AUSTRALIA NEW ZEALAND

ENTERAL NUTRITION

MANUFACTURERS ASSOCIATION

SUBMISSION
ON DRAFT ASSESSMENT REPORT P242

FOR FOODS FOR SPECIAL MEDICAL PURPOSES
– PROPOSAL P242

MARCH 2003

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1. EXECUTIVE SUMMARY

ANZENMA believes Food Standards Australia and New Zealand (FSANZ) in their attempt to apply foods standards regulations to Foods For Special Medical Purposes (FSMP) have grossly underestimated the adverse impact that draft proposal P242 with have on consumers, healthcare professionals and industry.

Industry believes that the food standards code may be generically more suitable to fast moving consumer foods in an otherwise healthy population. In contrast, FSMP products are relatively low volume products targeted to population groups of consumers that have conditions, diseases, or inborn errors of metabolism that are acute or chronic. These products generally are recommended and their use supervised by healthcare professionals. By implication, these products propose less of a risk to public health and safety than any other food group that is under FSANZ regulatory standards.

Industry rejects the implication by FSANZ 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"

FSMP products have been sold and distributed in Australia and New Zealand for over 25 years without any reported issues or problems with regards to public risks to health and safety. These products are almost exclusively imported from manufacturing facilities producing for the two major FSMP markets in the world, the United States of America and the European Union, with populations of 250 million and 570 million respectively. These facilities are fully compliant to the codes of Good Manufacturing Practice.

The implication of the FSANZ statement is that regulated products from these markets are unsafe and are likely to compromise the health of Australian and New Zealand consumers if they are not further regulated. **Industry does not accept this implication.** Further regulations proposed by FSANZ would not result in any significant improvement in the safety of the products currently procured from these sources. **The assumption that these products are unsafe is a concept which industry opposes.**

The Australian and New Zealand affiliates of the manufacturers of FSMP without exception take formulations from these markets. Thus any deviation from accepted product guidelines from these markets threatens the continued access to FSMP products for consumers and healthcare professionals and the viability of FSMP market for the region.

Endorsing FSMP within the food standards code under option two of the initial assessment report of October 2001 would sanction these products and remove concerns for AQIS (Australian Quarantine and Inspection Service), and provide Australia and New Zealand a continuing supply of high quality, specialised product ranges.

It would also contribute to the on-going investment in local research and development as part of global product development plans. The continued access to the latest products available from research and product development would also benefit consumers and healthcare professionals.

Adopting the proposed standard in its current format would result in up to 95% of all products being non-compliant in a number of areas and given the relatively small market size, the majority of products would never comply even after the FSANZ proposed transitional timetable.

Industry members key concerns are:

The compositional requirements

- Maximum nutrient levels
- Nutritive substances listings
- Food additives and processing aids listings

Labelling Requirements Unique to Australia and New Zealand

- Contraindications

Application of Generic Labelling Requirements

- Nutritional panel requirements
- Date marking requirements
- Proposed address requirements
- Warning and advisory statement inclusions

- **Proposed restrictions to advertising**

2. ANZENMA

The Australian and New Zealand Enteral Nutrition Manufacturers Association represent the following companies.

Abbott Australasia Pty Ltd

Abbott Laboratories (New Zealand) Limited

Nestle Australia Ltd

Nestle New Zealand Limited

Novartis Consumer Health Australasia Pty Ltd

Nutricia Australia and New Zealand

Membership is open to any manufacturer of enteral nutrition feeding products.

3. DEFINITION OF FSMP

Codex definition has been proposed by FSANZ. Industry would suggest only minor changes in the proposed definition and proposes the following:

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

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

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

4. CURRENT MARKET AND DISTRIBUTION

The current distribution channels for FSMP allow consumers access to these products at globally competitive prices. FSANZ has agreed there is not any evidence of market failure or concerns for public health and safety with the current methods of distribution. By restricting distribution FSANZ may unwittingly reduce competition and see prices rise.

4.1 Australia

'The majority of FSMP (90%) are provided through healthcare settings (e.g. public and private hospitals, nursing homes), under the supervision of health professionals such as dietitians, nurses or medical staff.'

FSANZ has stated that the use of these products is being supervised by health professionals and has not demonstrated that this has resulted in any safety concerns. Should the prescriptive regulatory measures proposed be put into place, FSMP while now relatively expensive to the consumer will become more expensive and less accessible, as they will cease to be cost effective.

4.2 New Zealand

'It is estimated that 95% to 99% of the FSMP market is distributed via a prescription (authorised by a medical practitioner)'

In New Zealand, a Doctor or Dietitian must write a prescription for a reimbursed medical nutritional product. The vast majority of medical nutritional products are supplied via this distribution channel in New Zealand.
FSANZ has not demonstrated a risk of safety in an unregulated environment, only that the majority of cases will receive close medical supervision. This far exceeds the supervision given with other 'food' items.

5 COMPOSITION OF FSMP

Industry concludes the implementation of the maximum levels stated in table would result in most products in the market place today being non compliant with little prospect of becoming compliant given these products are sourced from the EU or USA or Canada with formulas compliant to those markets regulations.

Compositionally, industry recommends that FSANZ set no maximums for micronutrients. Industry again wishes to highlight that these products are designed for nutritionally compromised consumers, not healthy individuals. These individuals can have micronutrients needs far higher that a normal well individual eg: A burns patient.

Industry generally accepts the micronutrient minimums in the draft assessment report on P242 as a standard for FSMP. These minimums industry notes are largely based on EU minimums, industry notes that EU compositional regulations are under review. However, there are some micronutrient levels that industry would like further consultation with FSANZ on. These will be addressed in a subsequent submission to FSANZ.

Industry notes that the EU allows for products to be marketed that have micronutrient Levels outside the compositional standards with scientifically justified formulations and would recommend FSANZ have a similar mechanism.

If compositional guidelines are introduced, industry strongly endorses the need for further consultation as any restrictions on composition may reduce existing market competition, reduce the number and types of products available, increase product costs and restrict consumer access to new and scientifically advanced products.

VLEDs

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

With respect to VLEDs, it is agreed that such products must be nutritionally adequate. Similar comments apply as above with respect to medical supervision and the appropriateness of imposed upper limits. For many people, it is unlikely that obesity is the sole condition being treated. According to the NH&MRC Draft Clinical Guidelines for Weight Control and Obesity Management in Adults (Sept 2002 NH&MRC) "very low energy diets, or VLEDs, usually provide around 1.7 to 3.3 megajoules (/kg) a day. In addition, they must contain 0.8 to 1.5 grams (/kg) a day of high-quality protein and the recommended daily allowances of minerals, vitamins, trace elements and essential fatty acids. They are used as the only source of nutrition for 8 to 16 weeks and are often a last resort for patients who have been unsuccessful on other programs and/or who have life-threatening co-morbidities. "

We appreciate that in the Draft Assessment Report, for many nutrients no maximum has been set.

Vitamin E is eligible for listing in complimentary medicines and there is no maximum set. Vitamin E does not have an entry in the SUSDP.

Even modest levels of nicotinic acid may cause flushing in the early days of administration. This does not apply to nicotinamide and we therefore question the upper limit for niacin equivalents, given that nicotinic acid is rarely used in formulating. Nicotinamide is not restricted in Australia/NZ for complementary medicine nor dietary supplement use. Nor is magnesium. Our comment re nutritionally complete food, and the inappropriateness of taking additional dietary sources into account in that circumstance, applies to the upper limit described for magnesium for VLED. There is no justification for a 350mg limit on magnesium.

Some of the nutrients allowable in medical foods are missing eg vitamin K, Chromium, Fluoride. We request their inclusion for VLED. We refer to our comments regarding permitted forms, and nutrient levels in Schedule 2 as they are applicable to Schedule 3 also.

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

As stated by NH&MRC very low energy diets are often a last resort for patients who have been unsuccessful on other programs and/or who have life-threatening co-morbidities so we cannot exclude the possibility that a complete 'medical food' may be indicated where the energy level may be within the 'very low' interpretation. Alternatively, a VLED may be indicated with modification to address the co-morbidities. With P235 on the horizon we would like to flag this matter for further discussion.

Additional compositional requirements for VLED.

(1) Formulas for very low energy diets must contain no less than 1880kJ and no more than 3350kJ in a recommended daily quantity of the food.
(1) Formulas for very low energy diets must contain, in a recommended daily quantity of the food, no less than
(a) 3g linoleic acid and 0.5g alpha-linolenic acid, and have a ratio of linoleic acid to alpha-linolenic acid of between 5 and 15; and
(b) (b) 50g carbohydrate; and
(c) (c) 50g protein.

4(2)(a)(b)(c) is not current practice but we expect it to be achievable by enactment. However we would appreciate the opportunity for further dialogue on formulation aspects of VLED.

We have mentioned elsewhere that sometimes VLED servings are continued in a non-complete program. In that context 3350kJ may be exceeded which hypothetically may take the product outside of the jurisdiction of this Standard. We believe there would be more clarity if the interpretation of VLED in item 1 was amended.

Eg Interpretation

Formulas for very low energy diets (VLED) means nutritionally complete formulas presented for use in energy restricted diets of not more than 3350kJ per day for the dietary management of obesity.

With 4(1) amended to

Formulas for very low energy diets must contain no less than 1880kJ in a recommended daily quantity of the food.

6 LABELLING OF FSMP

6.1 General Comment

As a general statement, any specific requirements of FSANZ, which are not in line with international labelling requirements, will have broader implications for both industry and the consumer. All Australian affiliates of multi-national companies account for a comparatively small percentage of the global market and the costs involved in unique labelling runs or over-labelling stock designated for such small affiliates cannot be justified to the parent company or to the local affiliate. With the increase in the cost to the consumer and reduction of patient accessibility, patient health may be compromised. The objective of FSANZ to protect public health and safety may not be achieved, as these types of products, formulated to inherently enhance public health by providing appropriate nutrition, may become unavailable. By enforcing regulation aimed at protecting public health and safety, FSANZ may unwittingly damage the market, resulting in the decline of patient health.

Industry has many concerns with the draft assessment report's recommendations in respect to labelling and notes that if the application of the generic labelling statements is imposed, a large percentage of the products currently available on the market will fail to comply.

Tables with a number of ANZENMA members' products will be forwarded to FSANZ highlighting non-conformance to the draft assessment reports compositional table in a follow up supporting paper. Examples from standard tubefeeds, supplements and specialised disease specific products will be included.

VLEDs

Likewise, VLED products are intended to be used under medical supervision and to be labelled as such. It may be that that the adolescent or elderly person is significantly obese. In that circumstance it is unhelpful, if not frightening (for the consumer), if the product is recommended by a healthcare professional and then found to be labelled as unsuitable. Compliance is a significant issue for weight reduction products. Users must be confident that the product is suitable and will be successful.

Item 10(2) requires VLED products to be labelled with a statement regarding the recommended daily consumption amount. As we discussed typically a VLED diet may be recommended for a month at the 600- 800KCal level and then reviewed. Thereafter, the frequency of consumption may be varied by the supervising healthcare professional, for example a reduction to 2 serves per day, with normal food replacing the third serve. Literally this would mean the product would become a meal replacement rather than a VLED product. Obviously this interpretation would cause regulatory confusion. So we propose that the statement regarding the recommended daily consumption amount be related to 'when the product is intended as a sole source of nutrition', but that it be recognized that this may not always be the case.

6.2 Specific Labelling Requirements for all FSMP.

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

FSMP products already have a statement pertaining to their use only under medical supervision. The inclusion of the term 'Important Notice' suggests the product is associated with a more substantial risk to patient health than actually exists and may serve only to discourage patient use. In addition, the inclusion of this statement is not a requirement in the USA or Canada

There is no evidence to date that FSMP have been responsible for adverse effects on the health of consumers.

'Permission for the labeling of a statement on the condition, disease, or disorder

Industry supports FSANZ in allowing permission to state the disease state and or condition for which the FSMP has been specifically formulated.

'For nutrition information requirements: nutritional information table

Industry strong recommends FSANZ accept global practice in respect to nutritional information statements.

the number of servings per package and serving size.

Industry contends that it is not always possible to determine the serving size of an FSMP as it is dependent on a number of factors:

Serving size is determined by the dietary prescription.

- If the FSMP is a tube feed, the appropriate RDI volume for the individual patient is calculated and administered as either a slow infusion or a series of bolus doses. A serving size in this instance is not valid.

