are available through pharmacy or after health service tender and assessment where supporting product information is available.

The AFGC **does not consider** that there is a need for additional words "Important Notice" to draw attention to the advisory statement. General labelling provisions require that all information be legible and the relevant information will be in the advisory statement.

The AFGC further considers this to be **impractical**, given the vast majority of FSMP are imported, already contain an advisory statement related to medical supervision, and this further requirement would, **for no particular gain in consumer information**, require over-stickering.

**The AFGC considers that the provision of domestic supplier details is adequately met by the supporting product literature.**

In the event of a safety risk to the consumer, the AFGC considers the likely response from a consumer would be to contact their relevant health professional for advice (given that the product is supplied under medical supervision), who would be well aware of the local supplier of such products.

The AFGC **supports** reference to disease states being permitted on these foods as they are designated as FSMP and this designates their purpose for use. Any claims related to such disease states must be capable of support through reference to sound science based substantiation.

The AFGC **supports** the provision of nutrition information on FSMP which is consistent with Codex requirements, even if it is in non-domestic format.

# 5 CONCLUSION

AFGC has one key objection to this draft assessment report.

**FSANZ has failed to demonstrate a market failure argument that would require regulatory intervention for FSMP.**

By their own admission there is no evidence of market failure in the production of foods for special medical purposes (FSMP) and sales of FSMP are controlled by health professionals and through hospital tenders which based on any risk analysis would "*provide adequate information…to enable consumers to make an informed choice*" while "*protecting public health and safety*".

**The AFGC considers that:**

- **as there is no evidence of increased risk to public health and safety; and**
- **no need to invoke the power of the FSANZ Act to change the current access arrangements for FSMP**

**there is no purpose in changing the regulatory requirements for FSMP in Australia and New Zealand.**

**AFGC recommends maintaining the status quo as the least cost option for all parties in line with established COAG policy and the principle underpinning the Revision of the food standard code "*less prescriptive, where appropriate*".**

