Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

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Dear Charlotte

The Infant Nutrition Council (INC) appreciates the opportunity to make a submission on the Response to the review of the Standard for follow-up formula (Codex Stan 156-1987) Second Consultation Paper, July 2014.

INC is the association for the infant formula industry in Australia and New Zealand and represents manufacturers, marketers and brand owners who between them are responsible for more than 95% of the volume of infant formula manufactured, sold and exported in Australia.

INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula industry in Australia and New Zealand.

The INC is a responsible body that voluntarily restricts its marketing practices to support government policies for the protection and promotion of breastfeeding. The companies represented by INC are:

Members:

- Abbott Nutrition Pty Ltd
- Aspen Nutritionals Australia
- Danone Nutricia Early Life Nutrition
- Fonterra Co-operative Group Ltd
- H. J. Heinz Company Australia Ltd & H. J. Heinz Company NZ Ltd
- Nestlé Australia Ltd & Nestlé New Zealand Limited
- Synlait Ltd

Associate Members:

- A2 Infant Nutrition Ltd
- Ardagh Group NZ Ltd
- Australian Dairy Park Pty Ltd
- Bayer Ltd
- Best Health Products NZ
- Biolife New Zealand Ltd
- Burra Foods Pty Ltd
- Cambricare New Zealand Ltd
- Dairy Goat Co-operative Ltd
- Danpac Ltd
- e-Babycare NZ Ltd
- Ever Health NZ Ltd
- Fresco Nutrition Ltd
- GMP Dairy Pty Ltd
- GrainCorp Pty Ltd
- Green Monkey Pty Ltd
- Milk World Natural Dairy Ltd
- Murray Goulburn Co-operative Co Ltd
- New Image Group Ltd
- New Zealand GoldMax Health Ltd
- New Zealand New Milk Ltd
- Tatura Milk Industries Ltd
- Unitech Industries Ltd
- Westland Co-operative Dairy Company Ltd

The INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants that are unable to have the benefit of breast milk.

Yours sincerely

Jan Carey
Chief Executive

Infant Nutrition Council

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AUSTRALIA & NEW ZEALAND

INFANT NUTRITION COUNCIL AUSTRALIA NEW ZEALAND

RESPONSE TO REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA

(CODEX STAN 156 – 1987) SECOND CONSULTATION PAPER, JULY 2014
by
Codex Committee on Nutrition and Foods for Special Dietary Uses
Electronic Working Group

COMMENTS FOR CODEX CONTACT POINTS

Question 1: **Do you have any amendments to make to the summary of submissions received to the first consultation paper?**

Response: INC has no amendments to suggest to the summary of submissions.

Question 2: If you have any additional data on dietary intakes or nutritional status please provide these to the eWG as an attached file or web-link. If the data is not available in English please provide an English translation of the key findings.

Response: INC has no additional data to provide.

Question 3: Do you consider the use of the WHO growth standards as the most recent and internationally relevant reference body weight for this age group to consider nutrient requirements?

Response: INC notes that the WHO growth standards are generally not appropriate for Asian population groups. Nonetheless, in the absence of acceptable alternative data, use of the WHO growth standards are supported.

Question 4: **Not provided.**

Please provide responses to the questions identifying individual nutrients of concern.
Question 5: Do you have any additional data or amendments that you wish to add to this section 3? Please provide the scientific justification for any amendments.

Response: INC believes it is appropriate to take account of new international recommendations when considering minimum protein levels and to take into account protein quantity as well as protein quality. INC suggests that an appropriate amino acid profile also be considered as part of the determination on minimum protein.

INC notes that high protein intake and its relationship to body mass index (BMI) in childhood is a hot topic amongst the scientific community and an area of active research.

It is important to note that the protein content of many currently marketed follow-up formulas is often high (>3 g/100 kcal) in order to comply with the Codex standard minimum protein requirement set at 3 g/100 kcal.

