Proposal P242 – Foods for Special Medical Purposes

What foods are likely to be considered FSMP?

We have identified the following foods as meeting the Codex definition for FSMP:

- Enteral feeds
- Foods for people with certain disease states e.g. celiac disease, protein and other allergies, kidney disorders, phenylketonurics, malabsorption syndrome
- Foods for patients recovering from surgery that may need to be nutritionally complete
- Foods for people that require low kilojoule diets or high kilojoule diets (e.g. aids patients)

Factors impacting on the need for FSMP

- Aging population;
- Mobility of an aging population that may have a greater requirement for FSMP;
- Centralisation of primary care facilities and sparsely populated countries;
- Emphasis on in-home recovery;
- Acknowledgement that providing special nutrient requirements in a form that is as close to the normal diet as possible is the preferred means of providing nourishment;
- More information available to consumers on the preventative effects of certain nutrients;
- Changes to systems for health care provisions in the community, including systems that recognise and are targeted to the multi-cultural diversity of New Zealand (and Australia?);
- Purchasing more medicines over the counter;
- Blurring of the distribution lines between supermarkets and pharmacies. In NZ we now have a pharmacy built within a supermarket with the next phase likely to be the removal of the pharmacy walls.

Please find below our comments on the specific questions you raised in section 6 and 7 of the Initial Assessment Report.

Section 6: Potential Impact of Regulatory Options

Tatua Co-Op Dairy prefers option 2 (recognition in volume 2 with minimal regulatory control). We acknowledge that elements of option 5 may be necessary for some foods, where they are the exclusive food for a disease or condition and the risk assessment has identified some areas where the use of the food needs to be restricted and managed. An example may be where there is a higher risk of possible contra-indications with some consumers.

Key Issues with Option1 - Status quo

- Only category of foods that would not be recognised under food law in Australia & NZ, resulting in ambiguity in the regulatory system
- Disagree that there would be no changes to the current range of FSMP available. Internationally, there is extensive research in the management of diseases and the role particular nutrients play in maintaining a person's health or aiding in recovery. It is likely that this will lead to new FSMP products.
- Enforcement issues

Key Issues with Option 3 – Co-regulation

- Multi-national companies produce most products. Questions arise over the resources these multi-nationals have in Australia & NZ to support a voluntary code of practice, given the small volume of FSMP foods sold and the relatively small market size by international standards.
- Issues with new companies manufacturing FSMP with regard to acceptance of the code and their role in administering a code of practice especially if they do not have the resources of the larger multi-nationals.
- Costs associated with administering and maintaining a code of practice

Key Issues with Option 4 – Full Regulation

- The current section 2.9 standards are more prescriptive than the requirements as detailed in Codex standard 180-1991 that only addresses labelling of and claims for Foods for Special Medical Purposes. Given that most of these products are imported and are produced in specialised plants by multi-national companies, regulations need to be no more prescriptive than Codex to reduce compliance costs.

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- FSMP foods are likely to be more expensive than usual food products. Often FSMP foods will be a significant or total portion of a person's diet. These 2 factors are likely to have a negative impact on a consumer's financial burden.
- Any prescription of compositional parameters needs to give consideration to any requirements that are specific to a specific condition or disease.

Key issues with Option 5 – Regulation by Pre-market Approval

- Possible delays to the launch of FSMP products.
- Pre-market approval is unlikely to give flexibility to the range of foods available.
- Need to address how FSMP's under development would be addressed during the clinical trial phase.

Tatua Co-Op Dairy does not currently manufacture foods for special medical purposes. Tatua Co-Op Dairy has a research program that identifies bioactive components in milk and develops procedures to produce these components commercially. Our products are mainly sold in export markets where they are predominantly used in foods.

Section 7: Issues Related to the Implementation and Review of the Development of a Standard for Foods for Special Medical Purposes

7.1 Regulatory Considerations

FSMP should be regulated in the category "special purpose foods" as they satisfy particular dietary requirements that exist because of a particular physical or physiological need. This is consistent with the principles adopted for other foods for special dietary uses.

These foods may be the only source of nutrients available to a person or may be a significant portion of the diet. The nutrients may include the macronutrients - fat, protein and carbohydrate. In some cases these may need to be offered in a particular form e.g. protein in the form of amino acids or short chain peptides, essential fatty acids. Additionally they may need to provide the full complement of vitamins and minerals to ensure appropriate and adequate nutrient content. Other substances with proven medical or nutritional contribution to human health may also be incorporated.

It is preferable that the principles underpinning the generic provisions of the Code are applied to FSMP wherever possible.

