

PEHS: 003/01/0285  
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**Environmental  
Health Service**

Dear Project Manager,

**RE: SUBMISSION -P242 - FOODS FOR SPECIAL MEDICAL PURPOSES  
(FSMPs)**

Thank you for the opportunity to comment on the above proposal for FSMPs. The following comments are the result of consultation with nutritionists from the major metropolitan hospitals in South Australia and are offered for your consideration.

1. Option 2 (regulation by a discrete standard under the FSC) is supported.
2. Availability  
Concerns have been raised by dieticians working in this area about the potential for restriction of these products. Any removal of the products from the market for an extended period (for relabelling or reformulation) or large price increases related to legislative restrictions could affect the availability of these products. FSMPs are crucial in the treatment of some disorders and in some situations, only one formulation is able to be used with no alternative. Note the importance of providing sufficient lead in time to ensure that there is no detrimental effect on a vulnerable user group.
3. Very Low Energy Diet (VLED) Formulas  
The definition from the Codex states that FSMP's are intended for 'exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolise ordinary food stuffs.....whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.'

The above definition excludes VLED formulations which are used for the treatment of obesity, as patients do not have limited or impaired capacity and since obesity can be managed by modification of the normal diet. It is clear throughout the Proposal that there are different issues relating to this category, particularly in the potential risks with the unsupervised and inappropriate use of VLED formulas. VLED formulas are freely available outside the healthcare setting.



**Government  
of South Australia**

It is therefore suggested that VLED formulas be included under Standard 2.9 as a separate category. [See below under 'Health Claims for more comments relating to VLEDs].

4. Labelling

Mandatory Advisory Statements

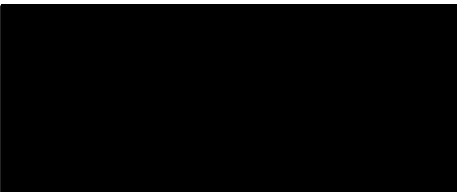
We would prefer to see the statement 'Use under medical supervision' expanded to include 'medical or dietetic/dietician supervision'. However, where this change in wording would mean removal of products for an extended time from the market, the alternative use of an advisory statement which is regulated by the intent rather than the wording is acceptable.

Health Claims

As most FSMPs are used under close medical supervision, we agree that labelling which specifically recognises the purpose of FSMPs is necessary and therefore an exemption from the restriction on referring to a disease state or disorder is needed. In the case of VLEDs, where these products are available via pharmacies or supermarkets, and are not necessarily being used under medical supervision, reference to a specific disorder may lead to self diagnosis. Consideration should therefore be given to whether additional restrictions on health claims should be applied to VLEDs.

I hope that these comments are of benefit in your consideration of the proposal.

Yours faithfully,



Scientific Officer  
Food Section  
Environmental Health Branch

Cleared by Brian Delroy, Manager Food Section