  Whether the patient is being given the FSMP as a supplement and if so, how much solid food he/she is consuming on any given day. The serving size will be modified accordingly. Some supplements are used as both the sole source of nutrition and also as a supplementary source of nutrition, thus making the proposed serving size irrelevant .For example a two calorie per ml feed may be used in volumes of around 900-1000ml as a tube feed for patients with increased protein and energy requirements or volume restrictions and also used in smaller volumes of 60ml given four times during the day as a supplementary source of nutrition for patients who are able to tolerate an oral intake, however have increased protein and calorie requirements to assist with healing of pressure ulcers and regaining lost weight. The serving size is determined by the treatment regimen prescribed by the health care practitioner. Both of these examples are appropriate serving sizes to meet the specific needs of the patient.

- Whether the patient is being given the FSMP as the sole source of nutrition and if so, the serving size is dependent on the patient's age, height, weight, activity level and any concurrent medical conditions. For example, if a patient has had part or all of the stomach removed but still enjoys consuming nutrition orally, he/she will only be able to tolerate small amounts & will feed more regularly. The individually determined RDI volume will be consumed at a rate or 'serving size' that is tolerable by the patient.

  In the case of a consumer with a metabolic disorder, the dose or 'serving size' of the specialised FSMP will change, sometimes daily, dependent on the level of activity of the metabolic process in question. This dose will also differ from patient to patient depending, on genotype of the disorder, blood levels of the offending amino acid and whether there is another food source.

6.3 Application of generic labelling requirements

The vast majority of products with the proposed FSMP category are for very small consumer / patient populations. Any requirement to further restrict access of product will potentially put some patient's health at risk, as well as reduce competition and supply of product.

Industry cannot meet the requirements set out in the draft assessment report with current and projected future product volumes, given the diverse and fragmented nature of FSMP and the wide variation within the patient / consumer population. There is again little evidence of market failure in terms of public health and safety with the current sale and distribution of FSMP products.

- Industry would consider the primary package as the "case or carton" quantity, which could display the local sponsors address details. Very few products are sold as individual units

  Expiry or Date Marking: industry strongly recommends that FSANZ accept Australian, EU, USA or Canadian methods of date marking. We request that permission be given in this Standard to alternatively use the EXP, or 'best before' prefix, or 'use by' or words of a similar meaning.

- Nutritional Panel Requirements: industry strongly recommend that FSANZ accept nutrient panels of current global practise, with the proviso that all nutrient panels presented to Health Care Professionals in the form of sales literature are listed as average values.

  Use under medical supervision: Industry strongly recommends adoption of approved formats that represent current global practise.

  Industry would strongly recommend that FSANZ accept current global practise for warnings and mandatory statements

6.4 Additional Labelling Specific to FSMP other than VLED

The labels of FSMP other than VLED to contain a statement:
that the product poses a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the product is intended

In general most FSMP products are composed 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.'

The advisory statement that the product poses a health hazard when consumed by persons who do not have the condition intended could be misleading for most of the products. Industry proposes that FSANZ accepts global practice in this respect and industry labels where appropriate advisory statements i.e.: products for inherited inborn errors of metabolism.

The statements 'not for parental use' and 'intended / not intended as the sole source of nutrition' are not mandatory statements in EU but are ' where appropriate'. Therefore products such as European low protein pasta and other solid forms of nutrition do not have this statement. Industry strongly recommends the adoption of the wording where appropriate.

Industry would strongly recommend that FSANZ accepts the labeling practices of EU, USA, Canada and Australia in respect to age specific labeling. These products form a part of a dietary prescription. Thus it is specific to a particular condition, disease and or nutritional status of the consumer under the care of a health professional.

6.5 Concerning the adequate precautions, known side effects, contraindications, and product-drug interactions

Although FSMP are formulated for the dietary management of particular disease states, they are ultimately still nutritional products composed of the same macro and micronutrients found within a normal diet. They may differ in composition but normal foodstuffs also exert any physiological effects FSMP may have.

Consider the effect of diet on a patient on warfarin therapy. Certain foods containing high levels of Vitamin K eg dark leafy vegetables, brussell sprouts, and broccoli, when added to the diet of this patient may adversely affect prothrombin time. This may result in adverse effects requiring modification of the warfarin dose.[1]

Conversely, some food items are recommended by physicians to be included in the diet to counteract the effect of drug treatment. Eg frusemide, a diuretic used to treat hypertension or fluid retention results in a loss of potassium from the body. If this loss is not acute enough to require a high dose potassium supplement in tablet form, the physician will recommend the patient eat a food such as a banana or an avocado, both concentrated sources of potassium, each day.[2,3,4.]

Furthermore a patient with impaired renal function, who has not yet commenced dialysis, would be advised by their health care practitioner to avoid potassium rich sources (eg bananas) to reduce their renal load. Taking this into consideration, the proposal to include the above information on the label of FSMP should also apply to foodstuffs containing high concentrations of vitamins/minerals as well, in the interests of public health and safety.

Industry does not believe FSANZ would want to set such a precedent on mandatory warning statements on FSMP which would have implications for certain fresh foods by setting such a prescriptive standard on contraindications, drug-nutrient interactions and side effects.

It would be impossible to include all drug nutrient interactions and or contraindications on the labels of FSMP. Industry believes it is the drug manufacturer responsibility to notify the contraindications not the food manufacturer

What is proposed is far in excess of what is internationally accepted. FSANZ has taken the codex standard (180-1991) completely out of context. Industry strongly advises FSANZ to accept global practise.

1. Ovesen L. Lyduch S, Idorn ML. *The effect of a diet rich in brussel sprouts on **warfarin** pharmacokinetics.* Eur J ClinPharm. 34(5):521-3, 1988.
2. Anonymous. *Low potassium levels may increase stroke risk for elderly taking diuretics.* Pharmaceutical Journal. Vol 269(7211) (pp 206), 2002. Date of Publication: 17 AUG 2002.
3. http://www.niddk.nih.gov/health/kidney/pubs/kidney-failure/eat-right/eat-right.htm#potassium
4. http://www.americanheart.org/presenter.jhtml?identifier=570

7 ADVERTISING

FSANZ states there is no evidence to suggest that the FSMP industry is unethically advertising products to the general public. Yet FSANZ also states that there are significant public health and safety risks associated with unsupervised and inappropriate use of FSMP by consumers. This contradicts an earlier statement by FSANZ that "there appears little evidence to suggest that there is an increased risk to public health and safety from the current unrestricted access to FSMP."

The vast majority of FSMP advertising is directed to healthcare professionals via journals, direct mail, seminars, trade exhibitions and printed sales literature.

Given that consumer access to healthcare professionals is not generally improving, industry would suggest that FSANZ could actually reduce public health by restricting consumer access to information on new or current products that can improve health and the quality of life of certain consumers, who are currently under medical supervision, with diseases such as cancer, diabetes or rare inherited disorders.

FSANZ must also recognize the growing use of new technologies such as the internet within Australia and New Zealand and the inability of governments to regulate its content. The Medical Departments of industry members often receive enquiries from consumers who have identified a medical nutritional via the internet and ask for further information.

Industry would also recommend that FSANZ allow advertising to consumers via patient support groups or disease specific consumer groups. A self-regulated industry advertising code could be implemented to maintain the high ethical standards that already exist.

The ability to advertise in mainstream media is regulated by in fact its costs and return on investment. Given the relatively low target group populations and the high costs of mainstream industry perceive the risks to public health and safety to be minimal by allowing unrestrictive advertising.

Industry would strongly recommend that no restrictions be placed on advertising including VLEDs.

8 TRANSITIONAL TIMETABLE

Industry cannot commit to a transition until we have a more certain understanding of the labelling and compositional requirements placed on it. At the very minimum a transition period of 4 years should apply to allow for the not insignificant task of reviewing and modifying all our product lines, with a minimum 2 years following expiration of the transition period to deplete the remainder of stock held in trade. Bearing in mind that up to 95% of the current products are non compliant under the proposed draft standard P242

10 CONCLUSIONS & RECOMMENDATIONS

ANZENMA considers that FSANZ has underestimated the negative effect that restrictions imposed in Option 2. We also note that FSANZ has made a quantum leap from the original proposal to industry and the discussion paper released for public comment. We particularly believe FSANZ has underestimated the application of generic labelling standards, particularly those associated with labelling and maximum limits, would have on both industry and the consumer and that the benefits stated have not shown to be an improvement in the status of the current environment.

Industry would challenge FSANZ on the emphasis placed on the 'assessed level of risk' in Australia and New Zealand where products are routinely used under medical supervision. For toxicity to occur with the inappropriate use of an FSMP, a very large quantity must be consumed over a long period of time, the barriers to which would be the cost involved as well as the desire to consume such large volumes. This would assume that professional health intervention is absent which is rarely the case. Any inappropriate use of an FSMP is identified and corrected under this care. The exception here would be the consumption of a complete, balanced nutritional supplement by a patient with a particular metabolic disorder. These patients, however, are under very close medical supervision and the risk of this occurring is very minimal.

Industry concedes that medical supervision cannot be solely responsible for compensating risks associated with the nutritional integrity of these products but we would again challenge both the emphasis placed on the level of risk anticipated and the suggested uncertainty of the nutritional integrity of the product manufactured to comply with legislation already in place overseas.

Industry will provide FSANZ the following documents in the future;

1 A detailed commentary on draft proposal P242 with supporting attachments Date: April 11th 2003

2. Industry responses to FSANZ specific questions as outlined in draft proposal P242. Date: April 11th 2003

3. A detailed listing of further nutritive substances and processing aids required industry. Date June 16th 2003.

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APRIL 2003

prepared on behalf of **ANZENMA**
by **Sue Akeroyd & Associates** *Apr-03*

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Executive Summary

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It would also contribute to the on-going investment in local research and development as part of global product development plans. The continued access to the latest products available from research and product development would also benefit consumers and healthcare professionals.

Adopting the proposed standard in its current format would result in up to 95% of all products being non-compliant in a number of areas and given the relatively small market size, the majority of products would never comply even after the FSANZ proposed transitional timetable.

We would like to continue participating in the necessary debate to seek resolution to the perceived issue of the lawfulness or otherwise of 'most FSMP-type products' at the point of sale. And to that end are happy to support the proposal for the development of an External Advisory Group if such a group is deemed necessary. We would expect stakeholders to include professional bodies such DAA, AusPEN, Royal District Nursing, Pharmacy, medical food suppliers, representatives of both distribution and support networks, bearing in mind the use of product in hospital as well as community/home settings.

With tenders now in dialogue which will run from mid-2003-2005 it is clear the enactment date will need further discussion subject to the final outcome. At least we would be seeking a transition period of four years with a minimum of two years stock in trade following expiration of the transition period.

Industry members key concerns are:

- **The compositional requirements**
  - Maximum nutrient levels
  - Nutritive substances listings
  - Food additives and processing aids listings

- **Labelling Requirements Unique to Australia and New Zealand**
  - Contraindications

- **Application of Generic Labelling Requirements**
  - Nutritional panel requirements
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Membership is open to any manufacturer of enteral nutrition feeding products.

The proposal

1 Interpretation

(1) In this Standard –

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

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

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

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

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

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

It is unclear if this definition applies only to minimum protein levels in VLEDs as they are the only products with a minimum protein content. Or if it would apply for the nutritional panel labelling of all products. If the latter, this would cause a harmonisation problem as most products are labelled with the protein content being determined by their nitrogen content.

We would like the opportunity for further discussion including consideration changing the heading to read "Minimum protein content of VLED"..

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

Recognising that more than 50%enteral FSMP in Australian supply are ex-USA we are conscious of the US interpretation of medical food as enunciated by the Center for Food Safety and Applied Nutrition [1]:.

However in the spirit of cooperation, and in line with previous discussions, we would support the DAR proposal modified in line with the EU Directive (as follows) and are hopeful it will not be an impediment to ongoing supply from US.

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

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

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

[1] U.S. Food Drug Administration, Center for Food Safety Applied Nutrition, Food Compliance Program. Medical Foods - Import and Domestic. Field Reporting Requirements Issued December 21, 1998

Medical Supervision

We have considered the settings where medical foods may be initiated, and how **medical supervision** might be interpreted.

The Victorian Ministerial Working Party on Home Enteral Nutrition [2] was set up to review policy framework and funding arrangements for home enteral nutrition (HEN) in Victoria. Enteral feed was described as 'the delivery of liquid high-concentration nutritional formula directly into the intestinal tract via a feeding tube'. The report focussed on clients receiving HEN initiated within public hospital settings, and did not cover supplementation for extra nourishment, or use in nursing homes (nursing home cost separately covered by Federal funding).

According to this report the large majority of HEN clients in Victoria 'have their therapy instigated in the public hospital system and ongoing management occurs predominantly in the public hospital outpatient setting.'

'In 1996, 59% of clients receiving HEN in Victoria were adults, with malignancy (33%) being the most common disease state leading to the initiation of HEN, followed by non-malignant neurological disorders (26%) and HIV/AIDS (20%). The most common disease state in children requiring HEN was neurological disorders, which account for over 50% of children on HEN.'

