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ACKNOWLEDGED

OUR REF	:		DATE	:	14 August 2002
YOUR REF	:				
TO	:	Food Standards Australia New Zealand			
ATTENTION	:	Project Manager	FAX NO	:	[redacted]
COPY	:				
SUBJECT	:	Submission - Proposal P235 - Review of Food-Type Dietary Supplements	No. OF PAGES (Including this page)	:	5

Dear Sir/Madam,

Following is the submission from Nestlé Australia Ltd and Nestlé New Zealand Ltd in response to the request for comment on Proposal P235 – Review of Food-Type Dietary Supplements. Thank you for the opportunity to comment and also for the extension granted in order to complete the submission.

Regards,
Nestlé Australia Ltd

[redacted]
Regulatory Affairs and Nutrition Manager
Oceania

NESTLÉ COMMENTS ON THE INITIAL ASSESSMENT REPORT ON THE REVIEW OF FOOD-TYPE DIETARY SUPPLEMENTS – PROPOSAL P235

This submission is made on behalf of Nestlé Australia Ltd and Nestlé New Zealand Ltd. Nestlé is a manufacturer and importer of a wide variety of foods for the Australian and New Zealand markets. Some of the brand names belonging to Nestlé include MAGGI, NESCAFE, MILO, NESTLE PETERS, PAPA GUISEPPI'S, FINDUS, LEAN CUISINE, SUNSHINE, NESTLE GOLD MEDAL, CARNATION, ROWNTREE, LIFESAVERS, ALLENS, KANDYLAND, MINTIES, INTERNATIONAL ROAST, COFFEE-MATE, MASTERCRAFT, IDEAL, BEARBRAND, SWEETACRES, THOMY, VIOLET CRUMBLE, WALCO, ANDRONICUS, ALPEN BLEND, BACI, CROSSE & BLACKWELL, VITARI, GOLD BLEND, BUITONI, PERRIER, VITTEL, WONKA and KIT KAT. In addition to the products that carry these brands, Nestlé also manufactures products that fall within the jurisdiction of the Therapeutic Goods Administration. These products include the SOOTHERS range and QUICK-EZE amongst others.

General Comments:

Nestlé supports the review of food-type dietary supplements under the joint Food Standards Code. Although we acknowledge that the products under discussion here will be regarded as foods, we believe that there is the potential for some food products to carry claims that are normally controlled under the Therapeutic Goods Act. This will thus create a disparity between manufacturers of certain therapeutic products and manufacturers of foods. In order to overcome this there needs to be a clear distinction between what is a therapeutic claim and what is not and a clear position on the controls necessary to ensure compliance of food-type dietary supplements.

We are concerned that food products might carry therapeutic claims and there will not be sufficient enforcement within the food area to ensure that the manufacturers making these claims either modify the claims or apply for a product licence through the relevant section of the Therapeutic Goods Administration (TGA). It is our belief that foods that are making illegal therapeutic claims would also be breaching the therapeutics legislation and should be able to be prosecuted under this legislation.

It is critical that Food Standards Australia New Zealand develops this standard in consultation with the TGA and the JTA project team. This will help ensure that those products that are legislated within the therapeutics area will not be captured in the food area.

Nestlé Position:

Care needs to be taken with the development of a definition for these types of products. The continuum of foods to therapeutics lists fortified confectionery products as food-type dietary supplements and the legislation relating to these types of products needs to ensure that products currently under the TGA system are not captured. Lozenges for the relief of the symptoms of a cold for example, might be considered as fortified confectionery if the definition is not suitable. These are, however, clearly regulated as a therapeutic and must continue to remain so.

The claims for these product types are critical in determining how they might be regulated. Within the document 'Guidelines for Levels of Evidence to Support Indications and Claims' that was released by the TGA in October 2001, there are descriptions for the different levels of claims based on the level of evidence available. General level indications and claims are those that relate to health maintenance, including nutritional support; vitamin and mineral supplementation and relief of symptoms not related to a named disease, disorder or condition. Whereas medium level indications and claims relate to health enhancement; reduction of risk of a disease/disorder/condition; reduction in frequency of a discrete event; aids/assists in the management of a named symptom/disease/disorder/condition and relief of symptoms of a named disease/ disorder/condition.

