



DANONE NUTRICIA

**Response to Food Standards Australia
New Zealand**

**Proposal 1028
Review of Infant Formula Products**

30th May 2016

INTRODUCTION TO DANONE NUTRICIA

{1} Danone Nutricia Early Life Nutrition (Nutricia) is part of Danone, a Fortune 500 company and one of the most successful health food companies in the world. With over 100 years of caring for babies and 40 years of ongoing research into breast milk and early life nutrition, Nutricia combines science and experience to support parents, carers and health care professionals.

{2} Breast milk is the ideal source for the healthy growth and development of infants and gives babies the best start in life and Nutricia fully supports and encourages breast feeding.

{3} Infant formula is recognised as the only acceptable alternative for those infants who are not breastfed for whatever reason. For those infants 0 – 6 months, infant formula can be the sole source of nutrition and it is therefore vital that its nutritional composition supports infant needs.

{4} Therefore, as an infant formula manufacturer, we have a responsibility to ensure that our products are not only safe for consumption, but to invest in research and development to support the nutritional needs of infants. We manufacture formulas for infants based on a scientific approach to nutrition, encompassing extensive research, clinical studies and co-operation with health care professionals around the world. We have major research centres in the Netherlands, Singapore and China, employing 1500 scientists and researchers, as well as a network of 400 staff across the globe to connect with other experts.

{5} This commitment to research includes close collaboration, partnerships and open dialogue with research institutes, universities, hospitals and industry suppliers around the world. For example, Nutricia Research has worked with more than 100 international universities and 125 hospitals to publish peer-reviewed scientific papers in the field of maternal and child nutrition.

{6} As a manufacturer, Nutricia complies, without compromise, with strict food safety and quality laws and regulations, as well as equally important industry standards and agreements.

{7} Nutricia is a member of the Infant Nutrition Council (INC) in Australia and New Zealand. As a member of INC, we have participated in and contributed to the INC submission to P1028.

{8} Nutricia is also a member of ISDI (International Special Dietary Foods Industries) and contributes to CODEX Standard deliberations in the area of infant nutrition. ISDI is the leading international expert association on special dietary foods. It brings together national and international associations that are active in this food sector from more than 20 countries over 6 continents.

{9} ISDI is a platform for debate on regulatory, technical and scientific issues regarding special dietary foods, including infant formula. The objectives of ISDI are:

- To promote high standards in the production and trade of special dietary foods;
- To collect, analyse and communicate information and documentation relating to special dietary foods;
- To collaborate with international institutes and organisations such as the Codex Alimentarius and the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO).

{10} We have used the above platforms and our Nutricia Research to help inform and validate our submission.

{11} Nutricia welcomes the opportunity to submit our comments to the Consultation Paper – Proposal 1028 Infant Formula. We support the objectives of the Proposal where;

- the health and safety of infants are protected
- there is consistency with advances in scientific knowledge, and
- industry innovation or trade is not hindered,

whilst adhering to the principle of minimum effective regulation. Danone is committed to regulation where, as outlined in the NZ Treasury's Good Regulation, Better Regulation guidance on 17 August 2009, that regulation should occur only when it is required, reasonable, and robust, having undertaken a full cost/benefit analysis.

ABOUT THIS SUBMISSION

{12} Nutricia is pleased to submit this response to Food Standards Australia New Zealand (FSANZ) for the review of the Infant Formula Products Standard – P1028. It is noted that this review has been limited to those regulations within Standard 2.9.1 that apply to infant formula, only, excluding follow-on formula and products for special dietary purposes.

{13} Important Note: Nutricia is providing this submission to FSANZ, however as a member of the Infant Nutrition Council (INC), Nutricia has participated in the development of that submission and the adoption of the positions expressed therein.

{14} Nutricia supports the INC submission. The following comments are intended to support the INC submission and to elaborate on specific points where appropriate.

SPECIFIC COMMENTS

{15}Nutricia is providing additional information on specific points that are detailed below.

1. Scope of the Review

{16}Proposal 1028 has been defined as encompassing a review of the permissions for composition and labelling of infant formula, only. FSANZ have determined that this review will not include the regulations for follow-on formula nor formula for special dietary purposes, standardised in Division 3 – Infant Formula Products for Special Dietary Use of Standard 2.9.1.

{17}Nutricia recommends that the scope of Proposal 1028 be revisited to be extended to cover infant formula products standardised in Division 3 – Infant Formula Products for Special Dietary Use.

{18}Infant formula products manufactured for Special Dietary Use, are permitted to be modified to meet the special dietary needs when required by certain infants. These provisions are detailed in Division 3 of Standard 2.9.1. However, in all aspects other than the specific dietary modification for their specific dietary purpose, those specially formulated products must comply with the requirements of Standard 2.9.1.

{19}Therefore all amendments that result from this review will need to apply to those modified products, excepting where the specific dietary modification is applied. Given that these products must also comply with the general provisions, it must logically follow that these products be considered as an integral part of this review.