Permission to include nutritive substances is necessary as some FSMP will be the sole source of nutrients within the scope of the proposed definition. If this is not addressed within a standard for FSMP, then consideration needs to be given to overriding the general prohibition in Standard 1.1.1 for FSMP.

The generic labelling provisions will normally address most of the potential labelling requirements. For products where the content and/or nature of the proteins, fats or carbohydrates are specially modified, additional labelling disclosure may be necessary consistent with the truth of labelling requirements in overarching Fair Trading law.

The addition of vitamins and minerals and other micronutrients may be required to meet the dietary needs of consumers for which FSMP is a significant or only source of nutrition. Extensive research is being undertaken internationally on the role of specific nutrients in disease prevention and rehabilitation. This is a rapidly evolving field. The roles of a number of bioactive components that occur naturally in a variety of foods or are produced during human digestion are being studied.

Microbiological limits may be critical for some FSMP's as the consumers may have greater sensitivity to pathogens due to the acute nature of their disease or illness.

There is no reason why the requirements for FSMP's should be any different to those for general purpose and other special purpose foods requiring pre-market approval. One area that is likely to be contrary to the proposed labelling requirements for health and other related claims will be the requirement to truthfully label FSMP as to the disease or condition that the food is appropriate for.

Some FSMP may comply with the definition for a formulated meal replacement or formulated supplementary food but have additional special requirements.

7.2 Definition of Foods for Special Medical Purposes

1. Tatua Co-Op Dairy considers that the following are necessary components of a definition for FSMP:

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- Recognises that foods may form a continuum from those that are the sole source of nutrients in the diet to those that supplement general purpose and/or other defined special purpose foods
- Conditions under which the FSMP may be used
- Recognises that foods which are for the partial feeding of patients may be used as an adjunct to normal foods or foods for special dietary uses
- Addresses who may manage/advise on the use of FSMP.

2. The Codex definition addresses most of the issues that we have deemed to be necessary in a definition. There is an issue with "under medical supervision" and the scope of these words.

3. The types of products needs to be fairly broad to accommodate the range of medical conditions that may need to be managed with FSMP and the different forms in which foods may be produced and offered for consumption. The scope needs to recognise the diversity of forms that foods may be produced for FSMP.

4. The inclusion of "under medical supervision" as a defining feature of the definition needs to address the issues raised below.

- Does "under medical supervision" mean a doctor registered by the medical profession? Tatua considers that if this is the intent, then it does not recognise current community based medical treatment facilities
- Doctors may refer a patient to a dietitian for dietary advice. Would a dietitian be considered to be a medical supervisor?
- In NZ, pregnant women are either under the supervision of a doctor or a mid-wife. Would a mid-wife be able to supervise the intake of FSMP if these were required?
- How will OTC FSMP be handled given the move to more medicines being available for OTC purchase? Is a pharmacist able to supervise or provide recommendations on FSMP?
- Does "under medical supervision" mean "by prescription only" or the looser "on medical recommendation"?
- Unqualified medical personnel may administer medicines in a managed diverse multi-cultural community based health system. Would this extend to FSMP?

5. The term "foods for special medical purposes" appears to reflect the intent of the description detailed in the executive summary

7.3 Composition of Foods for Special Medical Purposes

1. Foods need to be nutritionally complete or substantially nutritionally complete for the condition or disease being treated.
2. Foods may also need to meet special microbiological standards or be tested at a greater level of assurance in recognition of the higher at-risk status of people consuming FSMP.
3. Compositional regulation may be difficult to prescribe for a diverse range of liquid and solid foods. The compositional requirements may vary depending on the form the food is provided in and whether it is the sole source of nutrients or a supplement to normal and/or other special purpose foods and the age group that the food is designated for.
4. Given the special needs for some FSMP, a generic permission for the incorporation of vitamins, minerals and other nutrients consistent with the medical and nutritional requirements for the condition and/or population group may be most appropriate.
5. The definition for nutritive substance in volume 2 of the Code is too narrow. It does not include essential fatty acids. For example, it does not include bioactive substances containing ace inhibitory peptides or anti-thrombotic peptides, bioactive substances that have a role in dental or oral health e.g. lactoperoxidase.

