



June 2010

**Submission from the Dietitians Association of Australia
to Food Standards Australia New Zealand**

Proposal P242 – Foods for Special Medical Purposes (FSMP).

The Dietitians Association of Australia (DAA) is the national association of the dietetic profession with over 4200 members, with Branches in each state and territory. DAA is a leader in nutrition and advocates for better food, better health, and better living for all.

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DAA thanks FSANZ for the opportunity to provide input in their stakeholder consultation period and is pleased that Accredited Practising Dietitians (APDs) were invited to participate in teleconference meetings held in May 2010.

DAA agrees with the principles outlined in the Food Regulation Standing Committee's 'Recommended Policy Guideline on the intent of Part 2.9-Special Purpose Foods'. However, DAA is concerned that the public health and safety of consumers is not well protected by the current regulation regarding FSMPs and meal replacement products. There are a range of nutrition products on the market, particularly in the area of weight loss, including VLEDs (very low energy diets), meal replacements as well as specialised nutrition products for various medical conditions. It is pleasing to see FSANZ invest resources in making progress in this area. This submission addresses the key questions posed by FSANZ during stakeholder consultation.

1. Details on the medical conditions that could require products with formulations outside of the minimum and maximum limits proposed for nutritionally complete foods for special medical purposes (FSMP). It was noted during the teleconference that the use of products for end stage liver disease require lower sodium contents.

DAA agrees with allowing flexibility of nutritionally complete foods for special medical purposes (FSMP) but also supports compositional guidelines for nutritionally complete products. DAA supports harmonisation with the European Regulations¹ on standard definitions for nutritionally complete FSMP products as many FSMPs used in Australia are imported from Europe. Minimum and maximum limits for vitamins and minerals for standard complete FSMPs should be established. It is very important to include certain exemptions to

the minimum requirements for products aimed at particular medical conditions. However, exemptions need to be expanded to include copper, manganese, magnesium and carbohydrate. Alternatively, in line with the European Regulations, a general exemption could apply to any relevant nutrient based on the specific use of the product.

The following medical conditions could require products to be formulated outside of the minimum limits proposed for nutritionally complete FSMP products.

- Renal disease – should not have a minimum for sodium, potassium, phosphate and magnesium.
- Liver disease – should not have a minimum for sodium, copper or manganese
- Wilson’s disease – should not have a minimum for copper
- Conditions requiring ketogenic diets – should not have a minimum for carbohydrate

2. Information/data on how consumers are currently accessing foods for special medical purposes for:

- **Very low energy diet (VLED) products**
- **Products other than those for VLED**

DAA is concerned that people are able to buy VLEDs over the counter at pharmacies and over the internet. DAA agrees with the risk management framework proposed in 2004 by FSANZ that all FSMP products have a mandatory advisory statement on the label highlighting that the products are only to be used under medical supervision. DAA supports harmonisation with the European regulations¹ surrounding FSMP labelling such as;

- A statement whether the product is suitable for use as the sole source of nourishment
- A statement that the product is intended for a specific age group, as appropriate
- Where appropriate a statement concerning adequate precautions and contraindications

Easy access and advice from unqualified health professionals on meal replacement products is of concern to APDs on the grounds of patient safety. In a recent Choice investigation² there were numerous concerns about the effectiveness and safety of various weight-loss programs available in Australia. These include:

- Lack of adequate support for customers on meal replacement programs.
- Inadequate training of staff who supply and give advice on meal replacement products.
- Most consultants or staff did not assess and were not qualified to assess family history, exercise levels, usual diet and lifestyle, current psychological state, alcohol intake and previous weight loss attempts.
- Customers who are not overweight are eligible to use many of these programs.

DAA also supports the restriction of sale and advertising of FSMPs but further recommends that for FSMPs sold in pharmacies, that pharmacists should be directly involved in the purchase of these products to screen individuals for any potential risks and not delegate this task to other pharmacy staff. DAA also suggests that there is more time allocated in training pharmacy staff on screening purchasers of FSMP products. A screening checklist for pharmacy staff may also be useful. APDs should not be restricted from supplying FSMPs to consumers. Access issues for rural and remote areas will need to be considered where access to general practitioners and other health care providers is limited. FSMPs for inherited metabolic conditions are promoted to consumers through patient support groups and internet sites. This promotion is appropriate given the level of likely medical and dietetic supervision

in the Pharmaceutical Benefits Scheme (PBS) and the cost of these specialised products. Product disclaimers on websites may be sufficient protection for consumers in these instances.

