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Proposal P242 - Foods for Special Medical Purposes. Consultation November 2011

Thank you for the opportunity to comment on this consultation paper. The Ministry of Agriculture and Forestry (MAF) has the following comments to make in response to the questions noted in the paper. We have also provided some comments on the drafting proposed at the end of this letter.

MAF comments on questions in consultation paper on Foods for Special Medical Purposes (FSMP)

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

   MAF acknowledges the value in focusing the interpretation of 'food for special medical purposes' on the representation of products as foods for special medical purposes. However, we consider that it would be best to also include a substantive definition of food for special medical purpose as well as the representational one.

   As such, we recommend the following approach:

   Food for special medical purpose means a food that is—
   - (a). specifically formulated for the dietary management of individuals with a disease, disorder or medical condition; and
   - (b). represented as being—
     - i for the dietary management of a disease, disorder, or medical condition;
     - ii a food for special medical purposes; or
     - iii a medical food.

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

   As a general comment MAF does not consider that a restriction on sale is necessary. It is acknowledged that without the restriction there are risks that a wider range of product could be sold

as FSMPs in locations such as supermarkets and health food stores. However, the requirement to label FSMPs as being 'for use under medical supervision' and to identify the medical use of the product makes it clear that these products are not for the general public. Furthermore, these products are largely unregulated at present and there have been no problems identified with current distribution and retail practices.

Having said this, MAF recognises that a restriction on sale for FSMPs is consistent with the Forum on Food Regulation/Australia and New Zealand Food Regulation Ministerial Council Policy Guideline on the Intent of Part 2.9 of the Code – Special Purpose Foods. We also recognise that the intent of draft Standard 2.9.5 is to provide for continued access to FSMPs for those consumers that need them. We can therefore support a restriction on sale provided the drafting of the restriction does not affect current distribution practices, and provides scope for future changes to distribution practices that improve efficiencies for the consumers that need these products, medical professionals and suppliers.

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

MAF recognises that the drafting is intended to capture existing practices, and by and large we consider that it does so. However, we note the following issues with the drafting:

- The list of entities that can sell FSMPs identified in (a) may be incomplete. For instance, in New Zealand District Health Boards (DHBs) are responsible for funding health services and are established under the New Zealand Public Health and Disability Act 2000. It is conceivable that a DHB may, as a contracting entity, contract/arrange with a distributor to provide FSMPs to consumers that need them.
- Not all of the entities listed in (a) are, strictly speaking, 'businesses' or 'persons' as suggested in (c). It is suggested that (c) be redrafted to: 'a **business** or person that holds a written request from a business, person **or responsible institution** mentioned in paragraph (a) or (b) for supply of the food to consumers'.

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

The use of a written request/record keeping mechanism is a feasible approach. However, it requires further exploration. It is unclear from the consultation paper what form(s) the 'written request' should/can take. The consultation paper also mentions that some suppliers may have to change business practices. This may have costs. Good regulatory practice suggests that costs should be elaborated for decision makers. FSANZ should make enquiries with businesses currently distributing FSMPs on behalf of medical practitioners and dietitians to determine how they record and reconcile requests with sales and whether the proposed requirements would impact their businesses (and to what extent).

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

MAF considers that the requirements should be consistent with those of the EU and the US, so that importation can continue without the need for re-labelling. We note that FSANZ has required that inner packages should be labelled with the name of the food and any allergens. FSANZ notes that this is not a requirement in the EU, but that this information is often supplied anyway. MAF questions if this should be mandatory, as continuity of product supply should be maintained.

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

MAF considers that the requirements should be consistent with those of the EU and the US, so that importation can continue without the need for re-labelling. It is in the interests of manufacturers to label transportation outers appropriately. In our view, this aspect of the standard should not be overly prescriptive.

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.