'The majority of clients (64%) received HEN for more than 6 months, and only 5% received it for less than a month. Sixty-four per cent of clients were placed on standard feeds (1 Kcal/mL with or without fibre).'

Successful HEN therapy is described as requiring a 'multi-disciplinary team or a case management approach, a suitable and competent client/carer, an appropriate and supportive home environment, careful discharge planning and adequate monitoring and follow-up'. The Australian Society of Parenteral and Enteral Nutrition (AuSPEN) Clinical Practice Guidelines for HEN in Australia [3] advise that the best care of the patient receiving HEN will occur when the primary care physician working with a nutrition support team (comprising medical practitioner, nurse, dietician, stomal therapist) takes responsibility for the initial and ongoing care of the patient receiving HEN.

But medical foods are not only enteral feeds.

In the context of de-restricting advertisements of therapeutic goods directed to **healthcare professionals** the Therapeutic Goods Regulations [4] recognise:

(a) medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, dietitians, scientists working in medical laboratories or nurses; or

(b) persons who are:

  (i) engaged in the business of wholesaling Therapeutic Goods; or

  (ii) purchasing officers in hospitals; or

(c) herbalists, homoeopathic practitioners, chiropractors, naturopaths,

(d) nutritionists, practitioners of traditional Chinese medicine or osteopaths Registered under a law of a State or Territory.

[2] Report of the Ministerial Working Party on Home Enteral Nutrition in Victoria, 1997, by the Dept of Human Services.

[3] Clinical Practice Guidelines Home Enteral Nutrition. 1997. Australian Society of Parenteral and Enteral Nutrition (AuSPEN).

[4] Therapeutic Goods Regulations 1990 Part 2 Division 1 s4.

Also included in this context (healthcare professional) are persons who are 'members of an Australian branch (however described) of one of the bodies referred to in Schedule 1' [5]. And 'for the purposes of subregulation (2), a person is taken to be a member of an Australian branch of one of those bodies if, and only if, the person has the qualifications and training that are necessary or appropriate for membership of the relevant body.'

From a therapeutic viewpoint these are healthcare professionals recognised by Federal Therapeutic Goods legislation. We believe this provides a practical working precedent for the interpretation of 'medical supervision' in the context of medical foods.

We have also considered the persons for whom medical foods may be indicated. They will be from all ages and stages of life, including infants, and pregnancy. Metabolic conditions and serious ill health, for other reasons, are not mutually exclusive.

[5] Therapeutic Goods Regulations 1990 Schedule 1.

Division 1 – Composition

Division 1, Composition			
3(2)	Maximum Levels	All of Industry's nutritionally complete FSMP products would not meet at least one of the maximum in Schedule 2.	Have no maximums. However if maximums are required then only where there is a health and safety issue. This should be discussed with ANZENMA.
3(8)	Variants for special needs.	In addition to Sodium and Potassium there will be a need to vary other nutrients to meet the needs of people with special needs.	Use worlds from E.U. directive "….with a nutrient-adapted formulation specifically for a disease, disorder or medical condition….." (article I.3 (b) and (c).
3(4)	Maximum levels for non-complete foods.	Many non-complete FSMP have lowered energy levels. Lowering the energy allows other "permitted" foods to be eaten to supply energy. Basing the vitamins and minerals maximum on energy is not possible in such cases.	Do not have maximum levels for non-complete FSMPs.
3(5)	Nutrient levels of VLED.	Some minimum and maximum levels are not achievable. Need provision to add vitamin K Chromium and Fluoride.	Review maximum and minimums as in 3(2) and allow addition of Vitamin K, Chromium and Fluoride.
4(1)	Energy Levels for VLED	Product may be used as a meal replacement after it has been used as a total diet. Therefore concern that it would supply more than 3350kj per day.	1. Remove the maximum energy level or 2. Add to 4(1) the words "when used as a total diet" or other words to have the standard acknowledge that more calories may be used as the consumer has their diet relaxed.

2 General restrictions on composition

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

We presume there is no 'limit' on the incorporation of 'food'.

Page 47 of the draft assessment report indicates, correctly, that many FSMP require a nutrient profile that is unique to various disease conditions. A number of FSMP are characterised by an increase or decrease of nutrients beyond the limits of normal human nutrition as a means of meeting this purpose. Whilst we agree that the majority of modifications would be with macronutrients, variation in micronutrient requirements cannot be excluded.

3 Permitted nutritive substances

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

Column 1 seems to be derived from the EU Directive. The list differs from, and does not include some entries in the existing Schedule to Standard 1.1.1 which has general application to the foods which may have vitamins and minerals added. There are also additional forms in Standard 2.9.1 – Infant formula. We have attached a table describing the vitamin and mineral forms permitted in various Australian food standards, as well as those permitted in Listable medicines (Australian dietary supplements)[6]. New Zealand dietary supplements are not as limited in the forms able to used as Australia.

We request a reconsideration of the permitted forms in the light of the information provided. Noting that medical foods in the US are not so limited. We will also be seeking further input from our overseas affiliates with respect to both additional nutrients and their respective forms. We are hopeful of providing further detail on this matter by mid-June 2003.

[6] Comparison of Permitted Forms of Nutrients (SA&A) attached

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

It was our initial understanding that the intention of the Standard Proposal was to regulate (or deregulate) labelling requirements, and not to prescribe formulation. Schedule 2 as drafted excludes most of the medical foods presently being supplied based on the energy recommendations as labelled (Magnesium, Biotin, Niacin, Vitamin A). We are hopeful that this was not the intention.

The offshore products being brought into Australia are administered in clinical settings much like Australia's. They are not consumer-level products in Australia, nor elsewhere.

FSMPs are different from all other products referred to in the Food Standard Code, because they are not general purpose foods. The greatest proportion of FSMP is supplied on tender to Hospitals. Abstracts of a NSW tender request are attached[7]. In this example 99 formula/pack variants of enteral formula are described. Other purchasers include State Govt through Home Enteral Nutrition programs, and the Federal Government via Enteral Feeding Programs for people in Residential Care.

If a Standard were to be developed which was not in accord with current usage/requirements then supply could be seriously interrupted.

For example, in a current NSW tender request, which is for supply to July 2005, "Tenderers are required to provide evidence of compliance with Standards requirements as laid down by State or Federal authorities where relevant" (item 6.21.6).and "In all cases where Australian Standards exist, tendered products should conform to such standards. Tenderers are at liberty to offer products that comply with other recognised international Standards. However, where any inconsistency exists between other standards offered and the Australian Standards specified, full details of the inconsistencies are to be stated in the tender response" (item 6.21.7).

A 1997 Ministerial Review of Home Enteral Nutrition (HEN) in Victoria [8] is 'silent' on any formulation or safety issues, though it does recommend ' research trials' into outcomes and cost-effectiveness of HEN. Funding was recommended to be contingent upon the compliance with Australian Society of Parenteral and Enteral Nutrition (AusPEN) Clinical Practice Guidelines for HEN. in Australia. These guidelines, referred to previously, relate to professional clinical practice, and are also 'silent' on formulation.

With US and Europe markets to draw from, the small population of Australia currently has access to economies of scale in formulation and manufacturing that just would not be available if unique regulatory requirements were introduced.

Persons on nutritionally complete diets do not derive nutrients from other sources. So when determining upper limits, any constraints that may be applied because of other dietary intakes should not apply.

For all users of 'medical foods' which by definition are under medical supervision, one would expect that use of other nutrient sources eg dietary supplements, complementary medicines, OTC medicines, prescription medicines would be recorded and accounted for by that 'medical supervision'.

Similarly since medical foods are intended for exclusive or partial feeding of persons with limited or impaired capacity to take, digest, absorb or metabolise ordinary food or certain nutrients in the food OR persons who have other special medically-determined nutrient requirements it may be that a persons nutrient requirements might exceed 'normality' and so require nutrients in excess of the proposed range. For example the ASPEN Guidelines mention the altered nutrient requirements of geriatric patients.

In our view, given the medical supervision, there is no justification for any upper level restrictions for either complete, or non-complete formulations, except where there is sufficient evidence of adverse health

[7] NSW Dept Public Works & Services Request for Tender (0300425) 035/955 Enteral Feeding Products.
[8] Report of the Ministerial Working Party on Home Enteral Nutrition in Victoria July 1997 Dept Human Services.

effects at higher levels. Noting that some of our products, which may be used at higher dosages, will not be administered longterm at that level. And recognising that by increasing the nutrient level the usage may have moved beyond nutrition into 'supplementation'. We are aware that P235 – Food-Type Dietary Supplements is on the agenda for consideration and that presently there is only limited restriction of dietary supplements in NZ [9].

We have included a comparison of the restrictions applicable to nutrients when supplied in Australia as Listable complementary medicines, or New Zealand as dietary supplements[10]. In Australia (SUSDP) Schedule 2 and Schedule 3 restrictions means pharmacy or pharmacist only. These Schedules are not available to non-pharmacists for retail or direct supply, other than through making a recommendation for the 'consumer' to obtain the product from a pharmacy. Only Schedule 4 medicines require a doctor's prescription.

In recent years The European Scientific Committee on Food (SCF), The UK Food Standards Agency Expert Group on Vitamins & Minerals (EVM), as well as the US Institute of Medicine Food & Nutrition Board (FNB)[11] have considered the safety of certain nutrients. The drafted limits seem largely based on US considerations.

The References Values developed by the US FNB were intended for the 'healthy population in the US & Canada'[12]. These references values are intended to replace the previously issued RDA's. It is indicated that the 'DRI Committee intends to issue a subsequent report that will focus on the uses of DRI's in various settings'. The (US) Recommended Dietary Allowance is defined as 'the average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all individuals in a life stage and gender group'. The Tolerable Upper Intake Level (UL) is described as being the highest level of daily nutrient intake that is likely to pose no risk of an adverse health effects to almost all individuals in the general population. UL's are based on total intake of the nutrient from food, water and supplements if an adverse effect has been associated with total intake. However, if adverse effects have been associated with intake from supplements or food fortificants only, the UL is based on nutrient intake from those sources only not on total intake. The UL applies to chronic daily use.

We submit that the US UL, for example, has not been generated for this purpose (medical food), and is not applicable as drafted.

We have attached for your reference a table from the American Council for Responsible Nutrition (CRN) [13] tabling No Observed Effect Levels (NOAEL) and Lowest Observed Effect Levels (LOAEL) [14] for the key vitamins and minerals. The described NOAEL for magnesium, for example is 700mg/day and Biotin is 2.5mg/day. For both there is no LOAEL established. Further detail of the supporting data is available upon request.

As stated the levels in Column 3 of Schedule 2 would be breached by currently supplied product as labelled. This would not be corrected by modifying the Schedule to set upper daily limits and disconnecting the relationship between maximums and energy, without consideration of the upper levels themselves.

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[9] New Zealand Dietary Supplement Regulations, 1985

[10] Aust/NZ Restricted Vitamins and Minerals (SA&A) attached.

[11] for both US and Canada

[12] From the Preface of the Institute of Medicine, Food and Nutrition Board: Dietary reference intakes: calcium, phosphorus, magnesium, vitamin D, and fluoride, 1997: Dietary reference intakes: thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin, and choline, 1998: Dietary reference intakes: vitamin C, vitamin E, selenium, and carotenoids, 2000 Dietary reference intakes: Vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc. 2001 National Academy Press, Washington, DC.

[13] The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington-based trade association representing ingredient suppliers and manufacturers in the dietary supplement industry

[14] http://www.crnusa.org/pdfs/CRNrectableNLOAEL.pdf

Assessing maximum daily intakes is complex. Conventionally the nutrient levels of FSMP are linked with energy intake. Formulations will range between 1kCal/mL and 2kCal/mL. The energy density and dosage of the food will be determined by the needs of the patient and is related to energy and fluid requirements. Some patients for example burns patients may have high energy (and nutrient) requirements, whereas other patients e.g. renal failure may have low fluid requirements. ASPEN[15] has estimated that 35-40% of hospitalised patents may be obese. The ASPEN Guidelines when referring to specific disease states frequently state "the macronutrient composition/the determination of nutrient requirements, should be individualised 'while taking physiologic and patho-physiologic conditions into account'.

As has been mentioned before there is no market failure demonstrated for the diversity of product currently being supplied. Medical foods are often applied in serious, sometimes even life-threatening circumstances. With chronic illnesses the research objective is to improve quality of life and hopefully optimise cost-effectiveness. With such goals clinicians and other health-care professionals involved in the care of patients needing medical foods, including VLED, frequently travel overseas to stay abreast of the latest scientific developments and to confer with colleagues. It is entirely inappropriate for a country such as Australia with its high-grade reputation for medical care to be restricted in its access to cutting-edge product development.

