

Fonterra Co-operative Group submission on P242 – Foods for Special Medical Purposes

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Fonterra Co-operative Group

Fonterra Co-operative Group is New Zealand's largest commercial enterprise, and a multinational food marketing and manufacturing organisation.

1. General Comments

Fonterra supports the move to have consistent regulations applying to FSMP between Australia and New Zealand.

When developing Joint Regulations ANZFA must have regard to the promotion of fair trade. Should the promotion of fair trade follow on down to the end consumer? PHARMAC does not support 'fair trading' - anti competitive practises. Therefore FSMP are not subject to 'fair trading' due to traditional distribution channels.

'Under medical supervision' needs to be clearly defined in the regulations for FSMP. These products are typically recommended by Dieticians, with or without the input of medical professionals.

In New Zealand the current set up of PHARMAC listing FSMP making it more cost effective to access these products via a prescription rather than OTC should not be taken into account when determining where these products can be sold.

Option 4 is most likely preferred. Full regulation will provide the best protection for the consumer and give clear guidelines for industry. Co-regulation is not supported. The reason for this being that as most of the products are manufactured outside Australia and New Zealand (US and EU) industry resources are likely to be limited and little available to assist with the Co-regulation.

It is not acceptable to go with Option 1 - Status Quo. FSMP must be a lawful food.

2. P9. 21 CFR 101.9(j)(8)

This is Attachment 4 and not Attachment 3 as stipulated in the document.

3. P12 Specific objective No. 3 of P242

(Provide information to health professionals and consumers to enable them to make informed choices about the consumption of FSMP and to prevent misleading conduct) is not addressed in the document. How do ANZFA envisage this being addressed?

4. Relative to the risk, should FSMP have compositional regulation?

Only maximums - for safety reasons.

5. Should the definition of nutritive substances be clarified to extend beyond a potentially narrow definition of nutritional purpose for the purpose of permitting added substances to FSMP?

Yes e.g. Lactic acid bacteria may be beneficial but are not defined as a nutritive substance.

6. Does a public health and safety risk exist in the unrestricted access to FSMP?

There is a risk for those with certain medical problems e.g. renal impairment, diabetes but probably no more than any other food for the general population, which is why require medical supervision.

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

No

8. Should FSMP comply with the requirements of Standard 1.2.3 - *Mandatory Warning and Advisory Statements and Declarations*?

Yes. Advisory statements are preferred. The risks associated requiring the warning to be included in Standard 1.2.3 in the first instance are too great not to have these warnings stated on FSMP.

9. Should FSMP carry the warning "Use only under medical supervision"?

May be better for the warning to be given as a recommendation e.g. "Recommended to be used only under medical/dietetic supervision". As there are cases when they aren't under supervision (OTC).

Shiromani Jayasuriya
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