

Submission on Policy Options for the Regulation of Infant Formula Products

1st September 2009

Preface

This submission is made on behalf of the Infant Nutrition Council (INC), representing the collective views of its members.

The Infant Nutrition Council Ltd was established in 2009 and is an amalgamation of the Infant Formula Manufacturers' Association of Australia (IFMAA) and the New Zealand Infant Formula Marketers' Association (NZIFMA). The Infant Nutrition Council represents the significant majority of companies marketing and manufacturing infant formula in Australia and New Zealand.

The members of the INC work with key stakeholders to support the public health goals of promoting breastfeeding and good nutrition for infants.

The Council aims to:

- (a) 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;
- (b) represent the infant formula industry in Australia and New Zealand;

Marketing Codes

INC members who are marketers of infant formula are signatories to the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement 1992 (MAIF Agreement) and in New Zealand they have adopted the Infant Nutrition Council Code of Practice for the Marketing of Infant Formula (formerly the NZIFMA Code of Practice).

These agreements are the local interpretations in Australia and New Zealand of the World Health Organization International Code of Marketing of Breast Milk Substitutes (WHO 1981) (WHO Code) and prescribe how information about infant formula can be distributed.

INC members support the aims of the WHO Code, which is:

“...to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast feeding and by ensuring the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information and through appropriate marketing and distribution.”

The companies represented by INC are:

- Bayer
- Dairy Goat Cooperative (NZ) Ltd
- Fonterra
- Heinz
- Nestlé
- Nutricia
- Wyeth

The Infant Nutrition Council welcomes this opportunity to provide input and to express our views and concerns to the process of drafting a Policy Guideline intended to provide guidance for the review of the Standard for Infant Formula products.

Summary

The INC notes that breastfeeding is the normal way to feed infants as it has numerous benefits for both infants and mothers. When an infant is not breastfed the only suitable and safe alternative is a scientifically developed infant formula product.

To ensure the best possible nutrition for non-breastfed infants any policy instrument must ensure a balance between restrictions on use and formulation in order to protect public health, and providing flexibility and incentive for innovation for continuous improvement in infant formula products.

The INC considers that the key elements in policies and regulations governing infant formula products must allow for:

- consistency with the policy objectives outlined in other food-related policy decisions;
- the provision of a safe and nutritious food;
- a scientific, evidence-based approach which does not unnecessarily restrict the use of otherwise safe ingredients in infant formula products;
- flexible provisions in the food regulations, with minimal levels of prescription, to optimise innovation in infant formula products to promote health and wellbeing of infants;
- sufficient information to support informed choice by consumers enabling them to select products which are suitable to the dietary needs of their non-breast-fed infant;
- where approval is sought to add new or novel ingredients which are associated with a health benefit, the grounds on which substantiation of the benefit must be provided (as provided in the novel food standard);
- clear enforceability of the standard; and
- cost effectiveness to minimize the potential burden on industry and enforcement agencies, and minimize unnecessary cost impact on consumers;

- Retrospective permissions. No mention of grandfathering of current permissions has been made in the policy paper. INC is of the opinion that current permissions should be grandfathered rather than the entire current standard being reviewed. This opinion is on the basis that there is no market failure and that all products in the market at the moment are safe.

Industry bears a considerable onus of responsibility in the manufacture of safe and nutritious foods and must implement the highest possible standards of hygiene and quality control to ensure products are free from potential pathogens. The ingredients used in preparation for provision of specified nutrients will necessarily come from varied sources, depending on seasonal conditions, time of year and supply chain logistics. It is therefore essential that food ingredients approved for general use and for which there is no substantiated evidence of safety risk or nutritional inadequacy when used in infant formula products, should not be subject to prior approval requirements. To do so will unnecessarily add costs, reduce marketplace efficiency and impose a significant burden on regulatory and enforcement agencies.

The INC is concerned that an overly restrictive regulatory approach and mandatory requirements will result in an anti-competitive regulatory environment. The INC recommends adherence to the principles of minimum effective regulation, established in COAG, and further highlights the importance of avoiding unnecessary duplication of approval process for ingredient use in general use and in infant formula.

While the industry supports the position that breastmilk provides the best possible nutrition for infants, the assumption that breastmilk composition can be a “Gold Standard” against which the nutrient composition of infant formula should be considered is part of the picture and not the whole. Breastmilk is not a simple, single homogenous commodity; but rather a highly complex matrix of nutrients, and bioactive components, which can vary significantly from one woman to another depending on the nutritional state of the mother. The composition of breastmilk expressed by a woman varies considerably during the period over which she is breastfeeding.^{1 2} Furthermore, some breastfeeding mothers intentionally modify the composition of their breastmilk, for example by increasing their consumption of fish in order to boost the DHA levels.³

The INC recommends that consideration be given to the introduction of a category of ingredients specific to foods in Standard 2.9, tentatively called “Nutritive Ingredients”. Such substances would have a broader application than those defined under “Nutritive Substances”, and could capture those modified ingredients that do not fit the novel food definition or the Nutritive Substance definition, considered

¹ Archives of Disease in Childhood 1982, 57, 658-662

Variations in the composition of breast milk during the first 5 weeks of lactation. CM Hibberd, O G Brooke, ND Carter, M Haug and G Harzer

² [Br J Nutr.](#) 2002 Jul;88(1):29-37 Variation in fat, lactose and protein in human milk over 24 h and throughout the first year of lactation. [Mitoulas LR](#), [Kent JC](#), [Cox DB](#), [Owens RA](#), [Sherriff JL](#), [Hartmann PE](#)

³ Am J Clin Nutr 007;85:1457– 64. Printed in USA. © 2007 American Society for Nutrition 1457 Docosahexaenoic and arachidonic acid concentrations in human breast milk worldwide1–4 J Thomas Brenna, Behzad Varamini, Robert G Jensen, Deborah A Diersen-Schade, Julia A Boettcher, and Linda M Arterburn:

necessary to require assessment before use in infant formula. This could overcome some of the difficulties currently identified by FSANZ with the application of “Nutritive Substances” in the Food Standards Code.