One of the short-term objectives of our industry is to be able to simultaneously launch new medical food products in multiple markets. It would be unfortunate if Australian regulation were to prevent such events.

Whilst we have indicated that, in our view, given the medical supervision, there is no justification for any upper level restrictions, we expect there may be a need for further discussion on the matter, and we would be happy to participate in those discussions.

[15] ASPEN Guidelines for the Use of Parenteral and Enteral Nutrition in Adult & Paediatric Patients JPEN 2002 Vol. 26 No. 1

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

With professional involvement in the initiation and ongoing usage of medical foods we do not believe there is need for a standard that prescribes formulation rules.

Phosphate may be another nutrient indicated for reduction is certain instances (pulmonary disease)

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

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

Most products do not meet the maximum levels in table 2. Until decisions are made on the final levels it is difficult to be able to indicate which products will need permission to vary from the levels in table 2 to meet specific medical or nutritional needs,

However ANZENMA believes that there will be a need for a provision to cover well established needs as currently occurs for infant formulas in standards R7 and 2.9.2 of the Australian code and in the EU directive for FSMPs.

We believe phosphorus is an issue for some circumstances. And varied sodium and/or potassium may be indicated across both complete and incomplete foods as well as VLED.

The maximum limit prescribed in P242 for compositional requirements does not allow for future innovation and developments in medical nutrition to treat specific disease states with modified micronutrient formulations. It is important to retain flexibility in the compositional requirements to enable the Australian and New Zealand community to adopt developments based on medical/ scientific rationale in the nutrition management/ intervention of specific disease states. For example the role of EPA in the down regulation of cytokine production and ability to reverse tumour induced weight loss. Elevated levels of n-3 fatty acids have also been shown to correct lipid abnormalities in cystic fibrosis.

Concentrated formulas are beneficial to many patient groups, those with increased requirements, fluid restrictions, reduced feeding time availability and volume tolerance issues. Any medical condition involving altered metabolism of nutrients (eg cancer), malabsorption (post gut/ bowel surgery), impaired utilisation (eg pancreatic insufficiency), increased requirements (eg burns) or fluid restricted (eg cardiac insufficiency) will require higher levels of micronutrients to assist with the availability of these within the body.

Elevated levels of vitamins and minerals assists in the provision of adequate intake for patients with increased requirements. For instance, older adults require more vitamin D to over come hyperthyroidism associated with diminished renal function.

Patients with severe congestive heart failure are at increased risk of anaemia secondary to renal insufficiency, low levels of erythropoetin and blood loss from the use of ACE inhibitors. This patient group may benefit from increased iron and vitamin C intake.

High doses of glutamine have demonstrated benefits in critically ill patients. No evidence of harm has been observed.

The FSANZ minimum and maximum values are based on an "average" adult energy intake of 8.7MJ. There are many instances where this average is not appropriate; such as chair bound or bed bound elderly or rehabilitation patients, who may have an energy requirement of around 4.5MJ per day. The maximum levels are expressed as a proportion of energy; this also presents a problem where the FSMP is specially

designed to be a low energy product (non VLED product) or where energy is not one of the nutrients being supplemented. This format of expressing maximum permitted nutrient levels is not relevant to all types of FSMP.

FSMP have been used over a long period of time, there is no clinical evidence to date that exceeding the maximum levels of nutrients as proposed by P242 has negatively impacted on the health or safety of patients taking these products. Maximum values should only be set where a risk to health has been demonstrated. Abbott is not aware of any evidence to support a risk to health by consuming any of their FSMP.

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

We appreciate that this entry is intended to remove the lower limit that would apply to complete foods. Subject to further consideration on maximum levels we believe it would be clearer to state: ..."Although not required to contain minimum levels of vitamins and minerals foods for special medical purposes, other than those that are nutritionally complete, may contain vitamins and minerals only in an amount no more than that specified in column 3 of Schedule 2 of this Standard."

For our comments regarding the 'upper limits' (Column 3, refer above). We reaffirm our opposition to 'upper limits' being imposed in Australia that are at variance with product in global supply.

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

With respect to VLEDs, it is agreed that such products must be nutritionally adequate. Similar comments apply as above with respect to medical supervision and the appropriateness of imposed upper limits. For many people it is unlikely that obesity is the sole condition being treated. According to the NH&MRC [16] 'very low energy diets, or VLEDs, usually provide around 1.7 to 3.3 megajoules (/kg) a day. In addition, they must contain .... the recommended daily allowances of minerals, vitamins, trace elements and essential fatty acids. They are used as the only source of nutrition for 8 to 16 weeks and are often a last resort for patients who have been unsuccessful on other programs and/or who have life-threatening co-morbidities. "

We appreciate that in the Draft Assessment Report for many nutrients no maximum has been set.

Vitamin E is eligible for listing in complimentary medicines and there is no maximum set. Vitamin E does not have an entry in the SUSDP.

Even modest levels of nicotinic acid may cause flushing in the early days of administration. This does not apply to nicotinamide and we therefore question the upper limit for niacin equivalents, given that nicotinic acid is rarely used in formulating.. Nicotinamide is not restricted in Australia/NZ for complementary medicine nor dietary supplement use.

Nor is magnesium. Our comment re nutritionally complete food, and the inappropriateness of taking additional dietary sources into account in that circumstance, applies to the upper limit described for magnesium for VLED. There is no justification for a 350mg limit on magnesium.

Some of the nutrients allowable in medical foods are missing eg vitamin K, Chromium, Fluoride. We request their inclusion for VLED. We refer to our comments regarding permitted forms, and nutrient levels in Schedule 2 as they are applicable to Schedule 3 also. (refer attached table)

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

As stated by NH&MRC very low energy diets are often a last resort for patients who have been unsuccessful on other programs and/or who have life-threatening co-morbidities so we cannot exclude the possibility that a complete 'medical food' may be indicated where the energy level might be within the 'very low' interpretation. Alternatively, a VLED may be indicated with modification to address the co-morbidities. With P235 on the horizon we would like to flag this matter for further discussion.

[16] Draft Clinical Guidelines for Weight Control and Obesity Management in Adults Sept 2002 NH&MRC

4 Additional compositional requirements for VLED

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

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

(a) 3g linoleic acid and 0.5g alpha-linolenic acid, and have a ratio of linoleic acid to alpha-linolenic acid of between 5 and 15; and

(b) (b) 50g carbohydrate; and

(c) (c) 50g protein.

4(2)(a)(b)(c) is not current practice but we expect it to be achievable by enactment. However we would appreciate the opportunity for further dialogue on formulation aspects of VLED.

We have mentioned elsewhere that sometimes VLED servings are continued in a non-complete program. In that context 3350kJ may be exceeded which hypothetically may take the product outside of the jurisdiction of this Standard. We believe there would be more clarity if the interpretation of VLED in item 1 was amended.

Eg

Interpretation

Formulas for very low energy diets (VLED) means nutritionally complete formulas principally presented for use in energy restricted diets of not more than 3350kJ per day for the dietary management of obesity.

With 4(1) amended to

Formulas for very low energy diets must contain no less than 1880kJ in a recommended daily quantity of the food.

Division 2 – Advertising and Labelling

CLAUSE	TOPIC	PROBLEM	SOLUTION
DIVISION 2 *Advertising & Labelling*			
5(2)	Advertising of FSMP to Health Professionals	This clause would prohibit many of the current forms of advertising and promotion of FSMP to Health Professionals and would prevent some forms of communication to home care patients or patients with chronic conditions who purchase products via mail order. All these groups of patients would be under medical supervision.	See submission of 24th March.
6	Date Marking	Horizontal labelling provisions of the Food Code as interpreted in the FSANZ User Guide require nutritionally complete foods to be labelled "use by". The EU directive requires "best before" unless there is a microbiological safety issue. In the USA products are labelled with "expiry".	Allow "Use by" or "Best before" or "Expiry" or "Exp" or "words of similar meaning".
7(1)	Use of the term "free"	Clause 15 and 16 of Standard 1.2.8 prohibits the use of the terms lactose free and gluten free unless these foods contain no detectable lactose or gluten respectively. In EU and USA there is a maximum level of the nutrient below which a lactose or gluten free claim can be made. To meet the Australian standard labels will have to have these claims removed. These labels would not be able then to be used in EU and USA as consumers would be confused as they would no longer know the lactose or gluten status of these products.	Work with Industry and Health Professionals to convince ACCC that the "No detectable" standard is against consumers interests and that reasonable "clinically established maximum levels" should be written into standards for the "free" claim.

CLAUSE	TOPIC	PROBLEM	SOLUTION
7(3) (a) to (d)	Nutrient Levels per 100g or 100ml	This clause requires the nutrients be expressed per 100g or 100ml. For many products these values may be expressed per package, per serve, per 1500 calories, per days requirement or per litre.	Accept any one of these forms on the label. Other values can be obtained from manufacturers literature.
7(3)	Average Quantities	USA regulations require nutrients to be expressed as "not less than" a stated quantity.	Allow either average, maximum or minimum levels on the label. Average value can be obtained from manufacturer's literature.
7 (3)(e)	Serving Size	There are many products that do not have recommended serving size but the amount used depends on the needs and condition of the consumer. For example, the dosage of a low phenylalanine amino acid mixture used for consumers with PKU is dependent on the blood phenylalanine level of the person.	Serving size and number of serves per package should not be required by the standard.
7 (4)	Concentrated Product Nutrients	As discussed 7 (3)(e) above many products do not have directions that will give a specific concentration of the made up product.	Delete the clause
Horizontal Labelling Requirements			
	Horizontal Labelling	The horizontal labelling requirements of the FSANZ code are very prescriptive and although they have similar intent they differ in the detail and wording from those used in the USA and EU Specific problems include: a) Australian address of distributor b) Allergy labelling c) Labelling of ingredients including class names and declaration of ingredients in compound ingredients. d) Directions for use and storage e) Chacterising ingredients and components of food	Exempt FSMP from horizontal labelling and apply less prescriptive labelling requirements in standard 2.9.5

CLAUSE	TOPIC	PROBLEM	SOLUTION
Mandatory Advisory Statements for non VLED FSMPs			
	Important Notice	Not required in USA. Will not be on USA products. These products would not be able to be sold in Australia.	Make non compulsory. All information on the label is important.
"Foods for Special Medical Purposes are to be used only Under Medical Supervision"			
9 1st Box	Medical Supervision Statement	This statement is ambiguous and the word "only" is not compulsory on EU on USA products.	Only require the words currently used on USA or EU products. Simplify to "use under medical supervision".
9 3rd Box	Statement 1	This statement will not be on most imported products as the statement is either not required in the USA, or is only required "where appropriate" in the EU. When not appropriate it is usually misleading to use it and would not be used by our overseas affiliates in those cases.	Allow manufacturers to continue to act responsibility and add the appropriate message where required without prescriptive regulations that often would be misleading.
9 3rd Box	Statement 2	The EU Directive only requires this statement "where appropriate". Therefore EU low protein pasta will not have the above statement as nobody would try to feed pasta into a person's veins.	Leave decision to manufacturer. If this is not possible under Australian Food Law then the Law should be amended.
9 3rd Box	Statement 3	This type of statement is not required in the USA. Therefore will not be on some of the USA products.	Do not make compulsory.

CLAUSE	TOPIC	PROBLEM	SOLUTION
Additional Labelling Requirements			
10 (a)	Precautions, Side effects, Contraindications and Drug interactions.	a) not required in USA or EU therefore not on labels and for most products there would not be room for extra print. b) the problems of warning of every possible effect ie: fat content for people on low fat diets, carbohydrate content for people with diabetes, sodium content for people with hypertension.	Persons with various conditions can easily obtain the necessary information from the ingredients panel or the nutrition panel to determine if the product is suitable for them. For drug interactions this should be the responsibility of the drug manufacturer to identify and notify possible interactions with food when the drug is prescribed or purchased. With the number of new drugs being introduced manufacturers of FSMP would need to change the labels at unacceptably short intervals. Some products have a 3 year shelf life so information could be 3 years out of date before the product was consumed. Who would be legally liable if there was an adverse reaction if the consumer saw a large number of potential interactions but not for their drug and assumed there was no interaction? The consumer may not realize the product was manufactured before their drug was released onto the market.
10 (3)	Labelling of target disease and nutritional modifications	This clause is not needed in USA and is too prescriptive	Delete clause

Advertising

5 Prohibition on advertising

It is proposed that foods for special medical purposes must not be advertised except in health professional publications. Yet at the same time there is mention in the 'background' of the draft assessment report of the ACCC advising ANZFA re 'difficulties in implementing a Code of Practice that sought to restrict the sale and advertising of food'.

