Nestlé Health Science Submission

Proposal P1023 – Tutin, Tocopherol & Food for Special Medical Purposes Standards Amendments

Response – 30 October 2012

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

Nestlé welcomes the opportunity to provide comments in response to FSANZ's call for submission to assist consideration of the draft food regulatory measures with regards to Food for Special Medical Foods

Question for submitters:

Apart from the listed transitional arrangements, are there other elements of Standard 2.9.5 that would require time to transition if the Standard's commencement date was brought forward?

In addition to the listed transitional arrangements, other elements of Standard 2.9.5 which some of our products would require time to transition over are listed as follows:

- Clause 6 (1) (a) – Permitted forms of particular substances must be listed in Column 1 of Schedule 1 of this Standard if the substance is in one or more of the corresponding forms listed in Column 2 of that schedule.
  We have a product which contains an amino acid, L-Arginine Acetate (permitted in US regulations) which will require reformulation to remove/replace this substance in order to comply with the list of permitted forms in Sch 1 of this Standard.

- Clause 9 (d) & (e) – Mandatory information on a label must include information on the minimum or average energy, protein, fat and carbohydrate content as well as vitamin, mineral, electrolyte and any substance present (as listed under Column 1 of Schedule 1) in the food.
  We have some imported products used as enteral/tube feeds which will require nutritional information panels on the pack. These are shared labels with other countries also taking this product. The business will need to make the necessary arrangements to become compliant with this Clause of the standard.

- Clause 10 (1) (a) – Mandatory statement to the effect that the food must be used under medical supervision.
  This is not a mandatory requirement for products sold in the US. We currently import quite a number (15) of SKU's of these products where we share labels. We will require sufficient transition time to review labels and include this statement in the next artwork update.

- Clause 10 (1) (c) – Mandatory statement indicating the medical purpose of the food. Products currently imported from the US are not required under US regulations to have this statement clearly indicating the medical purpose of the food. We will require sufficient transition time to make these label adjustments.

- Clause 10 (2) (a) – Mandatory statement to the effect that the food is not for parenteral use if they are represented for use as a sole source of nutrition.

A small number of products will require this statement included on their labels. We will require sufficient transition time to make these changes.

- Clause 17 (2) (c) – Labelling requirements for inner packages to include a declaration of the presence of food of any of the substances listed in the table to this clause. A small number of products will require addition of allergen statements to inner packages. The complete allergen declarations are currently indicated on the outer pack labels. We will require sufficient transition time to make these labelling adjustments.

Further Comments:
Nestlé understands that the intention of this proposal is to provide Stock in Trade arrangements for those clauses in Standard 2.9.5 that are covered by the transition period, and that an additional 12 months stock in trade provision is provided for after the transition period (i.e. to June 2015). Nestlé requests that FSANZ makes this point clearer in the final report.

Whilst Nestlé is in support of FSANZ's proposal to bring forward the commencement date and provide transitional arrangements for food for special medical purposes, we trust that the above mentioned areas of Standard 2.9.5 will be considered and included in the final list of transitional arrangements as was originally intended when Standard 2.9.5 was gazetted. As most food for special medical purposes are imported either from the US or EU, it is important that we have sufficient time to execute the required changes or updates into labels and especially so for changes in formulations.