Finally, INC notes that cows' milk protein has a high protein quality and as such has been, and could continue to be, used as a reference protein for protein quality of follow-up formula for young children.

Question 6 [first]: Please comment on the Chairs' proposals for the nutrient intakes levels that should be considered adequate for the majority of older infants and young children.

Response: INC considers these to be appropriate.

Question 6 [second]: **Does the eWG share the view that follow-up formula is not considered nutritionally necessary in the diets of older infants and young children? This includes follow-up formula in its current form and any potential modifications made to improve the quality of the product.**

Response: INC considers that nutritional necessity should not be a singular criterion for the purposes of Codex Standards. INC believes that FUF should be considered in the context of the significance of food generally and the nutrients that food delivers specifically for the growth and development of the target population group.

A criterion of nutritional necessity would support only two food specific Codex standards: a breast milk substitute standard and a standard for some medical foods. No other single food is a nutritional necessity (as defined by the Oxford Dictionary) for any population group. Codex produces many standards for foods that are not nutritional necessities such as chocolate, spices and herbs, cocoa butter, corned beef, instant noodles, luncheon meat and sweetened condensed milks. This does not detract from the importance of these standards for consumer confidence in the food supply or their role in the market.

Many countries rely on Codex standards to provide the basis for their food regulatory systems, and to ensure minimum standards for foods they import, produce or export.

Consumers draw confidence in the food supply from assurance that the foods they choose are managed within a framework of regulatory oversight. A FUF standard provides this surety but, more importantly, ensures that products in the market deliver minimum requirements for the growth and development of older infants and young children at a critical developmental stage in life.

The more stringent requirements around delivering a safe product specific to older infants and young children addresses the particular vulnerability of the population group. The Standard ensures these more stringent food safety requirements are applied.

For developmental purposes, FUFs offer a nutritionally superior alternative to cows' milk and other milk alternatives for older infants and young children.

FUFs can deliver a range of nutrients that are or may be deficient in the normal food supply or difficult to ensure are consumed and can deliver these nutrients to fussy eaters where supplements in other forms (drops, pills or potions) would prove difficult.

Finally, FUFs could deliver specific fortificants to country or region-specific population groups that might be identified in the future.

Question 7: **Are tables 14-16 useful for the Committee to consider the eWG second term of reference?**

Response: The tables are useful but INC notes that Tables 15 and 16 are based on consumption levels of 450 mL and 300 mL of formula products for older infants and young children, respectively. The Consultation Paper states that these levels have been derived by considering a range of dietary guidelines and dietary intakes. INC considers both the levels are low. Consideration should be given to higher levels.

Follow-up formulas for older infants (6-12 months) are intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet. Follow-up formulas would be used as the principal liquid in a the diet of older infants who may be getting most of his/her nutrition from milk, and larger volumes are often recommended. In contrast, growing up milks for older children (12-36 months) are intended to replace cow's milk and the recommended volume should be kept within the global dietary recommendations.

Locally, the New Zealand Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2 years) states the adequate intake (AI) for older infants aged 7-12 months is 800mL per day of total fluids comprising 600mL per day from fluids (breast milk, formula and water) and for toddlers aged one to two years the AI of total fluids is 1400 mL of which 1,000 mL is from fluids with up to 500mL from milk or milk substitutes (NZ Ministry of Health 2012). These levels are drawn from the Australian National Health and Medical Research Council (2006) and so align with Australian levels.

INC would suggest the eWG consider these larger volumes in the evaluation of the adequacy of current follow-up formula in meeting nutrient requirements. Intake of at risk nutrients might be closer to dietary requirements.

Question 8: Do you have any suggested amendments to enable the Committee to assess the adequacy of the current infant and follow on formula standards to the nutritional requirements of older infants and young children?