It is our understanding that such a restriction would go beyond promotion in, for example, mainstream media, and prevent the distribution of catalogues, product leaflets direct to consumers.

According to The Code of Practice of the Australian Self Medication Industry (ASMI), the peak industry body representing over-the-counter medicinal products, the interpretation of advertisement includes labelling.

> ***"Advertisement"***[17] *includes every form of communication whether in a publication, or by display or any notice, or by means of any catalogue, price list, leaflet, booklet, letter (whether circular or addressed to a particular person) or other document, or by means of any packaging materials (including all labels, cartons, direction folders, and other packaging components bearing printed matter), or by words inscribed on any article, or by exhibition of a photograph or film, or by way of sound recording, radio or television, the Internet, in the spoken word, or in any other way.*

When we met with FSANZ representatives in early February 2003 we discussed the impact of this restriction and our opposition to the proposal. This was deemed to be a change from industry's previous position. This has come about because of the further advice received regarding the interpretation of this proposal and consideration of its impact. As well as considering that many pharmaceuticals, for diverse medical conditions, can be advertised directly to consumers.

There are two parts to advertising restrictions – the topic and the recipient.

We have described the therapeutic goods legislation view of the healthcare professional. Certainly there must be no restriction in the information able to be provided to health professionals.

We have noted Item 10(3) requires that the label include a statement indicating the condition, disease or disorder for which the food has been formulated. If the information can be included on the label then it must surely be able to be conveyed on other product literature.

There will be ranges of circumstances where medical foods may be indicated which are of unequal degrees of seriousness.

[17] Australian Self-Medication Industry - Code of Practice http://www.asmi.com.au/ASMI%20Code%202001.pdf

Even though the **Australian Therapeutic Goods Advertising Code** (TGAC) [18] restricts the advertising of products for what is described as serious medical conditions [19], there is an ability to seek special permission for such an advertisement.

"Even for serious medical conditions an advertisement for therapeutic goods may refer, expressly or by implication, to a disease, condition, ailment or defect specified in TGAC Table 1, provided that prior approval is obtained for such a reference. " The basis for such an approval would be what is described as 'public interest criteria'. In addition to assessing medical merits it might include weighting such matters as access to medical services (resources, distance), empowering patients to manage chronic conditions. There is considerable precedence in medicine advertising for medical claims to be allowed with the published caveat reminder to seek medical advice, or to be used only under medical supervision.

As was noted at our meeting in February 2003, FSMP are not necessarily distributed through normal pharmaceutical channels. Whilst consumers are typically introduced to the products in hospital, and certainly under medical supervision, the ongoing use of the products is supported within the community. We believe better utilization and compliance will be achieved if information regarding the products' purpose and usage is facilitated not restricted. We do not believe it is in the public interest (as described above) to restrict information to consumers on these specialised products.

Further, the recent Australian High Court case re offshore Internet publication [20] indicates that our global company websites could be interpreted as advertising in the Australian context. The restriction proposal therefore has a much more far-reaching potential impact than we believe you intended.

We discussed industry **Codes of Practice** that might apply, or be mimicked, in this area.

Medicines Australia (Previously Australia Pharmaceutical Manufacturers Association) and the **Australian Self-Medication Industry** (ASMI) both have had Codes of Conduct/Practice successfully operating for many years. They are living documents; the MA Code initiated in 1960 is now in its 14th edition [21]. The ASMI Code of Practice is supervised by the Executive Subcommittee, coordinated by the Executive Director, and monitored and reviewed by the Marketing & Ethics Subcommittee.[22] Both Codes have been authorised by the ACCC (or previously the Trade Practices Commission).

It seemed from our discussions that it was VLED products, not medical foods, that were causing the most anxiety with respect to advertising.

There are already Codes in place in both New Zealand and Australia specifically covering weight loss.

The **New Zealand Advertising Authority Inc** (ASA) when launching a new Code (Sept 2002) advised that 'weight loss and weight management advertising is complex. The new **Weight Management Code** combined with the **Therapeutic Code** attempts to clarify the position as much as possible and give clear, practical guidelines to consumers and the advertising industry.'

We agree that it is a complex issue, and that the community is <u>not</u> well served by restricting the flow of regulated information.

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[18] Therapeutic Goods Advertising Code Sept 2002 www.tgacc.com.au

[19] "Serious" in this context means "forms of those diseases, conditions, ailments or defects which are:

- Generally accepted not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional, and/or
- Generally accepted to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional."

[20] Dow Jones & Company Inc. v. Gutnick (High Court of Australia, December 10, 2002)

[21] http://www.medicinesaustralia.com.au/

[22] Australian Self-Medication Industry -http://www.asmi.com.au/ASMI%20Code%202001.pdf - latest revision April 2002, authorised by TPC 1994.

In Australia **The Weight Management Industry Code of Practice** has been developed by representatives of the weight management industry, consumer organisations, health and nutrition professionals and state and federal government fair trading agencies. The Code provides a comprehensive guide for the protection of consumers' rights and the conduct of weight management businesses. It is administered by Weight Management Code Administration of Australia, which has responsibility for managing its members' compliance with the Code.

The promotion of Medicines for weight loss would be within the jurisdiction of the Therapeutic Goods Advertising Code.

Novartis Consumer Health, the only VLED supplier in our group, is a signatory to both

- The ASMI Code of Practice, and
- The Weight Management Industry Code of Practice

Novartis would also be subject to the NZ ASA Weight Management Code if advertising in NZ.

Copies of the current Codes for each are attached.

The latter are suitable for VLED products [23].

The peak industry body for multilevel marketing companies is the Direct Selling Association of Australia. This association also has a Code of Practice.[24]

We believe that advertising of VLEDs should be further considered when the outcomes of the current round of Trans Tasman discussions on therapeutic advertising are known. We anticipate there will remain a preclearance requirement for therapeutic advertisements in publications directed to the general public. And there is a possibility that FSMP and VLED products and could be captured in therapeutic interpretations. In that case we would see no justification in prohibiting such advertising if it could be facilitated through a preclearance process. Therapeutic advertisements directed to professionals are not expected to require preclearance but it is expected there will be a mechanism for complaint handling via relevant industry Codes of Practice.

Obesity is a significant problem in the community it would be wrong for something like the 'grapefruit diet' (reputed to be as low as 800kCal/day) to be promoted whereas nutritionally complete diets with clinical evidence and a recommendation regarding medical supervision cannot.

There is no indication that the Australian Weight Management Industry Code of Practice is failing.

Q- Does the term 'health professional publications' suitably reflect the range of publications that should be permitted to contain advertisements for FSMP?

Q - If not, is there another term that better reflects the type of publications that should contain advertising on FSMP?

Advertising and promotion of FSMP should not be restricted to health professional publications. Current practices for advertising to health professionals not only includes professional publications, but also conferences, other educational forums and meetings where health professionals are in attendance. Other practices include direct mail campaigns and email to health professionals, and websites.

The standard should allow 'Advertising and promotion to Health Professional via any medium that is specifically directed to health professionals'.

We are specifically opposed to this (Food) Standard regulating the advertising of VLED products.

[23] The Weight Management Industry Code of Practice http://www.weightcouncil.org/
[24] http://www.dsaa.asn.au/DsaDocs.htm

Labelling

6 Date marking

Paragraph 2(1)(c) of Standard 1.2.5 is not to apply to FSMP. This means a use by date is required. Typically our industry uses expiry dates prefixed with EXP. We request that permission be given in this Standard to alternatively use the EXP, or 'use by' or 'best before' prefix, or words of a similar meaning..

7 Application of Standard 1.2.8 and declaration of nutrition information

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

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

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

(a) the average energy content expressed per 100g or 100mL; and

(b) the average quantity of protein, fat and carbohydrate in the food, expressed per 100g or 100mL; and

(c) the average quantity of vitamins and minerals in the food expressed per 100g or 100mL; and

(d) the average quantity of other nutritive substances where added to the food, expressed per 100g or 100mL; and

(e) the number of servings per package and serving size.

In place of 'average' in 7(3)(a), (b), (c), (d) we request 'average or minimum'.

Subject to the originating market (EU, USA), pack size, or end use, FSMP may be labelled per 100mL, per litre, per serve per 1500kCal, or otherwise. Since it was our original understanding that the intention was not to impose Australia-specific labelling on offshore source product we ask that 7(3)(e) be deleted, or 'optional'.

As we discussed the great proportion of medical foods (not VLED) are supplied ready for consumption (premixed). And are fully imported bearing overseas labelling. Products that are supplied in single serve packs are labelled per serve.

In US medical foods, such as those used to address the nutritional needs of patients with certain diseases are exempted from the requirement for nutrition labelling (NLEA). In 1996 the FDA issued an Advanced Notice of Rulemaking (ANPR) [25] on the Regulation of Medical Foods but so far no rule has been enacted. Additionally some are considered to be 'orphan drugs'.

[25] FR Nov. 29, 1996 (Vol 61 No 231) Regulation of Medical Foods

Typically in US, serving size remains the basis for reporting each food's nutrient content, albeit the measure is generally standardised (serving sizes now are more uniform and reflect the amounts people actually eat. [They also must be expressed in both common household and/or metric measures. FDA allows as common household measures: the cup, tablespoon, teaspoon, piece, slice, fraction (such as "1/4 pizza"), and common household containers used to package food products (such as a jar or tray). Ounces may be used, but only if a common household unit is not applicable and an appropriate visual unit is given--for example, 1 oz (28g/about 1/2 pickle).]

If Australia were to follow the EU Directive exclusively then because of the above, US-origin medical foods would effectively be 'blocked' from supply unless special exemptions could be granted.

VLED products are typically powder sachets to be mixed with water. They would normally be labelled per serve. Across product ranges (soup, mousse, smoothie etc) serving quantities may vary – 40g, 50g, 55g yet nutrient values per serve would be similar. We submit no purpose would be served by expressing nutrients per 100g in preference to per serve, in the absence of a per serve column since the foods are taken by serve. Nor can we see any value in a 100g/mL column, as comparison with other like products would be meaningless.

Standard 1.2.8 clause 11 indicates that an additional column 'may' be included where the food is to be prepared with at least one other food. We believe this is appropriate where the other (mixing) food is other than water.

With water as the mixing medium there would be no addition to the nutrient content that would need to be addressed by requiring the product to be labelled 'as prepared for consumption' if the product was labelled per serve.

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

Powdered product in a clinical setting is typically 'dispensed' as determined by the healthcare professional. The diluent could be water, or another food, for example milk, juice. We believe the relevant information is the amount / ratio of ingredients in the 'premix.'. Refer to our comment above where the mixing medium is water.

Labelling Comment

Other aspects of (consistent food) labelling are intended to be addressed by the consequential application of general labelling requirements in Standard 1.2. with some proposed exclusions from some sections already identified such as 2(1)(c) of 1.2.5 and significant parts of 1.2.8.

We have already indicated that Australia/New Zealand oriented printed product information is currently made available to healthcare professionals and consumers. If the 'regulatory problem' is as described in item 3 point 3 of the draft assessment which states 'health professionals and consumers being assured of appropriate and consistent information on the safe and effective use of FSMP' this can be addressed by formalising the type of information to be made available to health professionals and consumers along the lines of medicinal product information and consumer information as described in therapeutic goods legislation [26]. This would at the same time take pressure off the pack labelling problem, where there is no additional room on the packs, as supplied, to include Australia-specific label requirements which are at variance with off-shore practice.

We note the FSANZ view that product literature cannot deliver the risk management provided by a label. We disagree. These labels are crowded. The risk is hypothetical.

[26] Therapeutic Goods Regulations 1990 - Schedule 12 (prescription medicines) Schedule 13 (S3 medicines).

Q - Do you believe that the current distribution practices for the supply of supporting product information (in lieu of labelling) guarantees that health professionals and/or consumers receive all necessary information for the appropriate use of FSMP? Please provide evidence in support of your position when answering this question.

> We do believe this to be the case, as no product is prescribed or recommended (or launched) without supporting literature. No product is supported by health professionals without product information, relevant back up research and product specifications. Health professionals simply would not support/recommend or prescribe a product without a minimum amount of literature.

The consumer is introduced to the product by a health professional, generally a health professional team. There is ongoing professional supervision. Distribution points facilitate ongoing supply and cost maintenance. Ongoing education of the consumer, and family members, is an important factor in maintaining compliance.

Evidence

Literature and Information

ANZENMA companies have a wide range of product literature that is available for all health professionals using the products. It is delivered by face to face contact with sales representatives, is made available at conferences, mailed out to health professionals, or can be accessed on a 1800 number.