The INC supports the necessity that any change to regulatory requirements will be prospective and not retrospective, and that permissions currently provided in Standard 2.9.1 would be retained.

The INC supports elements of Option 2, which provides for demonstration of efficacy, and Option 4 which limits premarket assessment to specified categories of ingredients. The INC considers that Option 4 needs to provide rigour around the demonstration of health benefit, and recommends an amended Option 4 be considered as follows:

Specified categories of ingredients proposed to be used in infant formula products require a pre-market assessment assessing safety and where applicable: comparison with breastmilk and equivalence of physiological outcomes to exclusively breast-fed infants. The pre-market assessment does not include health benefit except where the ingredient proposed is being added for the purpose of a health benefit. In which case industry is required to have a level of evidence in order to demonstrate efficacy and also to be able to communicate the demonstrated benefit to the consumer.

Comments in relation to the discussion paper

Definition and Purpose

The INC supports the principle that the development of regulatory requirements should be based on risk analysis using the best available scientific evidence, to assess potential health and safety risks for specific substances for approval.

It is acknowledged that regulators have concerns about the need for greater clarity in the interpretation and requirements of the existing regulations. A further issue, given that infant formula is a sole source of food for physiologically vulnerable infants, is whether ingredients that are considered safe and suitable for use in general foods need further additional risk analysis as to whether they present a level of risk to infants. Underlying this issue is the need for clear policy principles, consistent with the broader principles of good governance and minimum effective regulation.

In order that a proper evaluation of the suitability and the need for risk analysis be performed, there must be quantification of a problem in terms of evidence of risk to infants. However, when considering the costs and benefits in risk mitigation and risk management, robust economic data must also be available to assess the disadvantage and social inequity that may be created by introducing restrictions aimed at diminishingly small probabilities of harm.

Life is not without risk. The food supply could never be considered as completely without safety concerns even though the probability of harm may be such a remote possibility that it may never occur, yet the risk remains. Therefore, the policy needs to balance the restrictions and costs imposed on industry and consumers to the minimum necessary to provide a reasonable level of assurance that the infant formula products are safe, suitable, nutritious, affordable and available.

The statement made in the conclusion that, “As food technology advances, manufacturers of infant formula products will seek to differentiate their products from their competitors” is an assumption only. As food technology advances, manufacturers of infant formula products will continue to seek to bridge the gaps identified between the physiological outcomes of formula-fed versus breastfed infants. The policy framework established must allow, and should encourage, the development and commercialisation of improved infant formula products that in turn promote improvements in health outcomes for infants not exclusively breast-fed for six months, and for whom breastmilk is not the principal milk food through until 12 months of life.

It was advised at the consultation meetings that the objective of the policy review is to be forward looking. As such, the policy should set a framework which facilitates a climate change regarding discussion and debate about all aspects of infant nutrition. The INC fully supports the promotion of breastfeeding as the normal and natural way to feed infants; and understands that breastfeeding confers benefits to both the mother and her baby in addition to the provision of nutrition. Those parties that encourage a highly politicised and evangelical approach to breastfeeding and associated vilification of infant formula manufacturers are acting against the best interests of infant nutrition.

This highly charged climate needs to be replaced by a calmer, more objective approach which promotes breastfeeding but also allows for open and informative discussion on technical aspects of breastmilk composition and infant formula. The infant formula industry is home to many experts on milk composition, as well as the technological aspects of infant formula manufacture, and there is much that could be gained by open exchange of information to improve understanding of both breastmilk and infant formula products.

Informed choice

The regulation of infant formula products must first and foremost protect the safety of those infants who receive infant formula. It is essential that policy objectives for infant formula products do not restrict information that supports informed choice and promotes safe use. Consideration needs to be given to the choice that a carer has in feeding their infant and their ability to choose a formula for a certain ingredient, or indeed the formula design to meet the specific nutritional needs of their child.

To improve overall health outcomes for infants there is a need to move beyond the simplistic mantra that “breast is best,” to a policy that promotes, “best from breast,” and clearly communicates that for those infants where breastmilk is not available or no longer available, infant formula is the only recognised alternative that is safe and will promote normal growth and development.

Consumers now, have ready access to information on the internet, which can be unreliable and can pose risks. They would benefit from an environment that encourages a more open and informative approach to ensure authoritative information is readily accessible to counter misinformation in circulation.

Support for improved product

Manufacturers of infant formula products have a twofold responsibility in that they must ensure they always provide a safe product for infants, but also that they provide improved formulations in these products as science evolves allowing a greater understanding of ingredients and how they can promote optimal health for the non-breastfed infant. While mothers are encouraged to exclusively breastfeed, there are a variety of circumstances where this does not occur. It is essential that the health of these infants is fully supported by the provision of safe infant formula. The regulatory environment should support the continued development, improvement and accessibility of infant formulas to ensure the potential health status of the non-breast infant is not compromised.

The INC supports the principle that breastmilk is the normal food for infants, however because women's nutritional status varies widely due to various factors such as geographical location, access to fresh foods, seasonality and access to a balanced diet; so breastmilk composition varies both from woman to woman, and across social-cultural-ethnicity-regional groupings.^{4 5} It is important that any discussion about the composition of breastmilk is considered in an environment that promotes an objective discussion.

