Consultation paper: Proposal P242 – Foods for Special Medical Purposes
November 2011

The Department of Health Victoria, welcomes the opportunity to comment on a further consultation paper since January 2011 for P242 – Food for Special Medical Purposes (FSMPs), prior to its progression to the final approval stage.

The department acknowledges that currently the majority of FSMPs are manufactured in Europe, with the remainder imported from the United States, and therefore the importance of harmonisation with these regulations to ensure an ongoing supply and adequate range of FSMPs in Australia. We also however, favour an approach to this new proposed Standard that captures any future changes to the domestic or international manufacture and production of FSMPs.

The department is particularly concerned about the proposed drafting of P242. Although we support the intention of the proposed standard in terms of restriction of access of sale for FSMPs, we have serious concerns about the current drafting that will create compliance and enforcement difficulties if left unchanged. **We do not support the progression of this proposal until the drafting is suitably altered to render it enforceable.**

Questions for stakeholders:

1. Do you have any comments/concerns with the proposed definition of food for special medical purposes?

The current emphasis on representation in the definition is not supported. There are risks with this approach. Foods represented as being for the dietary management of a disorder (e.g. assist in the alleviation of stress) could be sold in pharmacies and would be exempt from the requirements of the health claims standard/s.

The consequential drafting to provide direction on what is and is not captured by the standard would not be required if a prescribed name was mandated.

The preference is for the purpose statement to provide scope and the definition to provide the specificity on the nature/characteristics of FSMPs, and there would be a separate clause stating that FSMP is a prescribed name (with the option that 'medical food' would also meet this requirement).

Alignment of the purpose statement with the definition is critical. The preference is for the definition to include words to the effect that FSMPs are characterised by the need for medical supervision in their use, as this is characterisation and does not trigger a behaviour requirement that would have to be enforced and enforceable.

We suggest an approach to the definition that is similar to that for Standard 2.9.1 products, e.g. a FSMP means a food specifically formulated to satisfy the needs of those requiring the dietary management of a disease, characterised by the need for medical supervision in its use.

This approach would still mean that only not all Standard 2.9.1 products may be captured. However, a prescribed name together with a specific statement regarding the exclusion of 2.9.1 products could overcome this issue and provide certainty. This

would mean that all other clauses that reference what is in or out of the standard could be deleted, including paragraph 3 of the purpose statement.

2. Does the modification to draft Standard 2.9.5 clarify the restriction on sale?

Clause 4(c) is not clear and unenforceable. It raises a number of questions which pertain to compliance and to enforcement, as follows:

1. What does 'written request" mean? We request clarity and certainty regarding this term. We suggest that the term should be qualified with words such as "current and valid written request".
2. There is no obligation for the business in this category to store the written request. In which case, there is nothing to assess compliance against. We suggest that there should be a requirement that the person who receives the written requests be obligated to make them available upon request.
3. Whilst part (c) mandates who can provide the written request to a consumer, it does not stipulate who can respond to this written request and dispense the FSMP to the consumer. What is the intention of the restriction on sale? Perhaps this needs to be tightened to specify who can sell upon receipt of a written request

3. Does the revised restriction on sale capture existing practices with the sale of FSMPs?

We consider that the revised restrictions on sale do not capture existing practices and that to do so accurately, the issues raised in response to question 2, above, require redress.

Is it the intention of the restriction to cover Australian internet sales? If this is the case then Clause 4(c) may require further consideration to ensure that these sale types are also clearly captured should enforcement be necessary in the future.

4. Please comment on the feasibility and appropriateness of a requirement for a written request.

Whilst the reasoning behind the requirement for a written request is understood, we do not believe that the proposal as currently drafted is feasible or appropriate from a compliance and an enforcement perspective.

Please see comments under questions 2, above, for the issues that we believe require addressing.

It is considered appropriate to require a written request from a business or health professional (i.e. medical practitioner or dietitian) for an FSMP to be supplied to a consumer as a risk management strategy for restricting sales access of these products. It importantly also encourages health professional oversight for the use of these products which is consistent with the regulations of both the EU and US.

5. Please provide any comments on the proposed labelling requirements for FSMPs in inner packages

We support the approach taken by FSANZ to require inner packages to be labelled with the name of the product and certain allergens if present to facilitate international harmonisation of requirements.

We recommend that a statement to the effect that the food must be used under medical supervision that is proposed to be required on product package labels as a mandatory statement (clause 9 (1) a) is also required on the inner label.