2. Harmonisation with Codex

{20}Nutricia strongly supports harmonisation with Codex regulations where this is appropriate for the ANZ environment. Alignment between ANZ and Codex would support ANZ manufacturers and in turn, support parents and carers of infants, in allowing provisions to utilise world best practices, support innovation and support international trade.

3. Calculation of protein: nitrogen conversion factors

{21}Standard 2.9.1 currently specifies two nitrogen conversion factors: 6.38 for milk proteins and 6.25 for all other protein sources, except soy protein. It is noted that FSANZ is proposing that only two factors should be maintained, with the conversion factor of 6.25 to apply to mammalian milk and the conversion factor for soy protein should be retained at 5.71.

{22}It is noted that the Codex STAN 72-1981 adopted the use of the factor 6.25 for infant formula products.

{23} Nutricia supports the adoption of the conversion factor of 6.25. It is Nutricia's view that due to the promotion of lower protein formulas, that this it is also desirable so as to give us a slight (2%) safety margin to address the concerns of those who are concerned that by lowering protein, it may result in protein deficiency in a minor subgroup of consumers.

4. Amino Acids

{24} Nutricia supports alignment with Codex STAN 72-1981 minimums for tyrosine, phenylalanine, methionine, and cysteine.

{25} As these levels have been adopted by Codex, and in support of harmonisation, Nutricia supports the adoption of these levels, for these amino acids.

{26} This harmonisation with Codex, for amino acids is particularly important for goat milk based formulas. This will allow compliance with the naturally occurring levels, especially for cysteine and methionine.

5. Vitamin and Mineral advice

{27} FSANZ have asked for comment on linking nutrition advice with ingredient advice.

{28} Nutricia is strongly opposed to this position. A number of ingredients, and in particular whole milk and milk products, are complex, nutrient dense ingredients. However, other ingredients will individually provide some of those nutrients.

{29} The complexity that would result on labels, makes this totally unworkable. It must be expected that any resulting attempt at such labelling would be confusing to consumers and not provide any additional benefit.

6. Nutritive substances and novel foods in infant formula product

{30} Nutricia strongly supports the inclusion of Standard 2.9.1 Infant Formula Products in Proposal P1024.

{31} Nutricia is of this view, as detailed in our Submission to P1024.

{32} Nutricia supports the adoption of Option 3 – Develop an Alternate Framework, acknowledging the need for a higher level of data required for new ingredients/nutrients.

7. Additional Nutrients Listed in Nutrition Information Statements

{33} Nutricia does not accept that the inclusion of macronutrient subgroups in a nutrition information statement can be considered to be a nutrition content claim.

{34} The current Food Standards Code allows for a ranged of macro and micronutrients to be included in nutrition statements, some being mandatory.

{35} Standard 2.9.1—21 (1) (a) (iii) requires that nutritive substances, which include optional ingredients, to be declared.

{36} Standard 2.9.1—24 (1) (f) “Prohibited Representations” states that references to the presence of any nutrient or nutritive substance, may only be stated in the declaration of nutrition information and ingredient list.

{37} The resulting permission clearly allows for macronutrient subgroups to be listed in nutrition information statements.

8. Alignment of Ingredient Labelling Response:

{38} A proposal has been put forward to consider aligning ingredients with nutrient declarations. In practice this would be extremely cumbersome, if not impossible.

{39} It is Nutricia’s view that this would lead to considerable confusion for caregivers.

{40} Nutricia is also of the view that this would provide no substantive benefit to caregivers.

9. Informed Choice

{41} Currently, there are substantial difficulties in alerting caregivers to changes made to the composition of infant formula.

{42} This is, and should be, a major concern, not only to manufacturers but also to regulators.

{43} Infant formula is designed to provide a sole source of nutrition to a vulnerable population group. Caregivers have a right, to information regarding the composition and any subsequent changes to the composition of these products.

{44} Further, FSANZ second high order principle requires that the regulations be composed such that consumers have adequate information available to them, to make an informed choice.

{45} Research has been conducted by INC, on this. Nutricia would refer FSANZ to the detail in that submission.

10 Conversion Factors

{46} As has been detailed in the INC submission and discussed with FSANZ, it has become apparent that the energy conversion factor, converting kcal to kJs, has not been used consistently throughout Codex.

{47} This has not only caused confusion, it brings into question, the validity of the resulting regulatory limit or level.

{48}Nutricia is most concerned that the energy conversion factor, be consistently applied throughout the ANZ regulations.

{49}It is acknowledged that this may result in the need for revision of the resulting limits and levels, where corrections are required.

{50}Nutricia supports FSANZ addressing and making the necessary corrections, where required.

{51}Nutricia welcomes this opportunity to provide these comments. Please do not hesitate to contact us further, should you require any additional information.

Yours sincerely,




Regulatory Affairs Manager
Danone