Minimum effective regulation and harmonisation

INC supports minimum effective regulation. An excessively restrictive regulatory environment in Australia and New Zealand would not support the development, and promote the availability of, products that provide for the optimal health of non-exclusively breastfed infants. A regulatory environment that is significantly out of step with international standards will lead to a reduced choice and a less competitive marketplace and could inhibit trade and damage established export business.

The development and assessment of high quality infant formula is a very expensive and lengthy process and one that must not be compromised. Non-breastfed infants in Australia and New Zealand benefit from the considerable research that is undertaken in other parts of the world (America, Europe, Canada, and UK). It's important that our local regulatory environment supports the benefits provided by global research and gives consideration to the impacts on global trade and harmonisation with international food standards.

Efficacy versus Effectiveness

The discussion of efficacy versus effectiveness in the paper is confusing. Further clarification was sought at a consultation meeting in New Zealand and it became apparent that effectiveness was an inappropriate measure in terms of premarket assessment. INC does not support effectiveness (as defined) to be a feasible requirement in assessing changes to infant formula products.

⁴ Archives of Disease in Childhood 1982, 57, 658-662 Variations in the composition of breast milk during the first 5 weeks of lactation. CM Hibberd, O G Brooke, ND Carter, M Haug and G Harzer:

⁵ [Br J Nutr.](#) 2002 Jul;88(1):29-37 Variation in fat, lactose and protein in human milk over 24 h and throughout the first year of lactation. [Mitoulas LR](#), [Kent JC](#), [Cox DB](#), [Owens RA](#), [Sherriff JL](#), [Hartmann PE](#)

The INC supports a policy principle that where there are benefits for the use of a substance, or complex of substances, there should be some substantiation of the benefit. This is consistent with the policy on fortification of food with vitamins and minerals. However, as the determination of effectiveness can only be made once the product has been made available in the marketplace for a considerable period of use, this will rule out Option 1.

Nutrient versus Ingredient

The INC is concerned that the terms ‘nutrients’ and ‘ingredients’ appear to be used interchangeably, and with little consideration of the practical implication. In most cases, the regulatory environment is limited to providing explicit approval to the use of vitamins and minerals, additives, processing aids and nutritive substances. These may be present in ingredients, which are obtained from a variety of sources and may vary in the precise composition and origin in nutrients present.

Trials to evaluate efficacy of infant formula

Clinical trials to prove efficacy on an optional ingredient to be added to infant formula should be done against a controlled group of infant formula-fed infants. Where studies are based on a reference group of healthy infants that have been exclusively breastfed for six months and the infant formula under evaluation only, the trial data is likely to be difficult to evaluate.

The policy framework needs to take into account the shape and possible outcomes of future efficacy trials. Given that breastfeeding is the normal way to feed infants and should be encouraged, it cannot be expected that trials to assess health benefits of infant formula (as opposed to safety) will involve subjects who are fed infant formula from birth. Study designs that better reflect normal practice, where by subjects are breastfed for a period prior to the introduction of infant formula, should be encouraged where such design is appropriate for the assessment concerned. It is also important that there is a climate where the release of study findings is promoted to evolve knowledge even if some of the findings do not support the current infant feeding guidelines.

It is important to note that there are constraints on industry’s ability to perform clinical trials on infant formula that demonstrate statistical significance due to low number of eligible (non-breast-feeding) participants usually available for inclusion in trials.

Specific questions

Question 1 (p6): Do you have any comments on the definitions used?

The INC accepts the majority of the interpretations. Those for which we disagree or request an amendment are shown below. Of particular note is the definition of a nutritive substance that is under general review. It is proposed that a note be inserted that this may be amended and hence require subsequent amendment for its application and restrictions within Standard 2.9.1

INTERPRETATIONS:

Follow-on formula means an infant formula product represented as either a breastmilk substitute or replacement for infant formula and which constitutes the principal source of nourishment in a progressively diversified diet for infants aged from six months.’⁵

Note: INC supports an amended interpretation and would propose the following that includes reference to Codex.

PROPOSED INTERPRETATION

Follow-on formula means a product, intended for use as a liquid part of the weaning diet and which constitutes the principal source of nourishment in a progressively diversified diet for infants aged from six months.

Health outcome means growth and development or other health condition.

This definition is unacceptable to the Infant Nutrition Council and its members.

Reasoning: an “*outcome*” should arrive from some form of change or impact –it can be the addition, deletion or change of proportion/s of an ingredient/s to the feeding of an infant – however; although the context of this definition is for a food Standard; it is not clearly limited to the addition or deletion of ingredients.

Also; growth and development are the desired outcomes for an infant over time. This will then be distinguished as good or bad growth and development based on changes to ingredients.

PROPOSED INTERPRETATION

Health outcome means the impacts to the growth, development or health condition of an infant

Note: As INC is proposing a new definition for ‘health outcome’ we have attempted to clearly indicate in all following responses, where we are referring to growth & development and where we are referring to a ‘health outcome’ as defined above. FRSC should note that where there is any confusion arising from the changed definition; that the intent is that a health outcome does NOT refer to growth & development per se.

Infant formula means ‘an infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months.’⁷

Please delete: ~~Infant formula does not include Formulated Supplementary Foods for Young Children (aged 1 to 3 years), commonly referred to as “toddler formula”.~~

These additional words of explanation do not interpret or define what an infant formula is; but rather states what it is not. There are many foods that are NOT infant formula and so we see no benefit in stating that it is not one of the many that

could be referenced at this point. A clear definition will always exclude what it does not include.

