DRAFT ASSESSMENT REPORT
PROPOSAL P242

FOODS FOR SPECIAL MEDICAL PURPOSES

Comment from:
KAY GIBBONS
Manager, Nutrition Services, Women's and Children's Health
Parkville Victoria 3052
Tel 03 9345 5636
Email: kay.gibbons@wch.org.au

As a nutrition department head in a specialist paediatric hospital my comments relating to this proposal reflect the concerns I have in meeting the needs of a group of patients with very specific needs. Feeds for this group of children frequently fall within the area covered by this proposal. I also have general concerns about meeting the nutrition needs of a broader group of clients who are totally dependent for nutrition on products covered within this proposal. It is essential that products are available to meet a range of client needs, and at reasonable cost (often dependent on competition in the market). The current range of products in Australia is small, and any influence to reduce this would have a negative impact. I have addressed specific aspects of the proposal with some general recommendations.

EXECUTIVE SUMMARY & STATEMENT OF REASONS

2 options are presented for regulation, as identified from the Draft Assessment. While acknowledging the advantages which Option2 may offer in principle, there needs to be consideration of the practical implications:

- There has been little or no identified problem with the current model of Option 1. As indicated within the draft assessment most products are imported and are developed to comply with standards for a wider market than Australia; products are not developed without regard to best practice or a specific regulatory guideline. This provides basic nutritional 'insurance' for use of less specialized products if use is supervised by someone other than a nutrition professional. More specialised products and 'nutritionally incomplete' products are generally used under the duration of professionals. Client and product assessment would rely on accurate nutritional information, but estimation of volume and adequacy of individual nutrients would be based on knowledge of the client's need and condition. For example, formulations currently available may suit the nutrient needs of numbers of consumers. However, fine-tuning of nutrient needs and provision is regularly undertaken by professionals advising on nutrition need,and would be required within any regulatory model.

- Option 2 may limit the product range available in Australia, already

more limited than in Europe or the United states. Option 2 may act to limit the product range available, or discourage the limited range of companies presently doing business in Australia to limit their range further, or to withdraw from the market. Concern is specifically related to items for which there is limited sale, and for which additional costs of compliance would make the product not financially viable for sale in Australia.

p.12 Objectives	There is agreement with the objectives of Proposal P 242. Any issues arise from interpretation of means of achievement.
p.15	Use of the warning 'use under medical supervision' is considered adequate.
p.15	Prohibition of advertising to the public is supported, but would not be expected to change current practice. VLED are treated differently throughout for good reason, and some specific arrangement may need to be made for these products. While acknowledging the limitation on need for public advertising there may be a place for limited advertising. This is an area where perhaps knowledge of the product's existence may be useful to consumers. There is a wide range of commercial meal substitutes available in pharmacies and other outlets, and information about the specific use of VLED may be useful. Content of the advertising would need strict supervision.
P16	The term 'health professional publications' is a suitable description for the range of publications. This could include newsletters, specific publications for the purpose and professional journals.
P.16	For nutritionally complete non-VLED : The rationale for a decision not to prescribe macro-nutrient levels, but to prescribe maximum and minimum levels should apply to vitamins, minerals and trace elements, is unclear.
p.17	For VLED: a prescribed macro-nutrient content, and minimum and maximum levels for other nutrients, would appear to be inconsistent with the above.
p.17	Additional labeling: Most of the statements or declarations outlined (for example, side effects, contra-indications) for non-VLED are not considered essential on products available only under supervision. It is unlikely that consumers would consider using such products given their nature (often unappealing taste) and cost.
p.19	FSANZ is encouraged to work with ANZENMA to include the additives and processing aids currently included in included products
Para 7	**IMPACT ANALYSIS** The arguments raised within para. 7 present an accurate outline of the

current situation. The analysis supports the argument that problems with the current status of FSMP are largely theoretical, but that the model has proved acceptable in practice. Arguments raised in favour of Option 2 are largely hypothetical, with the possible consequence of additional costs and possible restriction of products and suppliers.

Consideration of the arguments outlined in the document for the 2 options would lead to an expectation of a decision in favour of option 1.

The expected costs to stakeholders of adoption of option 2 would be expected to be considerable, and perhaps more limiting than simply price increases associated with compliance. There may be some benefits of adoption of standard labeling, and perhaps adoption of an existing code in its entirety e.g., but the impact of this action is not considered here.

In Australia we need to accept the very small market share we control, and the small impact that the Australian share of a business may have in determining commercial decisions for companies. This is seen in other areas of the nutrition market, such as enteral delivery equipment and systems.

Attachment 2 proposal

The attachment gives a useful outline of the ways in which issues have been handled within the various codes, and therefore of the principle options for consideration.

Macronutrient requirements:
It is agreed that for VLED the macronutrient composition is important. However there is no evidence to suggest that this needs to be mandated for this group of products, any more than any other group. This is seen as a proposed inconsistency.

Vitamin, Mineral and Trace Element Requirements:
The proposal for Option 2 generally recommends adoption of Codex principles, and adoption of the EC regulations. In this specific area European values have not been accepted. This variation disallows easy acceptance of European products into the Australian market. By recommending a range of minimum and maximum based on an alternative source many (most) current products available in Australia fall outside the acceptable range. In principle, acceptable nutrient ranges should be based on evidence and practice; Upper Tolerable levels may well be developed /accepted by the EC in time. Adoption of the stance adopted is queried, given a willingness to accept the EU model in the absence of an UL for a specific nutrient.
Consideration of current products against the proposed range indicate that the amount by which a nutrient composition falls outside the range is relatively minor, and does not generally constitute a variation of multiple times the acceptable limit. (For example, considering Magnesium, each of the polymeric enteral formulae currently available would fail to comply with

the recommended maximum level of 4 mg/100kJ. For the 3 products available levels are 5.99, 6.9 and 5.48 mg/100kJ.) Variations of nutrient intake outside this range would occur regularly when nutrient requirement dictates use of a product or volume outside the usual range.

This recommendation for vitamin and micro-nutrient composition within the proposed standard would limit product choice and may mean absence of any single current product in some nutritional categories. Material advantage has not been demonstrated.

For VLED, similarly nutrients should meet acceptable minimum standards. For practicality, and because of the limitations of local RDIs, this does not need to be domestic RDIs.

Compositional Requirements Associated with Certain Medical Conditions:
There is indication in the document, and in this section, referring to permission for variation in certain circumstances. This appears to relate to need for nutrient requirement or metabolism variation in specific conditions, and it is not clear whether permission for variation would cover existing products for non-specific use. Even if this were possible, an extraordinary amount of time, financial cost and perhaps delays in availability would result, for little material benefit.

p.32 **Summary of recommendations:**

It is not clear why consideration of the options within the Draft assessment report leads to adoption of a recommendation for option 2.

However, if option 2 is to be implemented :
It is agreed that there should be

- Adoption of the Codex General principle to guide formulation
- Harmonisation with EU regulations.
- Permission for the addition of listed nutrients
- Adoption of the permitted forms of nutrients and additives as per the EC Directive

It is proposed that adoption of EU standards for the minimum and maximum levels for vitamin, mineral and trace elements be considered as an alternative to the model proposed, and that impact of adoption of this model on current product compliance be considered.