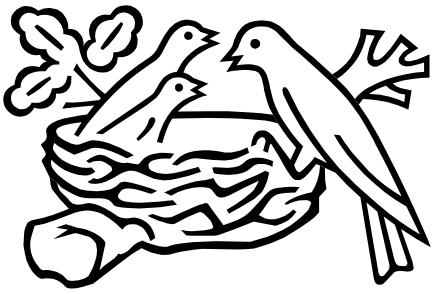

Nestlé Nutrition

Nestlé Health Sciences Submission

P242 – Foods for Special Medical Purposes
Consultation Paper

Response - 16 December 2011

Nestlé Health Sciences Submission

Proposal 242 Food for Special Medical Purposes

Consultation Paper (November 2011)

This submission is made on behalf of Nestlé Australia Ltd and Nestlé Nutrition [Nestlé].

Nestlé welcomes the opportunity to provide comments in response to the recently released Consultation Paper on Proposal P242 – Foods for Special Medical Purposes. Below are some of the points that Nestle would like to bring to your attention.

1. Restriction on the sale of FSMPs

The modification to Draft Std 2.9.5 clarifying the restriction on sale will enforce more processes, paperwork and most likely restrict supply of FSMPs to users. We are particularly concerned with section (c) whereby FSMPs must not be sold to a consumer unless the person holds a written request from a business or person mentioned in section (a) and (b).
In view of this requirement, we can foresee the following difficulties:

- HCP's response and compliance to the written requirement (very similar to prescription issuance).

- Distributor's difficulty in collection and monitoring of the written requests from home patients in instances of the HEN program which is a home delivery service.

- Accessibility of FSMPs to genuine consumers who have been put on these products at some point in time by as medical professional but have difficulty in obtaining a written request each time they want to purchase the product. One example would be home bound consumers who depend on delivery of products via the community distributors, online pharmacies etc.

We consider that there are a couple of controls in place with regards to the risk of inappropriate sale or usage. Firstly the medical warning statement on any FSMP label is an alert to consumer that the FSMP concerned needs to be taken with medical supervision. Secondly, distributors supplying FSMPs are listed with the manufacturers. In conclusion, we strongly discourage the proposal for a written request and recommend that the previous definition for part (c) i.e. 'a manufacturer of food for medical purposes or a distributor of a manufacturer of food for special medical purposes' to be re-instated. Alternatively, we propose that the 'written request' in (c) be substituted by 'initial authorisation' so that consumers do not need a written request each time they need to purchase any FSMP product. This means that an HCP would have reviewed and started the patient on the FSMP. This will also mean a less onerous burden on the Distributor.

2. Labelling requirements

- Nestle proposes the exemption from allergen declaration requirement.

There are a number of highly refined food ingredients, additives and processing aids which are prepared from food sources that contain allergens, from which the allergen component

has been effectively removed or denatured. The European Food Safety Agency provided advice to the European Commission that a number of these ingredients are unlikely to result in allergic reactions if consumed by sensitive consumers.

This advice relates to the following food ingredients:

- isinglass in beer and wine
- vegetable oils, phytosterols and tocopherols from soybean
- wheat based hydrolysates
- glucose syrups,
- maltodextrins
- distillates for spirits from cereals, nuts and whey
- lactitol from milk
- glucose syrups from barley starch

Nestle considers that the advice issued by EFSA with regard to providing labelling exemption for all of those foods where the allergenic risk has been effectively removed through processing should be encompassed into our local regulations. This would drive consistency internationally, it will help facilitate trade and result in less complex labels with no superfluous labelling when there is no risk to the consumer. Nestlé considers that allergen declarations remain not aligned with the EU declarations.

This will create the need for separate labels and restrict availability of these products in this region. Nestle considers that it is appropriate for allergen information to be available for FSMP's both the allergens formulated in the product as well as the allergens implicated via cross contact however proposes that for this very special category of medical foods (FSMP's) that the allergen labelling information requirements be aligned with the current EU Directive. An extensive range of FSMPs originate from the EU and most of these do not have Australia or New Zealand dedicated labels due to the smaller volumes. There is unfortunately no justification for Australia or New Zealand only labels which do not justify for dedicated labels.

Refer to attachments - Sample of imported label where wheat origin of glucose syrup is not declared.

- Labelling information for inner packages

With regards to the labelling requirements for inner packages, we would like to propose the inclusion of the lot identification/batch no for traceability of product as well as date coding/expiry date.

- Therapeutic claims – Allow or prohibit

By definition, therapeutic claims mean 'to alleviate, prevent or cure' a medical condition or disease state. Currently, our products do not indicate any therapeutic claims on their labels. However, we are in agreement that therapeutic claims should be allowed as in some medical conditions such as IBD and metabolic disorders, nutrition can be used as a first line therapy.