Infant formula product means ‘a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.’⁸ Infant formula products do not include Formulated Supplementary Foods for Young Children (aged 1 to 3 years), commonly referred to as “toddler milk drink”.

For clarity, please amend to refer to Toddler milks drinks as such – these are not “formula’s” as defined for infant and follow-on formula.

Nutritive substance means ‘a substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which, after extraction and/or refinement, or synthesis, is intentionally added to a food to achieve a nutritional purpose, and includes vitamins, minerals, amino acids, electrolytes and nucleotides.’¹¹

As this is under review the INC recommends that it be noted in the Policy document that consequential amendments may be required once the review of the definition is completed.

Question 2 (p17): Are there any international standards of relevance that have not been noted here? Please provide references.

The INC does not wish to include any further jurisdictions to those under consideration, as listed.

However INC believes it is essential for FRSC to also include consideration of the Codex Standard for follow-on formula.

Question 3 (p20): Are there any impacts for consumers, industry, government and public health stakeholders that have not been included here? Please provide details.

INC has noted several areas of importance that have not been dealt with within this document. These are detailed below.

Informed Choice

The consultation paper includes much consideration of the responsibility of manufacturers to provide considerable scientific data to allow for the addition of certain ingredients to Infant Formula Products.

However little if any, is said on how such information might be communicated to parents and carers, such that the verified benefit would flow through to the infant, as the final user of the product. This can only be achieved by inserting provisions for such information to be communicated to parents and carers for their consideration, into the Food Standards Code. It should also be noted that this would be in line with the overarching objectives that FSANZ is required to meet when drafting a Standard or change to a Standard.

The second overarching objective to which FSANZ must give regard to states:-

“the provision of adequate information about the food to allow consumers to make an informed choice”

The implementation of this policy principle would allow for informed choice, both from the perspective of choosing which company’s product will be purchased, and subsequently which of the company’s products and/or ingredients from the available range of products.

Communication of information is becoming more important as technology progresses. For those infants who, for whatever reason, are being bottled fed, research and innovation is leading to products moving closer to the composition of breast milk. Parents and carers must receive adequate and factual information of these innovations.

It should be noted that a question was raised at the FRSC Consultation meeting, that the policy should include a prohibition on “premium” products. The INC totally rejects these claims. Parents and carers must be provided with choice from which to choose the most appropriate product for each individual infant.

It is important to note that ideally a parent or carer will contact a health care professional before commencing bottle feeding, however this will not always be the case.

Consumer Impacts-Affordability

The cost impact of increased requirements with respect to evaluation of new ingredients/efficacy ultimately impact on the cost of the formulas to consumers. Clinical trials to evaluate efficacy of infant formula products cost from AU\$2.5million upwards. This concept is noted under industry impacts: “Requirements placed on industry must be reasonable and proportional to the risks presented to infants as the consuming population,” but there is also an impact to consumers.

- Unnecessary mandating of optional ingredients as ‘essential’ will result in the increased cost of product to the consumer.

Consumer Impacts-information

- Product and ingredient information on labels must be available for consumers since not all consumers consult health care professionals for advice when choosing to use an infant formula product.
- This may include a comment on health benefit claims. Market research shows that high percentages of consumers rely on infant formula cans as a source of information.

Public Health Impacts

- If policy determines that regulation of infant formula products must be brought in line with national nutrition policies and guidelines, there must be a mechanism to

also ensure that these policies and guidelines are updated regularly in line with latest recommendations. For Example: Latest Nutrient Reference Values not implemented into FSC & NH&MRC Infant Feeding Guidelines are also outdated. It would impact public health if regulation was consistent with outdated guidelines.

- It is essential for the public health of formula fed infants, that they have available the best range of product possible for parents or carers to choose from. The current restrictions on not allowing general level health claims on infant formula products does not allow this to occur, and as a result could be leading to consumers not choosing the best product for their infant.
- The impact on individual infants, of being given a wrong or unsuitable formula that may result from the lack of information being provided to parents or carers on labels, has not been quantified. Regardless of this not being quantified, it must be considered whenever a review of public health impacts is under consideration.
- Further, the INC is particularly concerned that consideration be taken of the impact of changes to the Standard that may result from this policy development to parents and carers in the lower socio-economic groups. It is essential that any changes do not affect pricing, such that this group does not revert to using cheaper substitutes for breastmilk that are both inappropriate but may also lead to negative health outcomes for the infants. Of particular concern is that this lack of information should not lead parents or carers to use unmodified cow's milk as a substitute for breastmilk for infants under 12 months.

Industry Impact

- Cost effectiveness of infant formula in the market is also heavily influenced by its harmonization or lack of harmonization with international regulations on infant formula. It cannot be assumed that these costs will always be passed on to the consumer. There are instances whereby the cost, or part of the cost, will have to be absorbed by the manufacturer.
- The policy options are silent on existing permissions for optional ingredients in infant formula products. This needs to be clarified so that an accurate regulatory impact for industry can be determined and considered for final policy document; as has been stated during stakeholder meetings.
- The importance of the impact of Australian and New Zealand regulations on nearby markets should also be considered when drafting this policy. Any resulting changes to the Standard for Infant Formula Products has the potential to affect exports from Australia and New Zealand.
- The final policy position should ensure continuing and future export market access for existing exports of infant formula products. This is in line with the overarching objectives for FSANZ development of Standards.

Question 4 (p22): What criteria should underpin the essential nutritional composition requirements?