MAF supports the proposed approach which is to exempt FSMPs from the requirements of Standards 1.3.2, 1.1A.2, and 1.2.7 (when gazetted). However, we note that current drafting does not fully take into account Standard 1.2.7. It is our understanding that Standard 1.2.7 and Standard 2.9.5 are scheduled to be considered at the same meeting of the Legislative and Governance Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council). MAF suggests that an alternative drafting should be prepared for FSMPs taking into account Standard 1.2.7 to be available for presentation to the same meeting. Gazettal of Standard 1.2.7 will have many consequential variations to other Standards which impact on the current drafting.

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.

MAF supports the use of therapeutic claims on FSMPs where they are used to meet the requirements of clause 9 (1) (c) and (d). We are of the view that in some instances these claims will assist in indicating the true nature of the product, and in order to communicate the specific indications for use, a statement of a therapeutic nature may be required.

Relationship between 'medical purpose' and 'therapeutic purpose'

MAF would like to signal to FSANZ the relationship between the restrictions on claims of therapeutic purpose in the New Zealand Medicines Act 1981 and the requirement in the clause 9(1)(c) of the draft standard for the label on a FSMP to include a statement 'indicating the *medical purpose* of the food..'.

- The Medicines Act applies to all 'Related products', including foods. The section 94(1) of the Medicines Act (http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM56098.html) provides that 'the term related product means any cosmetic or dentifrice or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose'. Therapeutic purpose is defined in the Medicines Act as (relevant aspects of the definition only):

  …the term therapeutic purpose means—
  (a) Treating or preventing disease; or
  (b) Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or…
  (e) Altering the shape, structure, size, or weight of the human body; or
  (f) Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way…

- All 'related products' must be approved by the Minister of Health, and are subsequently regulated under the Medicines Act.

- It appears there will be some cross over between 'medical purpose' in the draft FSMP standard and 'therapeutic purpose' in the Medicines Act. Therefore, it will most likely be necessary in New Zealand to amend the Medicines (Related Products (Exempted Foods)) Regulations 2003 (http://www.legislation.govt.nz/regulation/public/2003/0371/latest/DLM230508.html) to exempt foods that comply with Standard 2.9.5. Any exemption will not be able to proceed until Standard 2.9.5 has been gazetted. As such, the time provided for the transition period for proposed Standard 2.9.5 needs to take account of this process.

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

MAF supports the proposed approach.

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.

No comment

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?

MAF has the following comments in relation to FSANZ's proposal to adopt the minimum and maximum micronutrient composition levels in the EU Directive 1999/21/EC for FSMPs that are a sole source of nutrition:

- MAF supports the need for additional information on the composition and current usage of FSMP products to better inform the dietary modelling of nutrient intake levels and potential risk from under or over nutrition where the foods are the sole source of nutrition. This information will assist in informing the risk assessment and ultimately shape appropriate risk management strategies.
- It appears that the consultation paper is silent on the compositional suitability of these products for young children and adolescents. Attachment 2 reports that "…the European minimum levels were used to model daily nutrient intakes for the lower and upper end of the estimated energy requirement (EER) range for each age and gender group (as outlined in the 2006 Australia and New Zealand NRVs)." However Table 1, Attachment 2 summarises those nutrients with potential intakes below the relevant EAR for adult population groups only (i.e. individuals 19 years or older). MAF would like to see further detail in the risk assessment for individuals below 19 years of age given their relatively lower energy intakes.
- Given that the draft Standard 2.9.5 is proposing to permit variations from the composition requirements for special medical conditions, MAF is interested to know what situations or medical conditions are likely to exist that would necessitate this need for a variation? Is FSANZ of the view that an 'expressed permission' or 'approval' would be necessary for a company to deviate from the prescribed compositional requirements?
- MAF would like to see the above information before providing comment on the proposal to use the minimum and maximum micronutrient levels in the EU Directive 1999/21/EC given there is the potential for nutrient intakes to be below the 2006 Nutrient Reference Values for Australia and New Zealand.

Health Professionals

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

No comment

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

No comment

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.

    While we recognise that 'obesity' is the disease, are there any other teams that might be used instead of 'obesity' on the label of VLED products?

