Queensland Government

Queensland Health

PUBLIC HEALTH SERVICES

Enquiries to: [redacted]
Assistant Director, Food Services
Environmental Health Unit
Telephone: (07) 3234 0953
Facsimile: (07) 3234 1480
Our ref: GB012777
File No: EH-NFAP-0242
Your Ref:

23 November 2001

Submission – Proposal P242

Australia New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610

Dear Sir / Madam

Proposal P242 – Foods for Special Medical Purposes (FSMP)

Thank you for the opportunity to assess the Initial Assessment Report for Proposal P242 – Foods for special medical purposes.

The following comments address the questions posed in the document:

Which is your preferred regulatory option for FSMP and why?

Option 4, Full Regulation, is the preferred option. The potential benefits of Option 4 includes–

- The protection of public health and safety by having full regulatory control to manage risks
- The provision of adequate information to enable consumers to make informed choices
- The protection of misleading or deceptive conduct
- Consistent regulatory approach to FSMP creating clarity for import control and enforcement
- Clear and consistent regulations on composition, labelling and quality of products for both consumers/health professionals and industry
- Promotion of harmonisation between Australia and New Zealand

The potential benefits gained by using a Full Regulation approach would outweigh the costs to government, industry and consumers/health professionals.

Should FSMP be regulated as special purpose foods and why?

Yes FSMP should be regulated as special purpose foods because the definition of FSMP is consistent with the definition for special purpose foods ie. they are designed to deliver nutrition to at-risk groups whose dietary requirements cannot be satisfied by a normal diet and the regulation of FSMP should be underpinned by the same principles applying to special purpose foods.

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Office
10th Floor
Queensland Health Building
147 - 163 Charlotte Street
Brisbane Qld 4000

Postal
GPO Box 48
Brisbane Qld 4001

Phone
(07) 323 40953

Fax
(07) 323 41480

ould FSMP be required to conform to the existing Standards?

Yes FSMP should be required to conform to the existing standards as it assists with regulation.

What do you consider are the necessary components of a definition for FSMP?

The necessary components of a definition for FSMP include for use under medical supervision, where dietary management of a condition/disease cannot be met by modification of a normal diet or other foods for special dietary uses, and based on recognised scientific principles. The Codex definition for FSMP is appropriate in the Australian and New Zealand context and should encompass complete nutrition formulas administered either orally or enterally, very low energy diet formulas for weight loss and specialised dietary supplement formulas or foods.

The term FSMP is an appropriate term for this standard and the words 'use under medical supervision' should be a defining feature of FSMP as these foods should not be widely available to the general public eg. in supermarkets.

Are there any health and safety risks to consumers associated with the composition of FSMP?

Yes there is a risk to health and safety of consumers which is dependant on the contribution of the food to the overall dietary intake. Therefore FSMP should have compositional regulation based on product specific standards. The definition of nutritive substances is adequate however if there was to be a clarification of the definition of nutritive substances for the purpose of permitting added substances to FSMP then any changes should be based on scientific evidence and principles.

If additional nutritive substances were permitted to be added to FSMP, it should only occur with the criteria of safety, and scientific evidence. Nutritionally complete can be defined as supplying all nutrients – macro and micro in the required amounts to sustain physiological functioning.

Does a public health and safety risk exist in the unrestricted access to FSMP and are there any situations in which ANZFA should restrict the sale of FSMP?

There are definitely public health and safety risks if there was unrestricted access to FSMP. FSMP should be available only after recommendation by a health professional, at pharmacies or from the suppliers and the labelling should reflect this restriction.

Should FSMP be exempt from the various horizontal labelling standards in Volume 2?

No FSMP should not be exempt from the labelling standards in Volume 2.

Consumers should have access to the same type and amount of information on FSMP as is available on general foods. In addition, there should be a requirement to comply with Standard 1.2.3. There would be an additional cost to industry however the amount is unknown. The FSMP should be labelled with the contact details of the product supplier on the product as well as in the supporting information.

If changes cannot be made on product labels the other way to ensure the necessary information is available for consumers is in the supporting information. It is unnecessary for FSMP to make reference to particular disease states if they are only available following advice from health professionals who are aware of the scope of uses of the products. The supporting information could contain information about particular disease states but this information should not be on the label. Another term instead of using 'convincing' could be 'weight of evidence'.

FSMP should carry a note stating that they should only be used whilst under medical supervision.

Yours sincerely

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Assistant Director, Food Services