Infant formulas available in Australia and New Zealand must comply with the essential compositional requirements of Standard 2.9.1 and as such, have been adequate in providing nutrition to infants. There has been no evidence of failure in fulfilling this role. Unequivocal scientific evidence to demonstrate that a deficiency in that nutrient will result in impairment of normal growth and development would need to be demonstrated, to mandate that nutrient as essential composition in general purpose infant formula.

Nutrients considered essential in general purpose infant formula are those which if lacking may impair adequate normal growth and development of the infant - within the context of its use, i.e. as *sole* nutrition for infants up to around six months of age. Essential compositional requirements should be considered within the scope of normal “growth and development” and should not also include consideration of a health benefit – i.e. a better than normal outcome as this should relate only to optional ingredients added for that purpose

Essential nutrients contribute to both the immediate and future health status of the baby. And therefore INC supports the EU position on criteria underpinning the essential nutritional compositional requirements for general purpose infant formula. EU regulations (COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae) refer to the criteria for an ‘essential composition’ as follows: Clause (5): “The essential composition of infant formulae and follow-on formulae must satisfy the nutritional requirements of infants in **good health** as established by generally accepted scientific data”.

The INC supports that other criteria to be *considered* for essential compositional requirements were listed already by the expert panel in the development of the full assessment which was the precursor to Standard 2.9.1 in 1995 (pg. 13 in consultation paper):

- Nutrients for which there is an Australia Recommended Dietary Intake (RDI)
- If a deficiency disorder has been demonstrated;
- (For new additions) If there has been an unequivocal demonstration of their efficacy on the health **outcome** and there is robust science to support this;

And, the INC would like to further add -

- Using breast milk as a point of reference

INC questions the fourth point listed by the expert panel (1995) in developing 2.9.1 (pg. 13 in consultation paper):

That for essential nutrients:

- New substances should only be regarded as essential if there has been an unequivocal demonstration of their **efficacy** through long term, controlled, randomised clinical trials on healthy term infants (demonstration of growth alone will not be deemed sufficient).

The INC does not support that an ingredient demonstrating efficacy (as defined in the policy paper) is appropriate since the definition as defined in the policy paper is linked to a health **benefit**, as opposed to a health outcome. The definition of a health benefit is that it leads to an overall better health outcome. The INC believes that for an ingredient to be considered essential, it should demonstrate a normal health **outcome**. We do not agree with the interpretation of “efficacy” (pg 5) to mean addition of an ingredient has a health **benefit** if utilized in this context of what underpins an essential composition. Demonstration of a health **benefit** should be one factor for addition of an optional ingredient, not addition of an essential ingredient.

For pre-term infants or those where a deficiency disorder has been identified, an ingredient found to be conditionally essential to that condition, but not otherwise considered essential or permitted in general purpose infant formula can be added if the lack of it impairs a satisfactory health outcome for that infant. However, the INC considers that the proposed type and level of evidence should differ to these groups as it is not feasible to conduct large-scale, randomised controlled trials on such specific and small populations

The above should be the basis of essential nutritional compositional requirements for infant formula.

Question 5 (p23): Should any ingredients other than additives, processing aids and nutritive substances that are being used in infant formula products, require pre-market assessment?

The INC supports and recognises that infant formula regulation must ensure the protection of health and safety of infants using these products. Ensuring quality and safety for every ingredient used in infant formula is already an overarching requirement in the Food Standards Code with which industry must comply. There is no evidence to suggest that this is not adequate in Australia and New Zealand as demonstrated by the long safe history of infant formula use. This indicates that the internal validation process of the ingredients used in the general food supply and considered for use in infant formula that is used by industry in this market is robust.

Pre market assessment requirements on additives, processing aids, novel foods and nutritive substances already exist. It is possible that as science and technology advances other ingredients may be developed which may fall outside the current definition of nutritive substances or novel foods which may also need pre market assessment. The INC therefore proposes that clarification of the definition of nutritive substances would be useful in providing regulatory clarity around this class of ingredients. Alternatively, a new category of ingredients tentatively named ‘nutritive ingredients’ could be proposed by FRSC to cover those ingredients that should undergo premarket assessment for use in infant formula products which may fall outside the current definitions. Criteria to define those ingredients would require further, separate consultation.

The INC is of the opinion that Policy Options 1, 2 and 3 to pre-market assess every ingredient is not realistic and not warranted. Unnecessary pre-market assessment of every ingredient (apart from those listed in the question plus novel foods) simply adds regulatory burden, cost, impedes innovation, and therefore introduces also a consumer impact. Many ingredients used in infant formula products (such as maltodextrins, complex milk lipids, milk powders for example) are added to meet basic compositional requirements of the product, and not for a health benefit, and to impose increased regulatory hurdles for the use of these ingredients for which safety is already assured is a proposal not supported by the INC.

It has been queried during Stakeholder Conferences whether pre-market assessments, if regulated would be applied retrospectively for all the current permissions within the standard. The responses given by FRSC indicated that this would not be the case. Should the outcome of the consultation result in any level of pre-market clearance being applied by a policy directive, the INC suggests that a retrospective review of all ingredients in all classes already permitted for which no market failure has been demonstrated is **not** warranted.

Question 6 (p25): Is the health and physiological outcome of the full term, breast fed infant a useful benchmark in considering the composition of infant formula products?

For general purpose formulas (excluding infant formula for special dietary uses), the INC supports that the health and physiological outcome of full term exclusively Breastfed infants (fed with breastmilk from healthy mothers) would be a **useful** benchmark in addition to safety as a given, in considering the **essential** composition of infant formula, provided health & physiological outcome equals normal healthy growth. It would need to be agreed what those physiological outcomes would be since there are many factors which go to make up normal physiological outcomes.