Comment on Draft Standard at Attachment 1

Purpose
The first sentence in the *Purpose* statement seems to provide a definition of what a food for special medical purposes is. It states, *This Standard regulates the sale, composition and labelling of foods which are specifically formulated for the dietary management of individuals with a disease, disorder or medical condition.* This wording ought to be used in the definition of FSMP in clause 1 (see answer to question 1 above).

Secondly, the first sentence of paragraph 3 in the *Purpose* section says, *The application of this Standard to a particular food depends on how the food is represented in its labelling and advertising, rather than on its content or formulation.* This sentence does not reconcile with the first sentence of the *Purpose* section. Even though this Standard is about the sale and labelling of a FSMP, the product must first meet the definition of a FSMP. MAF suggests that the first sentence of paragraph 3 is deleted as the following sentence captures what the first sentence appears to state.

Clause 1
MAF supports the inclusion of the definition used in the *Purpose* section in clause 1.

Re (2) *A food is not a FSMP only because...* – the meaning of this clause is difficult to understand. Use of *merely* would be preferred to *only*.

Clause 4
MAF suggests rewording into the positive ie *FSMP must only be sold to a consumer by…* It is easier to understand what is required rather than what is not permitted.

The term *consumer* is not used in Parts 1 and 2 of the Food Standards Code. The term *purchaser* has been used more widely. This is just an observation to note as the purchaser is not necessarily the same as the consumer. For example, a parent may be purchasing the FSMP for their young child, or a person may purchase for or on behalf of their parent (in an aged care situation). If it is the intention that only the consumer purchases the product i.e. the person who will eat the FSMP has also purchased it, then more work needs to be done on restrictions, making this clearer and defining what a consumer is.

Clause 8 (e) (iv) – the text *any other substance if a nutrition claim as defined in Standard 1.2.8 is made in relation to that substance* is an example of drafting that will be impacted by the consequential variations associated with gazettal of Standard 1.2.7. Under P293 it is proposed that the definition for 'nutrition claim' as defined in Standard 1.2.8 is deleted.

Clause 11 (c) – the full reference should be provided.

Clause 14 (2) – We acknowledge that the term 'gluten-free' means free of any detectable gluten under both the Food Standard Code, and consumer protection/fair trading laws in both Australia and New Zealand. As 'gluten-free' is effectively covered by consumer protection/fair trading law, MAF suggests that the standard for FSMPs is silent on the requirements for 'gluten-free'.

Clause 14 (2) – this clause as currently drafted is problematic, as the Food Standards Code was not updated when the Codex limit for 'gluten free' changed from 200 ppm to 20 ppm in 2008. The Food Standards Code, when first published, had the Codex 'gluten-free' standard represented as 'low gluten' i.e 200 ppm, to enable a dual approach (i.e. persons with coeliac disease could choose 'low gluten' foods, on the advice of health professionals).

In addition, the terminology used by the EU and Codex, to support a dual standards approach, is 'very low gluten' (rather than low gluten).

We would be interested to know if FSANZ is considering reviewing the Food Code requirements for the 'low gluten' category, in light of the updated limits and terminology used by Codex and the EU. If this work is undertaken for the Food Code first, consideration could then be given to any changes required to the standard for FSMPs.

Clause 14 (3)

MAF does not consider that the standard for FSMPs needs to prescribe the requirements for the other categories (high gluten, as contained in the proposed clause14 (4)), as we are not aware of a medical need for these products.

Clause 14 (5) – could this be incorporated into the proposed clause 8 (e) (iv)?

Given the comments above relating to all of clause 14, it is our view that this clause could be considered for deletion from the proposed draft standard.

Formatting of the draft standard

There are several minor typographical errors in the draft standard. These are detailed below:
Page 36 bullet point **3** - '**two years fromthe**' should read 'two years from the'.

Page 36 bullet point [1.1] – '*clause 2the'* should read *'clause 2 the'*

Page 36 bullet point **[3]** - '***of*transportation outer***and*small package**' should read '*of* **transportation outer** *and* **small package'**

Yours sincerely

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Manager Food Safety