Response: INC suggests that more account should be taken of differing consumption levels at different ages across the range of groupings including socio-economic, ethnic, religious and special interest groupings. These can determine what is chosen for the infant/toddler diet and more importantly, what is excluded. Until the older infant is sourcing significant nutrition from solids, then breast milk or FUF supplies the majority of nutrients.

Question 9: Do you consider that there are different parameters to assess the adequacy of these standards for the two age groups: older infants (6-12 months) and young children (12-36 months). For example; different serve sizes, comparators, nutrient requirements, role and subsequent contribution to dietary intake. Please justify your response

Response: INC considers that there are several parameters that should be used to assess adequacy of the standard for the two age groups: older infants (6-12 months) and young children (12-36 months). These include:

- *Role of the products in growth and development* – for older infants (6-12 months), FUF provides essential nutrients for these infants transitioning from breast milk/breast milk substitute to a broader diet of solids and liquids. The transitional role of FUF ensures the development of this group is not disadvantaged nutritionally. For the young child, FUF provides a range of nutrients that may be either difficult to otherwise consistently and regularly source from the general food supply or that may be deficient in the food supply such as iron, zinc, vitamin D, LCPUFAs etc.
- *Serve sizes and serves per day* – for the young child, dietary guidelines generally refer to milk and dairy products. As a substitute for milk and milk alternatives, FUF serve sizes and serves per day are an important consideration.
- *Changing consumption of other foods* – for both older infants and young children, the changing consumption of other foods impacts on the overall dietary intake. FUF needs to reflect these changes between the two age groups.
- *Labelling* – Adequate information on the product should be provided to parents and caregivers for an appropriate use including specific nutrient reference values for these age groups.
- *Nutrient intakes* – If products for this age group fall under the general purpose food category (in the absence of a dedicated standard), of particular concern is the potential for adult nutrient reference values to be applied to the 12-36 month age range.

Question 10: What do you consider are the main findings when comparing current compositional requirements for the existing Codex infant and follow-up formula standards against the nutrient requirements which have been reviewed by the eWG taking into consideration dietary intakes and the role of follow-up formula products in the diet of older infants and young children?

Response: The nutrition of many older infants and young children, for a number of different reasons, is suboptimal irrespective of status of development of a country or region. Appropriately formulated formula products can address these nutritional needs.

For older infants (6-12 months) who are not breast fed, infant formula would not meet the nutritional needs for growth and development. This is confirmed by the modelling reflected in Table 16 which shows that the level of a nutrient such as vitamin D is not delivered by infant formula.

Similarly, for young children, the deficiencies of infant formula become more exaggerated with vitamins such as A, D, B6, Niacin and folic acid and minerals such as iron and calcium appearing deficient.

In response to the following questions please take the following aspects into consideration: consumer protection, consumer choice and current feeding practices,

marketing, enforcement by national authorities, legal clarity, international trade and product development.

Question 11: In your view, what would be the consequences of removing the Codex standard for follow-up formula? Do you think there would be advantages/ disadvantages at the global/national level? Please explain

Response: Irrespective of the existence of a Codex standard or not, these products will still be offered on the market. The products will not disappear as the need for supplemental nutrition will remain, regardless of the existence of this Codex Standard. If these types of products are not subjected to the controls within a Standard, risk to the older infant and young child will be created. These are risks that are minimised by the application of this Standard.

The consuming group is a vulnerable population group whose growth and development for future life is established in the first three years. The absence of a standard puts that vulnerable group at risk in two key areas:

Nutrients supplied

- Not getting a balance of essential nutrients in a managed maximum/minimum range
- Getting nutrients that are vastly out of balance with needs for growth and development. Where specific regulations exist these can provide appropriate limits for levels of key nutrients
- The possibility of a greater use of concentrated vitamin and mineral preparations, with risks of self-diagnosis by parents and a potential for over-use
- A standard has the opportunity to ensure the consuming group is getting a nutritionally balanced product.