However, whilst a useful bench mark, it should not be considered the sole, mandatory (i.e. considered, but not limited to) benchmark for infant formula. This is because of the natural variability in the nutritional properties of breast milk^{6,7}. Breast milk is considered the best, normal and sole nutrition for infants up to around six months of age. However this does assume that the breast fed infants have received high quality breast milk. Breast milk can be lacking in some nutrients (for example iodine levels) and this must be considered. The other consideration is that whilst nutrition is fundamentally responsible for health outcomes (normal health and physiological development) there are other factors which affect an outcome irrespective of nutrient

⁶ Archives of Disease in Childhood 1982, 57, 658-662 Variations in the composition of breast milk during the first 5 weeks of lactation. CM Hibberd, O G Brooke, ND Carter, M Haug and G Harzer:

⁷ [Br J Nutr.](#) 2002 Jul;88(1):29-37 Variation in fat, lactose and protein in human milk over 24 h and throughout the first year of lactation. [Mitoulas LR](#), [Kent JC](#), [Cox DB](#), [Owens RA](#), [Sherriff JL](#), [Hartmann PE](#)

intake. For example, one would expect that genetics would play a significant part in cognitive ability and disease susceptibility.

Relevance needs to be considered on a case by case basis and adequate quality data is needed for these breast-fed infants.

In selecting this data, one consideration is that the age of the breast-fed infant used as an indicator for the purposes of comparison in determining the ESSENTIAL composition of infant formula products should not be beyond six months of age. This is because complementary feeding starts from around 4-6 months and this introduction of solids may introduce a bias into the health and physiological outcome of the infant. For infants around 4-6 to 12 months of age, it becomes significantly more difficult to reliably measure a health outcome due to an increase in the number of confounding factors i.e. breastmilk or infant formula is no longer the sole source of nutrition.

The INC therefore proposes that the definition of health and physiological outcome would need to equal normal healthy growth at a particular age (most likely around 4-6 months prior to when solids are introduced)^{8,9}

Question 7 (p27): Is health benefit (as defined in this paper) a useful benchmark in considering the composition of infant formula products? Why or why not?

The definition of health benefit proposed in this paper is, “that the addition of an ingredient is likely to lead to an overall better health outcome than not adding the ingredient, “where health outcome means, “growth and development or other health condition.”

The INC unanimously supports the following principles:

1. Health outcomes of normally (breast) fed infants are appropriate benchmarks when considering the essential nutrient composition of infant formula. Normal growth and development are assessment criteria for establishing safety and suitability for purpose.

⁸ * *The above comments apply to general purpose formula only. For FSDP products, the INC supports the IDACE view (2003 Medical Position Paper “The nutritional safety assessment of breast milk substitutes and other dietary products for infants: A commentary by the ESPGHAN Committee on Nutrition”⁸ that: “FSMP are not fed to healthy infants and therefore data on growth and development cannot be compared to that of healthy infants. These products are destined for use in unhealthy infants. In the majority of cases, healthy breast-fed infants are therefore not suitable as a control group for a comparison of development, functional or clinical outcome. A positive outcome of a certain formula modification in infants fed FSMP may be masked by the medical condition concerned.*

⁹ IDACE (Association of the Food Industries for Particular Nutritional uses of the European Union) (2003) Comments on: Medical Position Paper “The nutritional safety assessment of breast milk substitutes and other dietary products for infants: A commentary by the ESPGHAN Committee on Nutrition”, in context with the 2002 workshop on “Characterisation of Infant Food Modifications in the European Union”

2. Health benefit(s), as defined in this paper, and demonstrated by defined levels of evidence, may be useful benchmarks in considering whether, “nutritive ingredients,” (as in approach proposed by INC) should be permissible optional ingredients in infant formula products. More information on the levels of evidence that would be required is needed to allow fuller consideration and comment.
3. Communication on the nutritive ingredient, and its physiological effects demonstrated by defined levels of evidence, should be permitted on infant formula product labels to allow consumers to make informed choices.

The benchmarks applied in considering the composition of infant formula need to be harmonized with international standards, particularly the Codex infant formula standard (Codex 2007), to avoid trade barriers. This Codex standard is very clear: **Section 3.1 Essential composition** states, “The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants.” i.e. health outcomes NOT health benefits as defined in the consultation document.

Question 8 (p27): Should ingredients not present as components of breast milk be permitted to be used in infant formula products?

- Yes! Otherwise it will be impossible to manufacture infant formula products. This question assumes that breast milk can be broken down to component ingredients which can be readily sourced such that a breast-milk substitute can be built up from the same building blocks. This is simply not the case. For example, all fat in breast-milk is milk fat but there are no suitable alternative milk fat sources which deliver a similar fatty acid profile, let alone other components such as the phospholipid profile in breast milk fat. To achieve a similar fatty acid profile it is necessary to use multiple sources of fat: a selection of vegetable oils with or without milk fat from mammalian milk. None of these ingredients are present in breast-milk.

Ingredients that are commonly used in the production of infant formula products and have already undergone significant safety assessment such as milk fat from mammalian milks, vegetable oils, lactose derived from mammalian milks, maltodextrin, starches and lecithin should be permitted without any further assessment being required. Many of these ingredients are essential to the manufacture of infant formula.

- Yes, when a physiological outcome is similar to exclusively breast-fed infants (i.e. supports growth and development of infants).

The INC unanimously supports the considered opinions expressed by the ESPGHAN Coordinated International Expert Group:

- that “data on the composition of human milk of healthy, well-nourished women can provide some guidance for the composition of infant formulae.”