Services

The following is a summary of the human resources that NZENMA member companies employ to communicate with health professionals and consumers.

Eleven marketing Product Managers who spend at least 50% of their time preparing product literature, organising and manning company trade displays at all relevant conferences, visiting key specialists and dieticians, and training sales representatives

Thirty-eight Sales Representatives who call on all hospitals, institutions, organizations and individual Health Professionals who use or recommend our FSMP products. The sales representatives provide hospitals and nursing homes with in-services training on the equipment and products.

Nine Clinical Nurse Consultants (CNC) are engaged by the hospital or institution before patients are discharged for home enteral nutrition. The CNC visits the person before discharge, manages the discharge, and visits the home to train the person or carer in the use of equipment and products. They then continue to supervise the person's enteral feeding. In in smaller states the sales representatives are qualified to fill the role of the CNC.

Four Enquiry Line Operators are available on 1800 lines during business hours to answer any enquiries from institutions or clients. Out of hours the sales representatives manager can be contacted on their mobile phones.

The staff outlined above are all degree qualified in Dietetics, Nutrition, Nursing or allied areas.

Q - If you do not believe this to be the case, can current distribution practices be altered to ensure the accompaniment of supporting product literature with the distribution/sale of a FSMP? If so, how costly and difficult would such a change be?

We believe the distribution practice is already in place.

8 Mandatory warning statement

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

Table to clause 8

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

Agreed

9 Mandatory advisory statements

Table to clause 9	
Column 1	**Column 2**
Foods for special medical purposes	Statement to the effect – Important notice: Foods for special medical purposes are to be used only under medical supervision
Formulas for very low energy diets	Statements to the effect that – 1. the product may not be suitable for pregnant, nursing or lactating women or by infants, children, adolescents or the elderly; and 2. it is important to maintain an adequate daily fluid intake while using the product.
Foods regulated in this **Standard**, other than formulas for very low energy diets	Statements to the effect that – 1. the product poses a health hazard when consumed by persons who do not have a disease, disorder or medical condition for which the product is intended; And 2. the product is not for parenteral use; and 3. the product is intended/not intended (as the case may be) as the sole source of nutrition.

FSMP - Whilst the EU Directive requires 'the words important notice or their equivalent' America-origin products do not have such a statement. Both do carry statements related to use under medical supervision. We have noted the comment on page 60 regarding 'medical supervision'. We agree that it is the 'intent' not the wording that is important. And 'medical supervision' is typically already on offshore product. We have said elsewhere that there is opportunity for explanation in accompanying literature.

We have noted (and discussed) the EU Directive qualifier 'as appropriate' for items such as health hazard, parenteral use. If this document can be sufficiently flexible to say 'statements to the effect that' could it not be 'where appropriate, statements to the effect that ....'.

The ability to 'get around' the limitations of the Aust/NZ legislation, which we discussed, is demonstrated by 10(b), which in contrast to the EU note of 'as appropriate' only requires an age group statement where the product has been formulated for a specific age group.

VLED – Likewise VLED products are intended to be used under medical supervision and to be labelled as such. It may be that that the adolescent or elderly person is significantly obese. In that circumstance it is unhelpful, if not frightening (for the consumer), if the product is recommended by a healthcare professional and then found to be labelled as unsuitable. Compliance is a significant issue for weight reduction products. Users must be confident that the product is suitable and will be successful.

10 Additional labelling requirements

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

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

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

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

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

We agree with 10(3). It is important for consumers and professional alike to know the purpose of the product. Noting Item 10(3) contradicts the advertising prohibition proposal, which, as interpreted by certain Codes of Practice would apply to labelling.

With respect to Item 10(1)(a) the EU Directive does not have an equivalent requirement. Nor is it common practice for FSMP in US. For many products the labelling space is insufficient. However much more importantly we see this as a requirement for the Product Information of the applicable drug, not the FSMP. We discussed in February the impractical and unjustified concept of labelling grapefruit juice with drug contraindications.

Item 10(2) requires VLED products to be labelled with a statement regarding the recommended daily consumption amount. As we discussed typically a VLED diet may be recommended for a month at the 800kCal level and then reviewed. Thereafter the frequency of consumption may be varied by the supervising healthcare professional, for example a reduction to 2 serves per day, with normal food replacing the third serve. Literally this would mean the product would become a meal replacement rather than a VLED product. Obviously this interpretation would cause regulatory confusion. So we propose that the statement regarding the recommended daily consumption amount be related to 'when the product is intended as a sole source of nutrition', but that it be recognised that this may not always be the case.

Schedule 1 Nutritive substances and their permitted forms

We have attached a table comparing the permitted forms in Standard 1.1.1, Standard 2.9.1 Infant, FSMP proposal, Sports Std. 2.9.4, as well as the form permitted for used in Listed medicines.

Schedule 4 Prescribed method of analysis for protein

We have indicated in the 'interpretation' that we would like the opportunity for further input on this 'method' when we receive advice from our off-shore affiliates.

Generic Standards

Food Additives and Processing Aids

Our offshore colleagues are still working on this matter for us. You will appreciate it requires a detailed review of each formulation to identify the substance and the applied concentrations. We are hopeful that when we do submit the detail to you we will have been able to succinctly collate it and identify those substances which have prior acceptance elsewhere.

In other words the more time we can have the easier your job will be. We hope to be able to respond fully by end June 2003.

Foods requiring pre- market clearance

We are not seeking exemption from Standards 1.5.1, 1.5.2, 1.5.3. Whilst some of our products are sterilised it is not by irradiation.

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

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

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

Draft Standard P242 would require almost every product to be reformulated and relabelled and in most cases the reformulated product would be sold only in Australia and New Zealand. The resultant cost and inefficiency would result in most products being removed from the market.

ANZENMA believes that it would be more productive to supply detailed costing if necessary after the current draft standard has been revised. The time saved will be better spent working with FSANZ developing a standard that will not require these changes.

Footnotes

1. U.S. Food Drug Administration, Center for Food Safety Applied Nutrition, Food Compliance Program. Medical Foods - Import and Domestic. Field Reporting Requirements Issued December 21, 1998 US\CSFANMedFood98.pdf
2. Report of the Ministerial Working Party on Home Enteral Nutrition in Victoria, 1997, by the Dept of Human Services. Aust\henp_1.pdf
3. Clinical Practice Guidelines Home Enteral Nutrition. 1997. Australian Society of Parenteral and Enteral Nutrition (AuSPEN). Aust\AuspenClinPGuid.pdf
4. Therapeutic Goods Regulations 1990 Part 2 Division 1 s4. Aust\TGRPt2Div1s4.pdf
5. Comparison of Permitted Forms of Nutrients (SA&A) Aust\VitMinComp.pdf
6. Therapeutic Goods regulations 1990 Schedule 1. Aust\TGRSch1.pdf
7. NSW Dept Public Works & Services Request for Tender (0300425) 035/955 Enteral Feeding Products. Aust\NSWTend0300425.pdf
8. Report of the Ministerial Working Party on Home Enteral Nutrition in Victoria July 1997 Dept Human Services.
9. New Zealand Dietary Supplement Regulations, 1985 Aust\NZDietSup.pdf
10. Aust/NZ Restricted Vitamins and Minerals (SA&A) Aust\SUSDNZ.pdf
11. for both US and Canada
12. From the Preface of the Institute of Medicine, Food and Nutrition Board: Dietary reference intakes: calcium, phosphorus, magnesium, vitamin D, and fluoride, 1997: Dietary reference intakes: thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin, and choline, 1998: Dietary reference intakes: vitamin C, vitamin E, selenium, and carotenoids, 2000 Dietary reference intakes: Vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc. 2001 National Academy Press, Washington, DC.
13. The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington-based trade association representing ingredient suppliers and manufacturers in the dietary supplement industry
14. http://www.crnusa.org/pdfs/CRNrectableNLOAEL.pdf US\CRNrectableNLOAEL.pdf
15. ASPEN Guidelines for the Use of Parenteral and Enteral Nutrition in Adult & Paediatric Patients JPEN 2002 Vol. 26 No. 1 US\JPEN2002guidelines.pdf
16. Draft Clinical Guidelines for Weight Control and Obesity Management in Adults Sept 2002 NH&MRC
17. Australian Self-Medication Industry - Code of Practice http://www.asmi.com.au/ASMI%20Code%202001.pdf IndCodes\ASMI Code 2001.pdf
18. Therapeutic Goods Advertising Code Sept 2002 www.tgacc.com.au IndCodes\TGACSep2002.pdf
19. " Serious" in this context will mean forms of those diseases, conditions, ailments or defects which are:
    - Generally accepted not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional, and/or
    - Generally accepted to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.
20. Dow Jones & Company Inc. v. Gutnick (High Court of Australia, December 10, 2002)
21. http://www.medicinesaustralia.com.au/ IndCodes\MACode of Conduct Edition 14 - Jan 03.pdf
22. Australian Self-Medication Industry -http://www.asmi.com.au/ASMI%20Code%202001.pdf llatest revision April 2002; authorised by TPC 1994. IndCodes\ASMI Code 2001.pdf
23. The Weight Management Industry Code of Practice http://www.weightcouncil.org/ IndCodes\WeightCode _ Second Edition.pdf
24. http://www.dsaa.asn.au/DsaDocs.htm IndCodes\DSAACoP.pdf
25. FR Nov. 29, 1996 (Vol 61 No 231) Regulation of Medical Foods US\USMedical Food.pdf
26. Therapeutic Goods Regulations 1990 - Schedule 12 (Prescription medicines) Schedule 13 (S3 medicines). Aust\TGRSch12-13.pdf
27. 49th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) TBHQWHO40.pdf
28. NSW Tender seeks commitment from Aug 2003 to July 2005.

Attachments

Schedule 1 Part 2 does not apply to members of an Australian branch of one of these bodies

(subregulation 4 (2))

Column 1 Item No.	Column 2 Body
1	Acupuncture Association of Australia
2	Acupuncture Ethics and Standards Organisation
2A	Association of Natural Health Practitioners Limited
3	Association of Traditional Health Practitioners Incorporated
3A	Aust-China Acupuncture and Chinese Medicine Association Inc.
3B	Australasian Federation of Natural Therapists Inc.
4	Australian Acupuncture Association Ltd.
5	Australasian Association of Ayurveda Incorporated
5A	Australian Association of Exercise and Sports Scientists
6	Australian Association of Professional Homoeopaths
7	Australian Committee of Natural Therapies Inc. (SA)
9	Australian Federation of Homoeopaths
9A	Australian Federation of Homoeopaths (Qld.) Inc.
9B	Australian Federation of Homoeopaths (WA) Inc.
10	Australian Natural Therapists Association Ltd
11	Australian Naturopathic Practitioners and Chiropractors Association
11A	Australian Society of Homeopaths Inc
12	Australian Traditional Chinese Herbalists Association (Qld)
13	Australian Traditional Chinese Medicine Association Inc.
14	Australian Traditional Medicine Society
14A	Australian Unani Medicines Society Inc.
15	Chinese Medicine Association Pty Ltd
15A	Chinese Medicine Association of Australia Inc.
16	Complementary Medicine Association

Column 1 Item No.	Column 2 Body
16A	Federation of Chinese Medicine and Acupuncture Societies of Australia
17	Homoeopathic Education and Research Association
17A	International Association of Trichologists
17B	International Christian Association of Natural Therapists Ltd (ICANT)
18	National Herbalists Association of Australia
18A	Naturopathic Physicians Association of Australia Inc.
19	Queensland Naturopathic Association
20	Register of Acupuncture and Traditional Chinese Medicine
21	Society of Natural Therapists and Researchers [SNTR] Inc.
22	Society of Classical Homoeopathy Ltd
23	Traditional Medicine of China Society Australia
24	Society of Chinese Medicine and Acupuncture (Vic) Inc.
25	Naturopathic Practitioners Association Inc.
26	The Acupuncture Association of Australia, New Zealand and Asia
26A	The Alumni Association of Natural Medicine Practitioners Inc.
26B	The Australian Podiatry Association (NSW)
27	The New South Wales Research Association of Traditional Chinese Medicine