3. Any information you may have on how foods for special medical purposes (including VLED products) are promoted to consumers, as well as any estimates of the amount of product promotion that now occurs over the internet.

APDs report that their referrals for individuals taking VLED products are obtained from medical or allied health professionals. However, there have been instances where people have used VLED products without medical advice. Unsupervised use of VLED products should be minimised to prevent the adverse affects of weight cycling.

DAA recommends that it should be a requirement that VLED products contain instructions for use in each product package. Some companies charge an additional price for the instruction book. Anecdotally, consumers feel they do not need guidance with a meal replacement product. People have been known to use a friend's membership to purchase individual sachets, or lose the instructions and do not wish to purchase another set. It should be emphasised that what you eat with a meal replacement is as important as what is in the sachet.

DAA is very concerned about the marketing and availability of meal replacements which are not regulated as FSMPs, such as Celebrity Slim and Tony Ferguson. These are heavily promoted on television and via in-store promotions. They are not required to state "for use under medical supervision" when they are used in the same way as VLED products and have the same problems from lack of supervision.

4. Details on how VLED products can be (or currently are) used inappropriately, and type of inappropriate use that occurs.

Anecdotal evidence from DAA members tells us that VLED products are being bought without medical supervision by;

- parents for their children
- the elderly
- people with eating disorders
- family members of weight loss surgical patients without supervision

This is of great concern to APDs because incorrect and unsupervised use of these products could lead to vulnerable groups not meeting their nutritional requirements.

While some people cannot maintain strict compliance with these products for very long and therefore it may be considered that the risk of nutritional inadequacy is limited, many other clients do maintain strict compliance (and sometimes for longer than indicated) and the risk for these consumers is very real. Assessing the level of risk of a product for regulation purposes should not assume consumers do not comply with the instructions given on the product.

DAA is concerned about the lack of VLED supervision or accountability in this case. There may also be contraindications of certain VLED products highlighting the importance of stricter medical surveillance. Contraindications may include;

- liver cirrhosis

- gallstones
- renal failure
- insulin dependent diabetes
- pancreatitis
- people on lithium medication.

These concerns about inappropriate use also apply to meal replacement products.

5. Any further information on the importance of allergy declarations on the labels of foods for special medical purposes, specifically any feedback on how this information is used in a clinical setting.

To ensure access to imported products by health professionals, it is imperative that there are agreed standardised allergen declarations/claims and definitions. For example, the claim 'gluten-free' has different definitions and regulations between different countries meaning that some imported products claiming to be gluten free are in fact not according to the Australian standards definition.

DAA is aware that the food industry has developed the Voluntary Incidental Trace Allergen Labelling (VITAL) system³ which is **a standardised allergen risk assessment tool for food producers**. The voluntary use of the VITAL tool by food manufacturers appears to be assisting food allergic consumers to make informed food choices and aiding their understanding of food safety risks for packaged foods. This approach may be useful for FSMP products. As discussed in DAA's submission to the Food Labelling Law and Policy Review⁴, industry needs clear and practical direction to manufacture foods (including FSMPs) appropriately labelled to meet needs of consumers with allergies.

Another issue is that FSMPs are not required to have allergen labelling on the individual bottles. Some companies only have the labelling on the overwrap tray or cardboard carton. This is a significant safety issue because this overwrap is often discarded prior to a health professional or consumer receiving the product. It can be difficult for health professionals and consumers to access this necessary information quickly. DAA calls for all FSMP labels to include allergen information on each bottle or packet to prevent risk to consumers.

Dietitians are increasingly providing advice to consumers on limiting their intake of Fructose Oligosaccharides Disaccharides and Monosaccharides And Polyols (FODMAPs) due to food intolerance symptoms and so would also like to see FODMAP ingredients listed on nutritionally complete food products. Since these products may be used as a sole source of nutrition, exposure to potentially concentrated amounts of FODMAPs is likely which would be adverse for individuals intolerant to FODMAPs such as people with irritable bowel syndrome. It is currently difficult to identify those products which contain FODMAPs via the label.

6. Any additional comments

DAA reasons that consumers need to be supported by Accredited Practising Dietitians, the experts in nutrition, to ensure they meet their individual nutrition requirements when they have a medical condition or want to lose weight.

References

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4. DAA, 2010. Submission to the Food Labelling Law and Policy Review. Available at <http://www.daa.asn.au/index.asp?PageID=2145878624> Accessed 26 May 2010.