- “but gross compositional similarity is not an adequate determinant or indicator of the safety and nutritional adequacy of infant formulae”.
- And that “the adequacy of infant formula composition should be determined by a comparison of its effects on physiological (e.g. growth patterns), biochemical (e.g. plasma markers) and functional (e.g. immune responses) outcomes in infants fed formulae with those found in populations of healthy, exclusively breast-fed infants. Koletzko et al. (2005).¹⁰

Breast milk provides a number of benefits for which the specific components involved are not fully understood or fully characterised. Yet it may be possible to get the same health benefit or physiological outcome from other ingredients.

To permit only components of breast milk will limit the health benefits that can be delivered to infants post weaning from breastmilk.

- Yes, when required for a technological purpose (as already permitted in the form of additives). The permission for these ingredients should be continued since they have already undergone significant safety assessment.

Question 9 (p 28): When should an optional ingredient become a mandatory ingredient? What criteria should be required?

In this context we feel it is more appropriate to discuss nutrients than ingredients. Mandatory requirements should be restricted to essential composition only, that is, to nutrients for which there is a demonstrated deficiency state if levels are insufficient.

Nutrients for which there is a recognised RDI/AI should be mandatory (for example vitamins and minerals). Other nutrients proven by nutrient science to be essential should also be mandatory, (for example essential amino acids and fatty acids).

Nutrients that promote further health benefits, yet are not essential to promote human life, should not be mandatory. Mandating non-essential nutrients will:

- lead to increased formula cost and effect affordability, promoting inequalities in infant health
- result in trade barriers. The international norm is to apply mandatory requirements to essential composition only.
- increase the regulatory burden.
- potentially require public funded research of infant formula products to provide safety assessments of nutrients proposed to be mandated across the full spectrum of infant formula products.

¹⁰ Koletzko et al. 2005 Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group. *Journal of Paediatric Gastroenterology and Nutrition*. 205: 41: 584-99.

The last point above is important. Infant formula manufacturers have a responsibility to ensure they provide safe infant formula products and undertake assessments of their own products as they judge appropriate for modifications under discussion and evaluation. If non-essential nutrients are mandated this passes the liability for the introduction of these nutrients to all infant formulas to the government.

Scientific evidence for mandating of nutrients should be not merely substantial, but unequivocal. Further, proposals for mandating need to undergo public consultation:

- There may be commercial reasons why mandating is not actually possible.
- Harmonisation with international standards and regulations is essential to avoid trade barriers that could be potentially damaging to choice of formula available in Australasia and Australasian export trade.

In the case of infant formula for special dietary uses, we consider that an optional nutrient should become mandatory when the science has demonstrated the suitability of its inclusion to address the disorder and the safety in its use.

Question 10 (p 29): Should the policy principles for infant formula be the same for follow-on formula?

The INC is of the opinion that whilst it is appropriate for high order principles to be the same for both infant and follow-on formula that some differences in general order principles may be required. There is a very distinct difference in the purpose of these products that must be considered at a policy level. In addition the practical constraints of evaluation of efficacy of follow-on formulas could preclude the same policy principles being applied as for infant formula (depending on policy option adopted).

Infant formula provides sole nutrition. Follow-on formula forms part of a mixed diet for infants from six months (please refer to the Codex definition for follow-on formula). In assessment of health outcomes, more definitive results are seen in trials conducted on infants less than six months of age where breast milk and/or infant formula has been the sole source of nutrition. Science, to support the need to mandate individual ingredients, can be more difficult to conduct on infants beyond six months, as wider dietary factors confound results.

Should this resulting policy principle eventuate in a change in the consideration of mandatory versus optional ingredients, then INC is of the opinion that infant formula and follow-on formula should be treated differently. Increasing requirements for mandatory ingredients will add cost to infant formula products. Follow-on formula must be considered in context of an expanding diet for any cost benefit analysis.

INC members request that it be noted that member companies take the up most care in the manufacture of follow- on formula and that follow on formula is of the same high quality as that of infant formula.

Question 11 (p29): Are there any policy principles that should specifically guide the regulation of infant formula products for premature or low birth weight infants? Please provide details.

Question 13 (p29): Are there any specific policy principles that should specifically guide the regulation of infant formula products for infants with specific health conditions? Please provide details.

In response to both questions 11 and 13, the INC supports the status quo as this enables harmonisation with international standards as a key consideration for the regulation of infant formula products for premature or low birth weight infants (or other specific health condition). This has industry implications during the manufacturing of products sold globally, as well as impact on International Trade and government implications with respect to departments of health. Although international standards apply “special medical purposes” to some infant formulas, this is different to the proposed FSANZ Standard 2.9.5 ‘Foods for Special Medical Purposes’ which currently excludes infant formula products.

The structure of Standard 2.9.1, with a separate division for formulas for special dietary purposes is similar to Codex’s infant formula standard with a Part A and Part B for special medical purposes. There are terminology differences, which could easily be addressed by recommending that Standard 2.9.1 Division 3, ‘Infant formula products for special dietary use’ be changed to ‘Infant formula products for special medical purposes’ to conform to Codex and EU. However, Codex and the EU Directive provide further guidance and clarity on the regulation of these types of formula products.

Codex standard 72-1981, Revision 2007 is titled ‘Standard for Infant formula and formulas for special medical purposes intended for infants’. Within this standard, Section A and B regulate ‘Revised standard for Infant formula’ and ‘Formula for special medical purposes intended for infants’ respectively. Section B provides a comprehensive standard regulating the composition, quality, labelling and safety requirements for Formula for Special Medical Purposes intended for Infants. The standard states that:

“The nutritional safety and adequacy of the formula shall be scientifically demonstrated to support growth and development in the infants for whom it is intended, as appropriate for the specific products and indications. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.”

