November 2001

Dietitians Association of Australia

Comments on the ANZFA Proposal P242 Foods for Special Medical Purposes

DAA recognises that foods for special medical purposes (FSMP) have an important role in the treatment of people with specific medical conditions, and as such would want to ensure that the availability and price of these foods is not adversely affected with the introduction of unnecessarily restrictive food standards. However, DAA also believes that these products should be labelled with adequate information, that they meet standards for safety and that they are promoted and marketed in a way that does not risk public health and safety.

DAA offers the following specific comments on issues raised in the initial assessment report, P242.

Definitions:
DAA believes that a definition of foods for special medical purposes (FSMP) should cover complete nutrition formulas and specialised dietary/medical supplements. The Codex definition of foods for special medical purposes is appropriate as a basis for developing a definition for the Food Standards Code. However we also recommend that the ANZFA definition should state that these foods are to be used under medical *and/or* dietetic supervision.

In relation to very low energy diet (VLED) formulas, DAA recommends that a separate definition be developed for these products, which includes only those that provide complete nutrition. In addition, DAA recommends these products be available only on prescription from a doctor. VLED formulas are designed for a specific/limited range of medical conditions, ie obesity. In addition, DAA believes there is more potential for mis-use of these products by the community, and specific regulations/definitions are needed to help reduce inappropriate use. DAA recommends that other types of weight loss foods, such as meal replacement products, continue to be covered under standard 2.9.3 of Volume 2 of the Food Standards Code. Foods labelled/marketed as meal replacements should in addition to the current required labelling statements, include further warnings that these products are not a complete source of nutrition, and that they should be consumed as part of a balanced energy-reduced eating plan with adequate physical activity.

Recommended regulatory option:
DAA recommends that *Option 3* – Co regulation is the most appropriate regulatory option for FSMP. DAA believes there must be flexibility within regulations to allow manufacturers to add new compounds to these foods, based on sound nutritional research, which also considers safety aspects. However, DAA would support the

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development of a Code of Practice that provides guidelines for manufacturers on the advertising/promotion and sale of these foods.

Distribution of FSMP:
DAA believes consumers should only be able to purchase FSMP from pharmacies and hospitals or direct from the supplier or medical distributor, after consultation with a doctor and/or dietitian.

Labelling:
DAA recommends that the labels on FSMP should ideally be required to contain the following information –

- A statement that these foods should only be used under medical *and/or* dietetic supervision, and that the appropriate dosage of these foods should be determined by a dietitian. This is to help ensure that people are using the most appropriate product at the appropriate level for their nutritional requirements.
- Information on appropriate storage conditions and how long a product is suitable for consumption after opening;
- DAA also recommends that the labelling of FSMP conform to Standard 1.2.3, *Mandatory warning and advisory statements and declarations*. It is recognised that allergic reactions to foods can have serious effects on health in affected people. Ensuring that the presence of key allergens is declared on the labels of FSMP will further help protect against inadvertent consumption of allergenic foods by people with food allergies.

If manufacturers are not able to include necessary information on individual product labels (eg for reasons of manufacturing overseas for international markets), this information should be provided in product brochures that are distributed to health professionals and pharmacies. In addition, the requirement to provide this information should be included in a Code of Practice as recommended above.

It is recommended that FSMP be exempt from provisions that require pre-market clearance (Part 1.5 of the Code) but if they are a GM food or have been irradiated then this information be included in leaflets and brochures, as consumers are entitled to this information.

DAA also believes some *exemptions* to current labelling standards are needed. Specifically, it is recommended that FSMP be exempt from Standard 1.1.3, clause 1(3) and 1(4), health claims. DAA believes that FSMP must be able to include on labelling a statement that these foods should only be used under medical and/or dietetic advice and the specific medical conditions for which they are appropriate. DAA believes that including this information will help prevent against inappropriate use of these products by the public.

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