There is a need, however, for claims such as nutrition messages and nutrition content claims (which could be classified as health maintenance or nutritional support) to be made about food-type dietary supplements. We also acknowledge that with the review of health claims, this will further complicate the delineation between foods and therapeutics, particularly in the complementary medicine area. This makes it absolutely critical that the definition of a therapeutic is clear and concise and there is consistency between the agencies.

A risk-based approach needs to be adopted for the management of these products. Within this risk-based approach, labelling, along with safety assessments of certain ingredients, will clearly be a part of that management process.

Ingredients that have been approved for use in the complementary medicines category of the TGA should not necessarily be considered novel for food, nor should they always be considered as unsafe. Generally the materials used under this category of TGA products are considered a low risk. Novelty should be based on whether consumers have an understanding of the use of the material and whether the labelling requirements will suitably manage this aspect. If there is sufficient knowledge about the ingredient then it should not be considered novel even if this has been determined safe by other jurisdictions rather than under the food legislation.

It is stated in the document that a conservative approach has been taken in both Australia and New Zealand with respect to the addition of nutritive substances, especially vitamins and minerals. While this is true, an exception was made with the category of formulated

caffeinated beverages, as was mentioned in the document. This provides the opportunity for a change with respect to the policy direction of the addition of vitamins and minerals. Advice needs to be sought from the Ministerial Council on the policy direction for the addition of vitamins and minerals, particularly for their addition to general foods. A policy direction is also needed for the addition of particular botanicals in food as the current food standards prohibit the addition of some botanicals that could easily be present in food-type dietary supplements already on the market in New Zealand.

We see no reason why food-type dietary supplements cannot be added to other foods. Provided the resultant food is classified a food-type dietary supplement with the necessary labelling requirements, then there should be no regulatory difficulty.

We believe that products that might 'normally' be considered as foods could fit within the definition of food-type dietary supplements. We believe that different foods may be suitable vehicles for carrying different types of ingredients. Certain foods might be a more suitable vehicle for providing a certain ingredient or group of ingredients to consumers. There is a need to ensure that any of the ingredients that are added to these foods are not added at levels that would be considered therapeutic.

Food Standards Australia New Zealand questions whether there are some foods that should be excluded from mixing with food-type dietary supplements. There should be no exclusion of specific foods as this may remove a suitable vehicle for consumption of certain ingredients. The examples of foods given within the document include confectionery and soft drinks. The NZ DSR includes lozenges and pastilles as permitted formats for these products. Consumers can quite easily perceive these as confectionery products that are carrying particular ingredients for a particular need (eg fortified confectionery). Soft drink is another food category that is questioned. The category of soft drink is not defined within the food standards (except for brewed soft drink) or within the document. Again, this type of food might be a suitable vehicle for carrying some of the ingredients that might be contained in food-type dietary supplements and the standard should be open to allow this. We have already stated that food-type dietary supplements should be permitted to be added to all foods. Where this occurs in these cases also, the resultant food would have to be classified as a food-type dietary supplement with the resultant labelling requirements and any particular compositional aspect that might be required under the standard.

Options:

We do not agree with the retention of the status quo. This will not be an equitable approach to the regulation of these product types.

Our preferred option would be the development of a new and fully regulated vertical standard. We believe that a co-regulatory approach in the management of these products can only work where there are the necessary sanctions in place to allow for a high degree of compliance and unless this occurs, we cannot agree to this approach at this time. It is necessary that those manufacturers that are complying with the requirements for these types of products be assured that those that choose to breach the requirements can be brought into compliance so that there is minimal damage to the businesses of the compliant manufacturers.

Nestlé Australia Ltd

[redacted]

Regulatory Affairs and Nutrition Manager
Oceania