

Proposal P242 – Foods for special medical purposes Consultation November 2011

Comments from the Department of Health and Human Services, Tasmania, December 2011

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The Department of Health and Human Services, Tasmania (the Department) appreciates the opportunity to comment on the Consultation Paper for the P242 Foods for Special Medical Purposes

The Department supports the development of a new standard to regulate foods for special medical purposes. Where food for special medical purposes means food that is represented as being for -

- a) *the dietary management of a disease disorder or medical condition; or*
- b) *a food for special medical purposes; or*
- c) *a medical food*

The Department believes that the definition suggested captures the key elements of this very specific range of foods which are currently not adequately regulated and is consistent with regulatory regimes overseas where most of these products are manufactured.

The Department supports the restriction of the sale of these products to consumers except by -

- a) a pharmacy, hospital, hospice, aged care facility or disability facility; or
- b) a medical practitioner or dietitian; or
- c) a person who holds a 'written request' from a business or person mentioned in (a) or (b).

This level of restriction should ensure that these products are provided to consumers with an appropriate level of advice. It will not restrict the sale to consumers who require these products through a residential care facility, pharmacy or hospital on recommendation from a medical practitioner or dietitian. In Tasmania we are aware of two other major distributors of foods for special medical purposes that provide foods for special medical purposes following referral from a dietitian.

Further work will be required in order to implement a 'written request' system. While some businesses already operate under a referral model, others have telephone hotlines or standing orders.

Some medical conditions which require special medical foods require ongoing dietary monitoring by a health professional. Consumers who are in regular contact with relevant health professionals should be able to easily access a 'written request'. The supplier will need to ensure that they have a suitable record system. For other medical conditions,

once stabilised people may require ongoing special medical foods with limited input from health professionals. We do not want to see a system established which leads to unnecessary costs or need for services consumers.

Repeat prescriptions for medications are valid for 12 months. It may be worth allowing dietitians and medical practitioners to nominate the validity of the 'written request' for example 3 months, 12 months, or up to 5 years.

The Department supports inclusion of the name of the product and allergy statements on inner packages at a minimum.

The Department supports exempting foods for special medical purposes from the health claims standard on the condition that the sale is restricted as described above. To allow sale of products with reference to specific disease or medical states without the adequate medical or dietetic advice increases the potential for inappropriate use of foods designed for special medical purposes. Depending on the composition of the foods and the impact on the individual this could create a risk to public health. In addition, to exempt a generally available class of foods from health claims and compositional requirements may lead to manufacturers positioning products as 'foods for special medical purposes' to gain a marketing advantage. This could bypass regulations on health claims and compositional criteria such as vitamins and minerals. This would not promote fair trading in food with other products which adhere to the relevant standards.

The Department supports continuing access of foods for special medical purposes which are used by a limited number of people. The Department recognises that these foods are generally imported in small quantities and extensive re-labelling for the Australia New Zealand market would make importing economically unattractive.

Labelling of foods for special medical purposes still needs to protect consumers from being misled. Exempting foods for special medical purposes from the prohibition on therapeutic claims should not mislead consumers and any claim should be able to be substantiated. A statement of the medical purpose of the food for special medical purpose is appropriate. However this should not permit unsubstantiated claims about effectiveness.

The Department notes that the drafting adopts the European Union Foods for Special Medical Purposes Directive minimum nutrient requirements. As these levels are lower than the NHMRC Nutrient Reference Values, the Department would like further clarification on the risk of inadequate intake of some micronutrients when products are used as the sole source of nutrition.