Column 1 **Vitamins or minerals**	Permitted forms **Standard 2.9.1 Infant Formula**	Permitted Forms **Standard 1.1.1**	Permitted Forms **FSMP**	Permitted forms **TGA Listable Subject to SUSDP or CMEC restrictions**	Permitted Forms **Sports Std. 2.9.4 In addition to Std 1.1.1**
Vitamin A	Retinol forms Vitamin A (retinol) Vitamin A acetate (retinyl acetate) Vitamin A palmitate (retinyl palmitate) Retinyl propionate Carotenoid forms Beta-carotene	*Retinol Forms* Vitamin A (retinol) Vitamin A acetate (retinyl acetate) Vitamin A palmitate (retinyl palmitate) Vitamin A propionate (retinyl propionate) *Carotenoid Forms* beta-apo-8'-carotenal beta -carotene-synthetic carotenes-natural beta -apo-8'-carotenoic acid ethyl ester	Retinol Forms Vitamin A (retinol) Vitamin A acetate (retinyl acetate) Vitamin A palmitate (retinyl palmitate) *Carotenoid Forms* beta-carotene	Vitamin A (retinol) Vitamin A acetate (retinyl acetate) Vitamin A palmitate (retinyl palmitate) *Carotenoid forms* Beta-carotene & natural forms	
Vitamin C	L-ascorbic acid L-ascorbyl palmitate Calcium ascorbate Potassium ascorbate Sodium ascorbate	L-ascorbic acid Ascorbyl palmitate Calcium ascorbate Potassium ascorbate Sodium ascorbate	sodium L-ascorbic acid Ascorbyl palmitate Calcium L-ascorbate Potassium L-ascorbate Sodium L-ascorbate	Sodium l-ascorbic acid Ascorbyl palmitate Calcium l-ascorbate Potassium l-ascorbate Sodium l-ascorbate Zinc l-ascorbate	
Vitamin D	Vitamin d_2 (ergocalciferol) Vitamin d_3 (cholecalciferol) Vitamin d (cholecalciferol-cholesterol)	Vitamin D_2 (ergocalciferol) Vitamin D_3 (cholecalciferol)	Vitamin D2 (ergocalciferol) Vitamin D3 (cholecalciferol)	Vitamin d2 (ergocalciferol) Vitamin d3 (cholecalciferol)	
Thiamin	Thiamin hydrochloride Thiamin mononitrate	Thiamin hydrochloride Thiamin mononitrate Thiamin monophosphate	Thiamin hydrochloride Thiamin mononitrate	Thiamin hydrochloride Thiamin mononitrate	
Riboflavin	Riboflavin Riboflavin-5'-phosphate, sodium	Riboflavin Riboflavin 5'-phosphate sodium	Riboflavin Riboflavin 5'-phosphate sodium	Riboflavin Riboflavin 5'-phosphate sodium	
Niacin	Niacinamide (nicotinamide)	Niacinamide (nicotinamide) Nicotinic acid	Niacinamide (nicotinamide) Nicotinic acid	Nicotinamide Nicotinamide ascorbate Nicotinic acid	

Column 1	Permitted forms	Permitted Forms	Permitted Forms	Permitted forms	Permitted Forms
Vitamins or minerals	**Standard 2.9.1 Infant Formula**	**Standard 1.1.1**	**FSMP**	**TGA Listable Subject to SUSDP or CMEC restrictions**	**Sports Std. 2.9.4 In addition to Std 1.1.1**
Vitamin B_6	Pyridoxine hydrochloride Pyridoxine-5'-phosphate	Pyridoxine hydrochloride	Pyridoxine 5'-phosphate Pyridoxine dipalmitate Pyridoxine hydrochloride		
Folate	Folic acid	Folic acid	Folate Pteroylmonogluta mic acid		
Pantothenic acid	Calcium pantothenate Dexpanthenol	No permitted form specified	d-pantothenate calcium Dexpanthenol d-pantothenate	D-pantothenate calcium Dexpanthenol D-pantothenate Dl-pantothenate Sodium pantothenate	d-calcium pantothenate Dexpanthenol d-sodium pantothenate
Vitamin B_{12}	Cyanocobalamin Hydroxocobalamin	Cyanocobalamin Hydroxocobalamin	Cyanocobalamin Hydroxocobalamin	Cyanocobalamin hydroxocobalamin	
Biotin	D-biotin	No permitted form specified	d-biotin	Biotin	
Vitamin E	dl-alpha-Tocopherol d-alpha-Tocopherol concentrate Tocopherols concentrate, mixed d-alpha-Tocopheryl acetate dl-alpha-Tocopheryl acetate d-alpha-Tocopheryl acid succinate dl-alpha-Tocopheryl succinate	dl-alpha-Tocopherol d- alpha - Tocopherol concentrate Tocopherols concentrate, mixed d- alpha - Tocopheryl acetate dl- alpha - Tocopheryl acetate d- alpha - Tocopheryl acetate concentrate d- alpha - Tocopheryl acid succinate	d-alpha-Tocopherol dl-alpha-Tocopherol d-alpha-Tocopheryl acetate dl-alpha-Tocopheryl acetate d-alpha-Tocopheryl acid succinate	D-∝-Tocopherol D-∝-Tocopheryl acetate D-∝-Tocopheryl acid succinate Dl-∝-Tocopherol Dl-∝-Tocopheryl acetate Dl-∝-Tocopheryl acid succinate Tocopherols concentrate – mixed (high alpha type & low alpha type)	
Vitamin K	Vitamin K_1, as phylloquinone (phytonadione) Phytylmenoquinone	No permitted form specified	Phylloquinone	Acetomenaphthone	

Column 1 Vitamins or minerals	Permitted forms Standard 2.9.1 Infant Formula	Permitted Forms Standard 1.1.1	Permitted Forms FSMP	Permitted forms TGA Listable Subject to SUSDP or CMEC restrictions	Permitted Forms Sports Std. 2.9.4 In addition to Std 1.1.1
Calcium	Calcium carbonate Calcium chloride Calcium citrate Calcium gluconate Calcium glycerophosphate Calcium hydroxide Calcium lactate Calcium oxide Calcium phosphate, dibasic Calcium phosphate, monobasic Calcium phosphate, tribasic Calcium sulphate	Calcium carbonate Calcium chloride Calcium chloride, anhydrous Calcium chloride solution Calcium citrate Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium oxide Calcium phosphate, dibasic Calcium phosphate, monobasic Calcium phosphate, tribasic Calcium sodium lactate Calcium sulphate	Calcium carbonate Calcium chloride Calcium citrate Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium hydroxide Calcium oxide Calcium phosphate, monobasic Calcium phosphate, dibasic Calcium phosphate, tribasic	Calcium amino acid chelate as a source of calcium Calcium carbonate Calcium citrate Calcium gluconate Calcium glycerophosphate Calcium hydrogen phosphate (& anhydrous) Calcium lactate Calcium lactate gluconate Calcium orotate Calcium phosphate Calcium phosphate-monobasic Calcium sodium lactate Calcium succinate Calcium sulfate (& dried, anhydrous)	Calcium hydroxide Calcium oxide Calcium sulphate
Chloride	Calcium chloride Magnesium chloride Potassium chloride Sodium chloride				
Chromium	Chromium sulphate	No permitted form specified	Chromium chloride Chromium sulphate	Chromium (iii) chloride Chromium nicotinate nmt 50mcg cr/day Chromium picolinate nmt 50mcg cr/day High chromium yeast nmt 50mcg cr/day	*Inorganic forms:* Chromic chloride *Organic forms:* High chromium yeast Chromium picolinate Chromium nicotinate Chromium aspartate
Copper	Copper gluconate Cupric sulphate Cupric citrate	No permitted form specified	Copper lysine complex Cupric carbonate Cupric citrate Cupric gluconate Cupric sulphate	Copper gluconate Copper (ii) oxide Copper (ii) sulfate Cupric sulfate monohydrate Cupric citrate nmt 750mcg cu/day	*Inorganic forms:* Cupric carbonate Cupric sulphate *Organic forms:* Copper gluconate Copper-lysine complex Cupric citrate
Iodine	Potassium iodate Potassium iodide Sodium iodide	Potassium iodate Potassium iodide Sodium iodate Sodium iodide	Potassium iodide Potassium iodate Sodium iodide Sodium iodate	Potassium iodide Sodium iodide	

Column 1	Permitted forms	Permitted Forms	Permitted Forms	Permitted forms	Permitted Forms
Vitamins or minerals	**Standard 2.9.1 Infant Formula**	**Standard 1.1.1**	**FSMP**	**TGA Listable Subject to SUSDP or CMEC restrictions**	**Sports Std. 2.9.4 In addition to Std 1.1.1**
Iron	Ferric ammonium citrate Ferric pyrophosphate Ferrous citrate Ferrous fumarate Ferrous gluconate Ferrous lactate Ferrous succinate Ferrous sulphate	Ferric ammonium citrate, brown or green Ferric ammonium phosphate Ferric citrate Ferric hydroxide Ferric phosphate Ferric pyrophosphate Ferric sulphate (iron III sulphate) Ferrous carbonate Ferrous citrate Ferrous fumarate Ferrous gluconate Ferrous lactate Ferrous succinate Ferrous sulphate (iron II sulphate) Ferrous sulphate, dried Iron, reduced (ferrum reductum)	Ferric ammonium citrate Ferric sodium diphosphate Ferric pyrophosphate Ferric saccharate Ferrous carbonate Ferrous citrate Ferrous gluconate Ferrous fumarate Ferrous lactate Ferrous sulphate Iron, reduced (ferrum reductum)	Ammonium iron (iii) citrate Ferric chloride hexahydrate Ferric glycerophosphate Ferric pyrophosphate Ferrous carbonate Ferrous chloride Ferrous fumarate Ferrous gluconate Ferrous lactate Ferrous phosphate Ferrous succinate Ferrous sulfate (& dried) Iron amino acid chelate Iron (iii) chloride	
Magnesium	Magnesium carbonate Magnesium chloride Magnesium gluconate Magnesium oxide Magnesium phosphate, dibasic Magnesium phosphate, tribasic Magnesium sulphate	Magnesium carbonate Magnesium chloride Magnesium gluconate Magnesium oxide Magnesium phosphate, dibasic Magnesium phosphate, tribasic Magnesium sulphate	Magnesium acetate Magnesium carbonate Magnesium chloride Magnesium citrate Magnesium gluconate Magnesium glycerophosphate Magnesium lactate Magnesium phosphate, dibasic Magnesium phosphate, tribasic Magnesium hydroxide Magnesium oxide Magnesium sulphate	Magnesium amino acid chelate as a source of magnesium Magnesium aspartate Magnesium carbonate Magnesium chloride Magnesium citrate Magnesium gluconatemagnesi Magnesium orotate Magnesium oxide Magnesium phosphate (& dibasic trihydrate) Magnesium sulfate (incl mono/tri hydrate)	Magnesium citrate Magnesium hydroxide

Column 1 Vitamins or minerals	Permitted forms Standard 2.9.1 Infant Formula	Permitted Forms Standard 1.1.1	Permitted Forms FSMP	Permitted forms TGA Listable Subject to SUSDP or CMEC restrictions	Permitted Forms Sports Std. 2.9.4 In addition to Std 1.1.1
Manganese	Manganese chloride Manganese gluconate Manganese sulphate Manganese carbonate Manganese citrate	No permitted form specified	Manganese carbonate Manganese chloride Manganese citrate Manganese gluconate Manganese glycerophosphate Manganese sulphate	Manganese amino acid chelate as a source of manganese Manganese aspartate Manganese chloride Manganese gluconate Manganese glycerophosphate Manganese (iv) oxide Manganese sulfate	
Molybdenum	Sodium molybdate vi dehydrate	No permitted form specified	Ammonium molybdate Sodium molybdate	High molybdenum yeast nmt 62.5mcg Mb/day Molybdenum trioxide (max 187.54mcg/day Mb 125mcg/day)	*Inorganic forms:* Sodium molybdate *Organic forms:* High molybdenum yeast
Phosphorus	Calcium glycerophosphate Calcium phosphate, dibasic Calcium phosphate, monobasic Calcium phosphate, tribasic Magnesium phosphate, dibasic Potassium phosphate, dibasic Potassium phosphate, monobasic Potassium phosphate, tribasic Sodium phosphate, dibasic Sodium phosphate, monobasic Sodium phosphate, tribasic	Calcium phosphate, dibasic Calcium phosphate, monobasic Calcium phosphate, tribasic Bone phosphate Magnesium phosphate, dibasic Magnesium phosphate, tribasic Calcium glycerophosphate Potassium glycerophosphate Phosphoric acid Potassium phosphate, dibasic Potassium phosphate, monobasic Sodium phosphate, dibasic	Calcium glycerophosphate Calcium phosphate, monobasic Calcium phosphate, dibasic Calcium phosphate, tribasic Magnesium phosphate, dibasic Magnesium phosphate, tribasic Potassium glycerophosphate Potassium phosphate, monobasic Potassium phosphate, dibasic Potassium phosphate, tribasic Sodium phosphate, monobasic Sodium phosphate, dibasic Sodium phosphate, tribasic		Magnesium phosphate, monobasic Phosphoric acid Potassium phosphate, dibasic Potassium phosphate, tribasic Sodium phosphate, dibasic Sodium phosphate, monobasic Sodium phosphate, tribasic

