

## **NUTRICIA ADVANCED MEDICAL NUTRITION SUBMISSION FOR:**

Proposal P1023 -  
Food for Special Medical Purposes standard amendment

**Submission date: 30 October 2012**

### **Nutricia Advanced Medical Nutrition**

Nutricia Australia Pty Ltd  
Level 4, Building D  
12-24 Talavera Road  
Macquarie Park NSW 2113

Tel: 02 8875 0300  
[www.nutricia.com.au](http://www.nutricia.com.au)

### **Nutricia Advanced Medical Nutrition**

Nutricia Ltd  
37 Banks Rd  
Mount Wellington  
Auckland 1060

Tel: 09 570 0970  
[www.nutriciaclinical.co.nz](http://www.nutriciaclinical.co.nz)

Table of contents	Page
Executive Summary	3
Nutricia Advanced Medical Nutrition response to submission questions	4
Nutricia Advanced Medical Nutrition comments regarding FSANZ temporary exclusions from operation of the Standard (2.9.5) from gazettal of this Proposal until 28 June 2014 <b>[ This section is provided commercial-in-confidence ]</b>	6
Conclusion	7
References	8

## **EXECUTIVE SUMMARY**

---

These comments are being submitted to Food Standards of Australia and New Zealand (FSANZ) on behalf of Nutricia Advanced Medical Nutrition, as a division of Nutricia Australia Pty Ltd and Nutricia Ltd.

Nutricia Advanced Medical Nutrition (“Nutricia AMN”) welcomes the opportunity to comment on FSANZ’s Proposal P1023 - Foods for Special Medical Purposes (FSMPs).

Nutricia AMN in Australia and New Zealand supplies a wide range of food for special medical purpose (FSMP) products or stock keeping units (SKUs) suitable for the dietary management of patients with various medical conditions.

Nutricia AMN agrees with FSANZ’s proposal of Option 1 and also agrees with the currently listed transitional arrangements proposed by FSANZ.

In this document, Nutricia AMN refers to FSMPs as described by FSANZ Code *Standard 2.9.5 – Food for Special Medical Purposes gazetted 28 June 2012*.

## NUTRICIA AMN RESPONSE TO SUBMISSION QUESTION

**“Question to submitters:** *Apart from the listed transitional arrangements, are there other elements of Standard 2.9.5 that would require time to transition of the Standard’s commence date were brought forward?”*

In response to the question above, Nutricia AMN requests FSANZ to consider granting Nutricia AMN additional time, and where applicable exemption, to transition or comply with the following provisions:

- (1) Mandatory declarations of allergenic substances as stipulated by Standard 2.9.5, Division 4 Subdivision 2, Clause 11, subclause (1) and (2); and Subdivision 3, Clause 17, subclause 2.
- (2) Mandatory statements regarding phenylalanine and the laxative effect of sugar alcohols, as stipulated by Standard 2.9.5, Division 4, Subdivision 2, Clause 10, subclause 3(b)(e).

The rationale for our request is listed as follows:

### Rationale in relation to point (1):

- I. These provisions are new requirements for the labelling of FSMPs.
- II. Due to the limited volume of product sales in Australia and New Zealand there is a need to share product labels with European Union (EU) countries.
- III. Nutricia AMN already makes provision for multiple languages on packaging which therefore limits space on the product label; as a result of shared product labels, text must be translated into different languages.
- IV. Subject to compliance with the new EU directive 1169/2011, font size has been increased on EU/ANZ product labels to 1.2 mm which means space on packaging has been used to full capacity
- V. Nutricia AMN is currently in the process of updating all product labels to include mandatory declarations of allergenic substances to accommodate the new EU directive 1169/2011, Article 21 (published November 2011).
  - a. Within the directive, the declaration of allergens by use of bolding text is accepted as being compliant.
  - b. Further, the bolding of allergens alone is deemed an acceptable alternative by the Australian Food and Grocery Council’s (AFGC) *Food Industry Guide to Allergen Management and Labelling*. This guide is recommended on the NSW Food Authority website.

**NOTE:** Therefore, it will only be possible for Nutricia AMN in Australia and New Zealand to declare the allergen by the use of bolding text; the allergen will be identified by its common name similar to the form listed as per Table to subclause 11(1) (e.g. cow’s **milk**). It will therefore not be possible for Nutricia to accommodate for an additional declaration statement (e.g. Contain/May contain milk) on the product’s outer and inner label.

- VI. Label transition takes a considerable amount of time and has financial implications for the ANZ business. Therefore Nutricia AMN requests that FSANZ takes this into consideration when making further amendments to the Standard (2.9.5).
- VII. Nutricia AMN does not foresee any risks to public health and safety as a result of allowing more time to align or allowing more time to transition to Standard 2.9.5, Division 4 Subdivision 2, Clause 11, subclause (1) and (2); and Subdivision 3, Clause 17, subclause 2, as all product labels and communications include a clear statement emphasising the use of our products under healthcare professional supervision. Therefore, the potential for any adverse health effects relating to allergy is considered to be extremely unlikely due to the element of medical supervision. Additionally, allowing more time to comply with these provisions will permit Nutricia AMN to continue to sell our FSMPs lawfully and also allow consumers who rely on these products to continue to receive access.

**Rationale in relation to point (2):**

---

- I. This provision is a new requirement for the labelling of FSMPs.
- II. Due to the limited volume of product sales in Australia and New Zealand there is a need to share product labels with European Union (EU) countries.
- III. Nutricia AMN already makes provision for multiple languages on packaging which therefore limits space on the product label; as a result of shared product labels, text must be translated into different languages.
- IV. Subject to compliance with the new EU directive 1169/2011, font size has been increased on EU/ANZ product labels to 1.2 mm which means space on packaging has been used to full capacity.
- V. For any new products that contain these ingredients and are imported within the next 2 years, the additional time to transition will allow us to consult with other countries that share the product label for the new product and consider possible arrangements/alternative to allow for the additional provisions on the product label.



[REDACTED]

- [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**CONCLUSION**

Nutricia AMN appreciates the opportunity to provide comment and seek clarification in relation to P1023 – Food for Special Medical Purposes amendment.

## **REFERENCES**

---

1. Australian Food and Grocery Council (AFGC) (2007). Food Industry Guide to Allergen Management and Labelling – 2007 revised edition. pp 12 – 13.
2. NSW Food Authority. <http://www.foodauthority.nsw.gov.au/industry/food-business-issues/allergies-and-intolerances/> [accessed 24/10/2012].
3. NSW Food Authority – ‘Gluten free’ products. <http://www.foodauthority.nsw.gov.au/science/market-analysis/gluten-free-products/> [accessed 26/10/2012].
4. Codex Alimentarius Commission STAN 118-1979 (2008). Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten.
5. Official Journal of the European Union (2011). Regulation (EU) No 1169/2011 of the European Parliament and of the Council.