Reduced control with respect to food safety:

- Without specific regulations regarding the ingredients permitted for FUF for the 12-36 month age range, all ingredients used in general purpose foods would be permitted, for example flavourings, artificial sweeteners and prebiotics.
- In addition follow-up formulas that are sold as ready-to-feed are commercially sterile and powdered follow-up formulae are covered by the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children CAC/RCP66-2008.
    - General purpose food milk alternatives used by this age group do not have additional controls in place which take into account the increased vulnerability of this population segment compared to the general population.
    - In other words, the integrity of these products will no longer be guaranteed to the extent they are now. The consumer will not necessarily recognise the impact of this change and the integrity of the food supply may be damaged as a result.

For countries/regions that rely on Codex standards to underpin their food regulatory framework, the absence of a standard exposes their most vulnerable population groups to broader, competitive market forces. Regulators will not have a basis for controlling composition and labelling.

For trade purposes, the standard ensures a global benchmark is in place and no country/region is otherwise disadvantaged because of resourcing, technical expertise

or compositional variation that might result from economic considerations rather than child health reasons.

For labelling purposes, the standard provides for minimal provision of information to parents and caregivers for an appropriate use including specific nutrient reference values for this age group.

Question 12: If you are of the view that regulatory specifications (including both labelling and composition) are required for follow-up formula, please indicate if you think the current age range as specified by the current Codex follow-up formula standard (6-36 months) should be maintained, or should the age range be modified? Please provide justification for your answer.

Response: INC considers that the current age range in the standard should be modified to reflect two groups: 6-12 months and 12-36 months. This is on the basis that the nutritional needs of the transitioning older infant and the young child are different (Koletzko et al 2013).

INC considers the overlap of FUF for the older infant (6-12 months) with infant formula (0-12 months) is recognition of the different developmental and growth rates of individual infants, providing for a range of needs for the group. Having very fixed and arbitrary cut-off points for dietary change does not take into account individual growth differences and needs.

Having two sections in the revised Follow-up formula Standard, one for older infants (6-12 months) and one for the young child (12-36 months), would allow for the optimisation of nutritional composition, safety, quality criteria as well as labelling requirements.

Question 13: If you consider regulatory specifications (including both labelling and composition) are necessary for both older infants and young children, please comment on alternative regulatory options that could be considered. Concepts could include such things as; variation within the standard for different age ranges, a less prescriptive standard, or a standard that focuses on a few key compositional or labelling components only. Please explain your proposed concepts.

Response: As noted in response to Question 12, INC considers that variation within the standard for different age ranges will deliver sound and nutritionally balanced products to both older infants and young children.

Variation within a standard could also guide two differing levels of prescription to recognise that the growth and development needs of the young infant transitioning from breast milk are more demanding while those of the younger child are being addressed in part by a broader diet that reflects the lesser prescription of the general food supply. As well, less prescription for FUF for young children provides the flexibility for the FUF to be tailored to address country/regional nutritional needs.

With regards to labelling provisions, given the importance of appropriate and responsible marketing, it is crucial to ensure that the age group for which the product is intended is clearly identifiable as well as its instructions for use, storage, handling and preparation.

References

Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children CAC/RCP66-2008.

Koletzko B, Bhutta ZA, Cai W, Cruchet S, El Guindi M, Fuchs GJ, Goddard EA, van Goudoever JB, Quak SH, Kulkarni B, Makrides M, Ribeiro H, Walker A. 2013. Compositional requirements of follow-up formula for use in infancy: recommendations of an international expert group coordinated by the Early Nutrition Academy. *Annals of Nutrition and Metabolism* 2013; 62(1): 44-54.

NZ Ministry of Health, 2008. *Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2): A background paper*. (4th Ed) Partially revised December 2012. Wellington New Zealand: Ministry of Health.

NHMRC, 2006. Nutrient Reference Values for Australia and New Zealand. Canberra: Commonwealth of Australia.