SA HEALTH SUBMISSION

Proposal P242 - Foods for Special Medical Purposes Consultation

16 December 2011

General Comments

- SA Health appreciates the enormity of developing a new Standard for a currently unregulated area of food and acknowledges the effort FSANZ has expended in consulting on the new drafting of this Standard since it was suspended in 2004 to await the development of Policy Guidance on the intent of Part 2.9 – Special Purpose Foods.
- This is a complex area which deals with foods which are outside the usual scope of products and stakeholders dealt with by enforcement agencies. Since restarting this process, the drafting of the Standard has changed significantly, especially in relation to the definition of FSMP's, sale and advertising and labelling.
- SA Health therefore recommends that a further round of consultation is warranted prior to notifying Ministers particularly if the drafting changes significantly as a result of this round of consultation.

1. Comments re: Proposed definition of FSMP

- It is considered that 'Food for Special Medical Purposes' should be a prescribed name in line with the rest of Part 2.9 of the Code. This would clarify which products are foods for special medical purposes and which are not and would negate the need for the current proposed drafting about how foods are represented.
- In relation to the aim of avoiding conflict with imported products labelling requirements, another clause could capture these products by stipulating that these products are caught by the prescribed name eg. 'products labelled as medical foods are deemed to be foods for special medical purposes'.
- It is queried whether the current proposed definition adequately reflects the type of products to be captured. The definition should align more closely with the Purpose. Possibly the previous definition (page 2 of consultation paper) was more reflective of the types of products included.
- 1.1- If retained, the term 'represented' need further definition/clarification.
- 1.2 and 1.3: it is suggested that these clauses are combined and the following wording used:- " A food is not a food for special medical purposes if it is – " and list excluded food products.
- 1.3(b) - change 'dietary management of obesity to "dietary management of overweight and obesity". The rationale is that the definition of obesity is a Body Mass Index (BMI) of 30 or more. However consumers who are overweight i.e. BMI of 25-29.9 seek use of such products for weight management.

Other definitions

- 2(1) definition of 'responsible institution' should also include 'rehabilitation facility'

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

- Suggest Clause 4 (a) could include rehabilitation facility in the definition
- Clause 4 (c) is unclear and needs revising. See below comments on 'written request'. .

3. **Does the revised restriction on sale capture existing practices with the sale of FSMP's?**

- Current FSMP sales in SA are from a variety of health care facilities, they may be provided by hospital pharmacies for use at home at a subsidised price (or in some cases free of charge); or patients may be advised to purchase their own supplies from chemists and medical/healthcare distributors. Advice from clinical dietitians suggest that a written request is not always provided e.g. a patient might be advised to try Sustagen (which is fairly well known) so this may not be written down. Other FSMPs might be written on a piece of paper to help the consumer remember and purchase the correct supplement from a distributor or chemist.
- Hence for patients purchasing 'over the counter' in a chemist or a medical distributor will not necessarily have a written request for the FSMP product they are purchasing.
- Some distributors also sell FSMP products on-line or by phone order. This does not require a written request.

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

- Given the proposed requirement for a written request is a change from what happens in practice currently, the feasibility of this requirement needs further exploration.
- While a written request is ideal in terms of ensuring consumers purchase the correct product for their medical nutrition therapy, the standard needs to define what entails a satisfactory written request and how long this is current for (the minimum requirement would be a written referral from practitioner mentioned in Clause 4, their address and contact details, the product required, and time frame valid for, e.g. ongoing or when review required.
- In regards to enforcement, it is acknowledged that a 'written request' is kept generic in order to not overly restrict access to products by consumers while retaining some medical oversight. Enforcement agencies in Australia and NZ would need to agree as to what constitutes a written request (i.e. minimum requirements) and the ability to track these requests; ie. are they kept on file by supplier? For how long? Furthermore, how would written requests be provided for phone and on-line FSMP orders.

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

- SA Health supports the current drafting as set out in Subdivision 3 to restrict the information on an inner package of an FSMP to the product name and description and any allergens. This appears to be reasonable if the inner package

is only used separately to the outer packaging in a hospital or health care setting where there is appropriate oversight of use as opposed to an online purchase of an FSMP.

General Labelling Requirements (Subdivision 2)

- SA Health has concerns about the lack of full labelling required on a package of food for special medical purposes. The drafting specifically exempts FSMPs from complying with Part 1.2 of the Food Standards Code (Labelling) except where otherwise provided. The draft Standard then stipulates only some of the labelling requirements from Part 1.2. A clearer drafting approach as per other standards may be to only list exemptions from Part 1.2?
- Also of concern is the fact that the name and business address of the distributor in Australia is not required under the current drafting. This is problematic for enforcement as an immediate first step in recalling a product which is unsafe would be to contact the distributor. This issue needs to be explored further.

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

- SA Health supports the proposed exemption for transportation outers, which only requires labelling of the name of the food, the lot identification and the name and address of the supplier (on the outer or in documentation accompanying the food) if this is not clearly visible through the transportation outer on the label of the FSMP within.

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

- SA Health supports the exemption for FSMPs from these standards on the basis that FSMPs require specialised composition and labelling information to appropriately inform the medical practitioner and the consumer about their intended use.

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)

- The Therapeutic Goods Act 1989 defines therapeutic use"1. A therapeutic claim would be a claim on a food product which refers to therapeutic use.
- SA Health acknowledge the need for FSMPs to make reference to a disease/ injury/ disorder however we have concern over the possible use of therapeutic

[1] *Therapeutic use* is defined as use in or in connection with:
(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
(b) influencing, inhibiting or modifying a physiological process in persons; or
(c) testing the susceptibility of persons to a disease or ailment; or
(d) influencing, controlling or preventing conception in persons; or
(e) testing for pregnancy in persons; or
(f) the replacement or modification of parts of the anatomy in persons

claims more broadly especially where the product is sold direct to the consumer online. This exemption could be open to abuse.

- If a consumer is under medical supervision, there would be no need for a health claim to be made although some exemption may be given to referencing a disease/ condition on the label. The exemption from Transitional Standard 1.1A.2 (health claims) as a whole including the prohibition on the use of therapeutic claims therefore does not appear to be justified and needs further consideration.

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

- SA health support the application of advisory and warning statements to 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.

- No comment

11. Can you provide further information on how nutrient levels declared in NIPs are derived? (Industry)

- No comment

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

- Dietitians give consideration to information provided by some manufacturers about at what volume/amount the FSMP provides complete nutrition according to the NRVs. Dietitians also calculate the amount required specific to the patients individual nutrition requirements. This is usually done by working out patient's energy and protein requirements (based on the RDI requirements for age and gender, and based on this, what volume of FSMP is required). Particular micronutrients may be monitored for specific medical conditions e.g. copper for Wilson's Disease; zinc, vitamins A and C for wound healing; sodium, potassium, phosphate and magnesium for renal disease etc. If it is known that any nutrients are not complete in a given volume over a long period of time, this would be monitored by the medical practitioner.

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

- Micronutrients at risk of being inadequate from FSMP consumption as a sole source of nutrition should be monitored by the medical practitioner; supplements can be recommended for any deficient micronutrients.

14. Comments re: new paragraph 1.3(b) to ensure that VLED products are not captured by draft Standard 2.9.5

- Support