- Impact of the proposed labelling requirements on the cost and availability of FSMPs

Nestle anticipates difficulty with regards to the requirement to indicate on the label the nutrient that has been modified to vary from the compositional requirements and how it has been modified. This impacts mainly the imported products with labels that are relevant for many Markets. Due to our smaller volumes, it will be difficult to obtain Australian dedicated labels to enforce this requirement especially for products coming from USA.

Nestle consider that the words "nutritionally complete" will continue to be suitable term or statement on FSMP labels. Products imported products from the USA and EU will continue to indicate the words "nutritionally complete" on their labels to satisfy their local regulations or requirements.

3. Compositional Issues

- Propose for the permission of additional additives to be included for FSMP

Nestlé supports the use of Phosphoric acid, Sodium hydroxide and Potassium hydroxide as acidity regulators (important for fruit flavoured beverages and some FSMPs) , as per EU & US regulations, in addition to the current permission as processing aid in Std 1.3.3. This permission will align the requirement with that of EU's. Currently, many FSMPs are imported from the EU with EU customised labels and these ingredients will appear on the label as additives. This willnot comply with the Australia's requirements as processing aids do not require to be listed on the label.

Recently, we had a product from the EU containing all three processing aids indicated as additives on the EU label. Two minerals, Potassium phosphate and Sodium phosphate, resulting from an 'in situ' reaction of these 3 ingredients were listed in the ingredient list as minerals. However, on the Australia dedicated label, these processing aids are not listed but the two minerals resulting from the chemical reaction of the combination will have to be declared and listed as minerals. In doing so, we lose traceability and justification of the origin of the two minerals.

Phosphoric Acid + Sodium Hydroxide => Sodium Phosphate (mineral)
Phosphoric Acid + Potassium Hydroxide => Potassium Phosphate (mineral)

Refer to attachment - 21CFR184.1631, 21CRF184.1763 & Council Directive No 95/2/EC on additives other than sweeteners and colors.

- Information on declared nutrient levels in the nutrition information panels

For existing products, our declarations are based on analytical values. However, for new products, we use a mixture of calculated values and/or analytical values if they are available from pilot or industrial trials.

Regarding the level to declare, it may be the average content or the minimum content, due to different labelling tolerances. Commonly, the USA requires minimum values to be declared and for EU Market average content is declared. This means that we can have different declarations for the same recipe according to labelling rules of the Market where the product is sold.

The average content as well can be different from the average amount of addition, especially for unstable vitamins where the stability of the vitamins needs to be considered taking into account processing conditions and potential distribution impacts.

- Gluten-free claims

Products sourced internationally may carry a 'gluten Free' claim. International regulations or industry best practice often reflect a gluten threshold level in foods of < 20ppm rather than the ANZFSC criteria of 'nil detected'.

The Australian and New Zealand model is excessively conservative and is confusing for industry to comply with, thereby reducing the range and availability of foods labelled as suitable for consumers with Coeliac Disease. In order to make a "gluten free" claim in Australia and New Zealand, a food must contain no detectable gluten however, the current standard does not specify the method of analysis to be used in making this determination. There are a number of commercial test kits, as well as in-house methods, available in Australia and New Zealand which are promoted as having limits of detection below 5ppm in particular food matrices. Problems arise for manufacturers of gluten free foods in identifying validated tests and determining the appropriate method of analysis for their specific foods. Compliance issues have arisen where manufacturers, despite having comprehensive QA procedures in place, including testing using established and validated methods, have lost orders, been required to modify labels or received notices of non-compliance with the Code following testing by customers or enforcement agencies using newer, purportedly more sensitive test kits. Ultimately, without reference to the Courts, there is no agreement within the food sector about the limit of detection and therefore, the absence of a numerical threshold drives a "race to the bottom" in terms of the acceptance of kits with lower limits of detection.

Nestle considers that the criteria necessary for determining a "Gluten Free" limit as a food regulatory measure includes that:

- it protects a majority of individuals with Coeliac Disease, whilst ensuring that they can still access a nutritious and varied diet, and
- it is achievable by the food industry under normal conditions of Good Manufacturing Practice, and
- there are validated methods of analysis, widely available to the food sectors, that are able to reliably and reproducibly detect gluten at the prescribed level in all relevant food matrices

Nestle proposes that because there is a drive internationally to establish a threshold for gluten at < 20ppm that locally we align with this view however understanding the potential complexity in progressing this we propose that alternatively there could be an exemption granted from the 'nil detected' criteria in the ANZFSC for this special category of medical foods. **Refer to attachment - Regulation EC No 41-2009 on gluten labelling.**