6. Please provide any comments on the proposed labelling requirements for FSMPs not in a package and for transportation outers containing FSMPs.

Transportation outers are generally discarded so it is important that the name and address of the importer or supplier in Australia are on the package label. This enables traceability, beyond just identification, should product have to be withdrawn from the market.

7. Please provide any comments on the proposed approach not to apply Standard 1.3.2, the Transitional Standard for Health Claims (1.1A.2) and Standard 1.2.7 (when gazetted) to FSMPs.

The current 1.3.2 standard already exempts part 2.9 Standards in the purpose statement. If the definition is amended as suggested (not based on representation, including the need for medical supervision, and supported by a prescribed name), then the exemption from compliance with the 'health claims' standard/s is supportable.

8. Please provide comments on whether therapeutic claims should be prohibited or not (noting the requirement in draft Standard 2.9.5 to state the medical purpose of FSMPs), with your reasons why/why not.

There is little justification for the need for a therapeutic claim on these specialised products. It is understood that these products will be required to provide information on their label to indicate the product's specific medical and/or nutritional purpose. It is also understood that it is the intention of this standard to restrict consumer access to these products and encourage medical or dietetic supervision of their use by consumers. It is therefore difficult to justify a particular purpose for therapeutic claims on these specialised products.

9. Please provide any comments on the proposed approach to apply the advisory and warning statements listed above to FSMPs.

In the interests of consistency with Standard 1.2.3, which requires particular advisory and warning statements, we support the proposed approach by FSANZ to apply these same requirements to the labels of FSMP products.

We consider that these statements are essential in terms of providing adequate information to consumers and health professionals. Importantly, these statements also assist in protecting the health and safety of consumers of FSMPs.

10. Please provide comment on whether any of the proposed labelling requirements are likely to impact on costs to industry and consumers, or on the availability of FSMP products (see summary table of the proposed labelling in the Labelling Requirements Update Page 19). If so, please specify the labelling requirement of concern and provide details e.g. what is the impact, the number and type of products likely to be affected, and estimated costs.

The costs of relabeling for one or more elements are much the same. Whilst we are aware that the drafting of this standard is, in part, to accommodate products already in the market with as little cost impost as is possible, we are also mindful that suppliers to this market may change.

If current suppliers have to re-label for other requirements then the addition of a prescribed name should not be at any additional cost.

We have broad concerns with the approach taken to accommodate existing products around exemptions from, or flexibility to, compliance with Part 1.2. of the Code. It is inconsistent with the drafting of most other Chapter 1 and Chapter 2 standards and makes the resultant standard very cumbersome. The current drafting is additionally inconsistent with the previous move away from vertical product standards to horizontal standards. We have already raised these concerns with FSANZ and are happy to discuss these matters further to seek a better outcome.

Industry stakeholders

11. Can you provide further information on how nutrient levels declared in nutrition information panels are derived? e.g. are these based on an average of the amount of addition in each product range, or on the minimum amount of a substance added? Is the amount determined analytically or by calculation?

No comment.

Health Professionals

12. What information do you use to determine the nutritional adequacy of a product when used as a sole source of nutrition?

The nutritional information provided by a manufacturer regarding the composition of a product is used to determine the nutritional adequacy of a product when used as a sole source of nutrition. The manufacturer provides a table detailing the content value for each nutrient which is compared with the corresponding Australian NRV as the reference value. This allows an assessment of the level of adequacy for a particular nutrient to be determined. The manufacturer also provides information regarding the total volume of their product that is required for nutritional completeness when used as a sole source of nutrition (e.g. nutritionally complete in 1.5 litres).

In general, the total energy and macronutrient content of a product along with the total volume to achieve nutritional completeness (i.e. micronutrient content) are used to assess the nutritional adequacy of a product when used as a sole source of nutrition.

13. How do you manage potential inadequate nutrient intakes in these circumstances?

At a cost to the consumer or the institution administering the FSMP to a patient a micronutrient supplement or multivitamin preparation is used to make-up the nutrient deficit and ensure nutritional adequacy.

14. FSANZ is interested in feedback as to whether this new paragraph 1.3(b) will ensure that VLED products are not captured by draft Standard 2.9.5.

We consider that the new paragraph 1.3(b) will ensure that VLED products are not captured by draft Standard 2.9.5. However, we need clarification from FSANZ that the current legal status of these VLEDs are not negatively affected by this statement.