7.4 Distribution and Access

1. A risk assessment framework should be drafted that will allow each food to be assessed as to the risks from a biological, physiological, health and safety basis. This would allow foods to be categorised according to specific criteria. With medical drugs and some FSMP there has been a shift in the level of access to these products over the last few years as more knowledge is gained about there efficacy and mode of action. For example, analgesics were generally restricted with only dispirin having unrestricted access. The current position in NZ, is unrestricted access to a range of analgesics including products such as

Nurophen that contain codeine. Ensure and Ensure Plus, produced by Ross Prodcuts, were restricted to medical pharmacy only but are now available OTC at retail pharmacies. There may be a potential health and safety risk if all individuals have access to some FSMP and no or negligible risk for other FSMP. A framework would allow FSMP to be categorised according to the identified risks.

2. FSMP that may have a contra-indication with medical drugs may need to be categorised as restricted access and be under more controlled supervision.
3. The issue of whether FSMP should be "by prescription only" or "on medical recommendation" or "by consultation with a health professional" needs to be addressed. "Prescription only FSMP" are likely to be more costly to the consumer or caregiver in both time and monetary terms, due to the need to obtain a prescription from the doctor and then collect the FSMP from a pharmacy or other outlet.
4. FSMP should be no less available than medicines with an equivalent level of risk. Given the current move towards more OTC medical products and a merging of the pharmacy and supermarket distribution channels placing undue restrictions on the availability of medical foods would add to distribution costs and the effort required by consumers to obtain these foods. It may also impact on a person's willingness to persist with a diet incorporating FSMP.
5. Consideration also needs to be given to the mobility of consumers on FSMP and the accessibility of these foods to them.

7.5 Labelling of Foods for Special Medical Purposes

1. FSMP should comply with the provisions of the various horizontal labelling requirements where appropriate. As FSMP are formulated to meet the requirements of a particular disease state or condition, a manufacturer would need to identify the particular disease state or condition on the label in order to comply with the generic provisions in Fair Trading law. This may be contrary to provisions within the draft labelling standard for health and related claims.
2. As we are not currently manufacturing FSMP products we are unable to report on the cost of relabelling products. The issues from a manufacturing perspective are run size and the costs associated with carrying additional inventory, down time associated with setting up to manufacture small production runs, warehousing and management of the additional product lines. Set up costs will need to be amortised over smaller volumes of product, increasing the price.

3. Communication technology is such that many multi-national company's have international call centres that can be accessed from anywhere in the world at any time of the day. This service may be at 2 levels – the consumer and the health professional. The need to require mandatory contact details of the supplier in Australia or NZ may not be necessary. Inclusion of the Australian and/or New Zealand contact details in supporting documentation would be the most practicable and least costly approach. If the FSMP are sold OTC then the information should be made available to the consumer at the point of sale.
4. The Codex Standard for Labelling of and Claims for Foods for Special Medical Purposes Codex Stan 180-1991 appears to address most of the requirements of the horizontal labelling standards, as they would apply to FSMP. One area that may not be addressed is the proportion of the Australian & NZ; RDA provided by a serving of the food. This could be included in supporting information provided to the health professional and the consumer.
5. The necessary labelling requirements are addressed in Codex Standard for Labelling of and Claims for Foods for Special Medical Purposes: Codex Stan 180-1991 where different to the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses: Codex Stan 146-1985 and in Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses: Codex Stan 146-1985. As the Australian and New Zealand Government are signatories to WTO the labelling requirements should be no more prescriptive than those in the relevant Codex standards.
6. The provisions of sec 3.0, 4.4.3, 4.5.1 through 4.5.4 of Codex Standard for Labelling of and Claims for Foods for Special Medical Purposes: Codex Stan 180-1991 address the marketing of specialised products and information requirements to prevent misuse of FSMP.
7. "Use only under medical supervision" is too restrictive given the different health professionals that may manage or advise on the nutritional management of specific diseases or conditions. We recommend "Use only with the supervision of or on consultation with or the recommendation of a health professional" or words with a similar meaning. The scope of the term "health professional" would need to be defined. If "use only under medical supervision " is retained the issue of frequency of consultation and the nature of the supervision need to be addressed.
8. To comply with overarching Fair Trading law the label should include a statement as to the disease, disorder or medical condition for which the food is intended as

per section 4.5.1 of Codex Standard for Labelling of and Claims for Foods for Special Medical Purposes Codex Stan 180-1991.

9. We have some concerns with regard to the ANZFA definition for "convincing".
   - What is meant by "little evidence to the contrary"?
   - How will "a substantial number of acceptable studies" be assessed? Will it vary with the type of disease or condition and the proportion of the FSMP in the diet?
   - Why would it be necessary to conduct trials in different population groups when the FSMP may only be targeted at a specific population group?
   - What level of significance will be required for laboratory evidence that is supportive or strongly supportive?