# Appendix 1: AFGC Membership List

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# MEMBERSHIP

As At 18/03/03

AUSTRALIAN
FOOD AND GROCERY
COUNCIL

AAB Holdings Pty Ltd
Arnott's Biscuits Ltd
  Snack Foods Ltd
  The Kettle Chip Company Pty Ltd
Asia-Pacific Blending Corporation Pty Ltd
Australia Meat Holdings Pty Ltd
Australian Pacific Paper Products
Beak & Johnston Pty Ltd
BOC Gases Australia Ltd
Bonland Dairies Pty Ltd
Boots Healthcare Australia Pty Ltd
Bronte Industries Pty Ltd
Buderim Ginger Ltd
Bundaberg Sugar Ltd
Cadbury Schweppes Asia Pacific
Campbell Australasia Pty Ltd
Campbell Brothers Ltd
Cantarella Bros Pty Ltd
Carter Holt Harvey Consumer Brands
  Sancella
Cerebos (Australia) Ltd
Chr Hansen Pty Ltd
Christie Tea Pty Ltd
Clorox Australia Pty Ltd
Coca-Cola Amatil Ltd
Colgate-Palmolive Pty Ltd
Consolidated Foods Australia Ltd
Coopers Brewery Ltd
Dairy Farmers
Darling Downs Foods
Demicombe Pty Ltd
Derby Industries Pty Ltd
Devro-Teepak Pty Ltd
Douwe Egberts
Dragoco Australia Pty Ltd
DSM Food Specialties Australia Pty Ltd
Fibrisol Services Australia Pty Ltd
Firmenich Limited
Fletchers Foods Pty Ltd
General Mills Australia Pty Ltd
George Weston Foods Ltd
  Allied Foods Co Ltd
  Baking Division
  Biscuit & Cake Division
  Meat & Dairy Division
  Weston Cereal Industries
  Weston Technologies
Gillette Australia Pty Ltd
GlaxoSmithKline
Golden Circle Ltd
Goodman Fielder Ltd
  GF Baking Australia
  GF Consumer Foods
  GF International
  GF Milling Australia
  GF New Zealand
Green's Foods Ltd
H J Langdon & Co Pty Ltd
Hans Continental Smallgoods Pty Ltd
Harvest FreshCuts Pty Ltd
Heimann Foodmaker Group
Heinz Wattie's Australasia
  Southern Country Foods Pty Ltd
Henry Jones Foods Pty Ltd
Herron Pharmaceuticals Pty Ltd
Hoyt Food Manufacturing Industries Pty Ltd
International Flavours & Fragrances
  (Australia) Pty Ltd
Johnson & Johnson Pacific Pty Ltd
Kellogg (Australia) Pty Ltd
  Day Dawn Pty Ltd
Kimberly-Clark Australia Pty Ltd
Kraft Foods Ltd
La Famiglia Fine Foods Pty Ltd
Madura Tea Estates
Manildra Harwood Sugar
MasterFoods Australia New Zealand - Food
MasterFoods Australia New Zealand – Petcare
MasterFoods Australia New Zealand –
  Snackfood
Mayne Healthcare Pty Ltd
McCormick Foods Australia Pty Ltd
Merino Pty Ltd
Merisant Manufacturing Australia Pty Ltd
National Foods Ltd
Nerada Tea Pty Ltd
Nestlé Australia Ltd
  Nestlé Foods & Beverages
  Nestlé Confectionery
  Nestlé Ice Cream
  Nestlé Chilled Dairy
  Nestlé Nutrition
  Foodservice & Industrial Division
Novartis Consumer Health Australasia Pty Ltd
NutraSweet Australia Pty Ltd
Nutricia Australia Pty Ltd
Nutrinova (Australasia) Pty Ltd
Ocean Spray International, Inc
PB Foods Ltd
PZ Cussons Australia Pty Ltd
Patties Bakery Pty Ltd
Peanut Company of Australia Ltd
Pfizer Warner Lambert Consumer Group
Procter & Gamble Australia Pty Ltd
Quality Ingredients Ltd
Quest International Australasia Ltd
Reckitt Benckiser
Regal Cream Products Pty Ltd
Ridley Corporation Ltd
  Cheetham Salt Limited
Roche Vitamins Australia Pty Ltd
Sanitarium Health Food Company
  Longa Life Vegetarian Products Pty Ltd
Sara Lee Bakery (Australia) Pty Ltd
Schwarzkopf and Henkel
Sensient Technologies Australia Corp Pty Ltd
Simplot Australia Pty Ltd
SPC Ardmona Operations Ltd
Specialty Cereals Pty Ltd
Spicemasters of Australia Pty Ltd
Sugar Australia Pty Ltd
Sunbeam Foods
SunRice
Tetley Australia Pty Ltd
Unilever Australasia
Wella Australia
Wyeth Australia Pty Ltd
Yakult Australia Pty Ltd

## Associate Members

Accenture
Amcor Fibre Packaging
Australian Dairy Corporation
Brooke-Taylor & Co Pty Ltd
Cap Gemini Ernst & Young
CHEP Australia
Clayton Utz
CROSSMARK Asia/Pacific
Ernst & Young
Food Liaison Pty Ltd
Foodbank Australia Limited
HAHT Commerce Pty Ltd
IBM Business Consulting Services
innovations & solutions
KPMG Chartered Accountants
KPMG Consulting International
Linfox Australia Pty Ltd
Manassen Foods Australia Pty Ltd
Meat and Livestock Australia Ltd
Monsanto Australia Ltd
Mayne Logistics Pty Ltd
Novozymes Australia
OTS Appointments
Porter Novelli Australia Pty Ltd
PricewaterhouseCoopers
Protein Technologies International Aust Pty Ltd
Queensland Sugar
Ronald L Cossen & Associates Pty Ltd
Strategic Horizons Pty Ltd
Sue Akeroyd & Associates
TMP Worldwide eResourcing Ltd
Weekes Preston
Wiley & Co Pty Ltd

Level 2, Salvation Army House • 2-4 Brisbane Avenue, Barton ACT 2600 • Locked Bag 1, Kingston ACT 2604
Telephone: (02) 6273 1466 • Facsimile: (02) 6273 1477 • www.afgc.org.au • ABN 23 068 732 883