Column 1	Permitted forms	Permitted Forms	Permitted Forms	Permitted forms	Permitted Forms
Vitamins or minerals	**Standard 2.9.1 Infant Formula**	**Standard 1.1.1**	**FSMP**	**TGA Listable Subject to SUSDP or CMEC restrictions**	**Sports Std. 2.9.4 In addition to Std 1.1.1**
Potassium	Potassium bicarbonate Potassium carbonate Potassium chloride Potassium citrate Potassium glycerophosphate Potassium gluconate Potassium hydroxide Potassium phosphate, dibasic Potassium phosphate, monobasic Potassium phosphate, tribasic		Potassium bicarbonate Potassium carbonate Potassium chloride Potassium citrate Potassium gluconate Potassium glycerophosphate Potassium hydroxide Potassium lactate Potassium phosphate, monobasic Potassium phosphate, dibasic Potassium phosphate, tribasic	Potassium aspartate Potassium citrate Potassium gluconate Potassium glycerophosphate Potassium iodide # Potassium orotate Potassium phosphate Potassium sulfate	
Selenium	Sodium selenite Seleno methionine	No permitted forms specified	Sodium hydrogen selenite Sodium selenate Sodium selenite	Selenomethionine Selenocysteine High selenium yeast Sodium selenite	*Inorganic forms*: Sodium selenate Sodium selenite *Organic forms*. Selenomethionine
Sodium	Sodium bicarbonate Sodium carbonate Sodium chloride Sodium chloride iodised Sodium citrate Sodium gluconate Sodium hydroxide Sodium iodide Sodium lactate Sodium phosphate, dibasic Sodium phosphate, monobasic Sodium phosphate, tribasic Sodium sulphate Sodium tartrate		Sodium bicarbonate Sodium carbonate Sodium chloride Sodium citrate Sodium gluconate Sodium lactate Sodium hydroxide Sodium phosphate, monobasic Sodium phosphate, dibasic Sodium phosphate, tribasic	Sodium chloride Sodium glycerophosphate Sodium phosphate	

Column 1 Vitamins or minerals	Permitted forms Standard 2.9.1 Infant Formula	Permitted Forms Standard 1.1.1	Permitted Forms FSMP	Permitted forms TGA Listable Subject to SUSDP or CMEC restrictions	Permitted Forms Sports Std. 2.9.4 In addition to Std 1.1.1
Zinc	Zinc acetate Zinc chloride Zinc gluconate Zinc oxide Zinc sulphate	Zinc acetate Zinc chloride Zinc gluconate Zinc lactate Zinc oxide Zinc sulphate	Zinc acetate Zinc carbonate Zinc chloride Zinc citrate Zinc gluconate Zinc lactate Zinc oxide Zinc sulphate	Zinc chloride Zinc citrate Zinc gluconate Zinc oxide Zinc succinate Zinc sulfate (& monohydrate)	
Amino acids			Cystine Glycine L-alanine L-arginine L-aspartic acid L-citrulline L-cysteine L-histidine L-glutamic acid L-glutamine L-isoleucine L-leucine L-lysine L-lysine acetate L-methionine L-ornithine L-phenylalanine L-proline L-threonine L-tryptophan L-tyrosine L-valine	Cystine Glycine alanine aspartic acid Cysteine Cysteine hydrochloride histidine Histidine hydrochloride Glutamic acid Glutamic acid hydrochloride glutamine isoleucine leucine Lysine Lysine hydrochloride Lysine monohydrate methionine Ornithine Ornithine aspartate Ornithine monohydrochloride phenylalanine proline threonine tyrosine valine [1]	

[1] TGA – amino acids - Through applied pharmacopeial standards the l- form can be assumed though not stated in the Australian Approved Name (AAN) unless specified

Column 1	Permitted forms	Permitted Forms	Permitted Forms	Permitted forms	Permitted Forms
Vitamins or minerals	**Standard 2.9.1 Infant Formula**	**Standard 1.1.1**	**FSMP**	**TGA Listable Subject to SUSDP or CMEC restrictions**	**Sports Std. 2.9.4 In addition to Std 1.1.1**
L-carnitine	L-carnitine		L-carnitine L-carnitine hydrochloride	Acetyl-levocarnitine hydrochloride propionyl-levocarnitine hydrochloride Levocarnitine hydrochloride Levocarnitine tartrate Levocarnitine fumarate Levocarnitine magnesium citrate	
Choline	Choline chloride Choline bitartrate		Choline Choline chloride Choline bitartrate Choline citrate	Choline bitartrate	
Inositol	Inositol		Inositol	Inositol	
Cytidine 5'-monophosphate	Cytidine 5'-monophosphate Cytidine 5'-monophosphate sodium salt			Cytidine 5'-monophosphate Cytidine 5'-monophosphate sodium salt	
Uridine 5'-monophosphate	Uridine 5'-monophosphate Uridine 5'-monophosphate sodium salt			Uridine 5'-monophosphate Uridine 5'-monophosphate sodium salt	
Adenosine 5'-monophosphate	Adenosine 5'-monophosphate Adenosine 5'-monophosphate sodium salt			Adenosine 5'-monophosphate Adenosine 5'-monophosphate sodium salt	
Guanosine 5'-monophosphate	Guanosine 5'-monophosphate Guanosine 5'-monophosphate sodium salt			Guanosine 5'-monophosphate Guanosine 5'-monophosphate sodium salt	
Inosine 5'-monophosphate	Inosine 5'-monophosphate Inosine 5'-monophosphate sodium salt			Inosine 5'-monophosphate Inosine 5'-monophosphate sodium salt	
Taurine	Taurine		Taurine	Taurine	

Substance	Aust. Limit	Source	Warning or SUSDP text (*if complex*)	NZ Dietary supplement limit
Chromium – organic (nicotinate, picolinate) Chromium chloride	Chromium nmt 50mcg/day No restriction	CMEC		
Copper citrate Copper oxide, Copper sulfate Copper compounds (incl. copper gluconate)	Copper nmt 750mcg/day Excepted in preparations for human internal use Copper nmt 5mg human oral/day	CMEC SUSDP SUSDP	Not eligible for listing if >750mcg/d S4 if >5mg/d	5mg/d
Iodine for human therapeutic use	Less than 300mcg/day	SUSDP	S2 if ≥300mcg/d and warning required **CAUTION** - Total iodine intake may exceed recommended level when taking this preparation. **WARNING** - Contains iodine - do not take when pregnant **except** on physician's advice	
Iron Iron oxides (excipient)	Nmt 24mg/day (packaging restriction applicable for dosage units containing more than 5mg iron) Nmt 10mg/dosage unit or nmt 1% in undivided preparations	SUSDP SUSDP	S2 if >24mg/d SUSDP S2 text : IRON COMPOUNDS (excluding iron oxides when present as an excipient, up to 1% in undivided preparations or up to 10mg per dosage unit in divided preparations) for human internal use **except**: when included in Schedule 4; or when labelled with a recommended daily dose of 24mg or less of iron: (i) in undivided preparations supplied in packs each containing 750mg or less of iron; or (ii) in divided preparations: (A) containing more than 5mg of iron per dosage unit in packs each containing 750mg or less of iron; or (B) containing 5mg or less of iron per dosage unit.	24mg/d
Molybdenum Yeast – high molybdenum Molybdenum trioxide Sodium molybdate	Nmt 62.5mcg/day max 187.54mcg/day Mb 125mcg/day Registrable (grandfathered)	CMEC CMEC		

Substance	Aust. Limit	Source	Warning or SUSDP text (*if complex*)	NZ Dietary supplement limit
Selenium for therapeutic use	Nmt 26mcg/day organic or nmt 52mcg/day inorganic. Sum of organic plus half of inorganic nmt 26mcg/day	SUSDP	S3 if sum of organic selenium plus half of inorganic selenium >26mcg/d but <100mcg/d S4 if >100mcg/d **SUSDP S3 text:** SELENIUM in preparations for human oral use with a recommended daily dose of 100 micrograms or less of selenium **except** where the sum of the organic selenium expressed in micrograms and half the inorganic selenium expressed in micrograms, contained in the recommended daily dose of the preparation, does not exceed 26 micrograms.	150mcg/d
Zinc	< 25mg/day unrestricted 25-50mg/day requires warning statement (or S4)	SUSDP	S4 ZINC COMPOUNDS for human ZINC COMPOUNDS for human internal use except: (a) in preparations with a recommended daily dose of 25 mg or less of zinc; or (b) in preparations with a recommended daily dose of more than 25 mg but not more than 50 mg of zinc when labeled with the statement: **WARNING** – May be dangerous if taken in large amounts or for a long period;or **WARNING** – Contains zinc, which may be dangerous if taken in large amounts or for a long period.	15mg/day

Substance	Aust. Limit	Source	Warning or SUSDP text (*if complex*)	NZ Dietary supplement limit
Vitamin A NB does not apply betacarotene	Nmt 5,000IU/day	SUSDP	S4 if >5,000IU/d VITAMIN A for human therapeutic or cosmetic use, **except**: (a) in preparations for topical use containing 1% or less of vitamin A; or (b) in preparations for internal use, containing 100IU or less of vitamin A per dosage unit of a divided preparation, or 100 IU or less of vitamin A per gram of an undivided preparation; or (c) in other preparations for internal use labelled: (i) with a recommended daily amount of 5 000 IU or less of vitamin A; and (ii) where the preparation is labelled for adult use, in bold face letters not less than 1.5 mm high: (A) with a statement to the following effect: The recommended adult daily amount of vitamin A from all sources is 2 500 IU. (B) and, at the beginning of the directions for use, with a warning statement to the following effect: **WARNING** – When taken in excess of 8 000 IU vitamin A can cause birth defects. If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.	3mg/day (10,000IU)
Vitamin D	Nmt 25mcg (1000IU)/day	SUSDP	S4 if >25mcg (1000IU)/d	25mcg/day
Nicotinic acid Nicotinamide	Nmt 100mg/dosage unit Excluded	SUSDP SUSDP	S3 if >100mg/dosage unit	Niacin or Nicotinic acid (& salts) 100mg/d
Pyridoxine	Nmt 50mg/day. If more than 50mg S4 unless warning applied	SUSDP	Warning applicable if more than 50mg/d (otherwise S4): **WARNING** - This medication may be dangerous when used in large amounts or for a long time. OR **WARNING** - This product contains [*insert pyridoxine, pyridoxal or pyridoxamine as applicable*] which may be dangerous when used in large amounts or for a long time.	
Vitamin B12 or Cyanocobalamin or Hydroxycobalamin				50mcg/day

Substance	Aust. Limit	Source	Warning or SUSDP text (*if complex*)	NZ Dietary supplement limit
Folic acid, Folinic acid for human therapeutic use	Nmt 500mcg/day	SUSDP	S2 if >500mcg/d	300mcg

Vitamin and Mineral NOAEL and LOAEL Values

No Observed Adverse Effect Level* and Lowest Observed Adverse Effect Level**

Nutrient	Unit	NOAEL	LOAEL
Vitamin A	IU	10,000 (3,000 μg RE)	21,600 (6,500 μg RE)
Beta-carotene	mg	25	None established
Vitamin D	IU	800 (20 μg)	2,000 (50 μg)
Vitamin E	IU	1200 (800 mg at α-TE)	None established
Vitamin K *(phylloquinone)*	mg	30	None established
Vitamin C	mg	more than 1,000	None established
Thiamin *(Vitamin B_1)*	mg	50	None established
Riboflavin *(Vitamin B_2)*	mg	200	None established
Nicotinic acid	mg	500 (250 SR)	1,000 (500 SR)
Nicotinamide	mg	1,500	3,000
Pyridoxine *(Vitamin B_6)*	mg	200	500
Folic acid	μg	1,000	None established
Vitamin B_{12}	μg	3,000	None established
Biotin	μg	2,500	None established
Pantothenic acid	mg	1,000	None established
Calcium	mg	1,500	More than 2,500
Phosphorus	mg	1,500	More than 2,500
Magnesium	mg	700	None established
Chromium (III)	μg	1,000	None established
Copper	mg	9	None established
Iodine	μg	1,000	None established
Iron	mg	65	100
Maganese	mg	10	None established
Molybdenum	μg	350	None established
Selenium	μg	200	910
Zinc	mg	30	60

* *NOAEL is a level that should be considered safe and requires no application of a saftey factor to determine a safe intake, based on the most sensitive subgroup.*

** *LOAEL is a level that should NOT be considered safe for everyone and may require the application of a safety factor to calculate a safe intake.*