The Codex standard also permits the addition of optional ingredients to ensure the formulation is suitable for the dietary management of a particular disease, disorder or medical condition.

The PARNUTS section of the EU Directive includes Foodstuffs intended for particular nutritional uses (89/398/EEC). Within this section is the Commission directive 1999/21/EC: on dietary foods for special medical purposes, which includes foods for special medical purposes intended for infants. Article 3 of the directive states:

“The formulation of dietary foods for special medical purposes shall be based on sound medical and nutritional principles. Their use, in accordance with the manufacturer’s instructions, shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data.”

It is recommended that harmonisation with international regulations; particularly Codex, is used to develop policy guidelines for the regulation of infant formula products for low birth weight or premature infants.

Question 12(p30): Should pre-market assessment of infant formula products for premature or low birth weight infants require the same level of evidence and assessment standards as infant formulas for general use?

Question 14(p30): Should pre-market assessment of infant formula products for infants with specific health conditions require the same level of evidence and assessment standards as infant formulas for general use?

In response to both questions 12 and 14, and in regard to pre-market assessment of infant formula products for low birth weight/prematurity or for special health conditions, the INC supports status quo as this enables harmonisation with international standards. This is required to ensure this particularly vulnerable group of infants are provided nutritional products specific to their health condition (or prematurity/low birth weight), in line with the latest scientific evidence and opinion. Primarily, harmonisation with international assessment standards will address the concern raised in the policy consultation paper that additional or restrictive requirements applied by Australia and New Zealand may result in the region’s medically cared-for infants being denied access to the products they need.

Infants of prematurity/low birth weight or with special health conditions are particularly vulnerable and require at minimum, the same level of vigilance applied to the regulation of general infant formula products. The INC considers that the proposed type and level of evidence should differ to these groups as it is not always feasible to conduct large-scale, randomised controlled trials on such specific and small populations. Furthermore, an appropriate control group needs to be considered when evaluating these products as healthy term infants may not be relevant. Depending on the ingredient or product being assessed, the control group or comparator may vary. For example, *in utero* development may be the desired comparator/outcome, as opposed to the growth exhibited by exclusively breast-fed healthy term infants.

The INC refers FRSC to the IDACE comment on the 2003 Medical Position Paper “*The nutritional safety assessment of breast milk substitutes and other dietary products for infants: A commentary by the ESPGHAN Committee on Nutrition*”¹¹. IDACE recommend that although foods for special medical purposes (FSMP) may be the sole source of nutrition for some infants, the clinical evaluation of these products should differ from the criteria used for clinical evaluation of infant formula products for general use. This is due to the limited number of patients eligible for clinical trials investigating a specific health condition, the notion that healthy infants or healthy breast fed infants may not be the appropriate control group for FSMP trials and patients with certain diseases may be heterogeneous making data analysis difficult.

Question 15 (33): If an ingredient is proposed to be added to an infant formula product with the intention of achieving a health benefit, is a pre-market assessment of that benefit warranted?

Before responding to the question at hand, INC would like to point out that the definition of nutritive substances is under consideration by FSANZ, and suggests that the resulting definition potentially impacts the answer to this question.

The INC would like to take the opportunity to present a new concept, a new definition (potentially nutritive ingredient) that would be specific to the infant formula standard. The definition could include nutritive substances as defined in the Code, novel foods and other substances that fall outside of the current definitions and provisions where these ingredients are specifically added with the intention of providing a health benefit or enhanced physiological outcome.

¹¹ IDACE (Association of the Food Industries for Particular Nutritional uses of the European Union) (2003) Comments on: Medical Position Paper “*The nutritional safety assessment of breast milk substitutes and other dietary products for infants: A commentary by the ESPGHAN Committee on Nutrition*”, in context with the 2002 workshop on “Characterisation of Infant Food Modifications in the European Union”

Specified categories of ingredients proposed to be used in infant formula products require a pre-market assessment assessing safety and where applicable: comparison with breast milk and equivalence of physiological outcomes to exclusively breast-fed infants. The pre-market assessment does not include health benefit except where the ingredient proposed is being added for the purpose of a health benefit. In which case industry is required to have some level of evidence in order to demonstrate efficacy and also be able to communicate the demonstrated benefit to the consumer.

Whilst the INC agrees in-principle that pre-market assessment is warranted when a new ingredient is to be added with the intention of achieving a health benefit, we do not think it is appropriate to apply this requirement retrospectively.

The INC considers that if pre market assessment of a physiological benefit is required that it would be appropriate to permit communication of that benefit on the label to allow consumers to make an informed decision in their purchase choice. Health professionals are an important source of information for consumers and it is important that the ability for industry to speak to health professionals about the attributes of specific products is not removed. This was recognised by the Codex Committee for Food Labelling in discussions pertaining to advertising where it was recognised that advertising did not include communications to health professionals¹².

The INC considers that the level of evidence required be a level that demonstrates that the ingredient **may** have the intended effect on physiological outcome. When the evidence becomes unequivocal it would be expected that the ingredient could be mandated for inclusion in infant formula. The proof that is required should relate to infants under the age of six month and before the introduction of weaning foods which may confound results.

The question of whether the evidence proves efficacy or effectiveness also requires discussion. INC considers an assessment of efficacy is appropriate in that an assessment is undertaken to ascertain if the intervention 'can' work. We don't consider it appropriate to specify levels and types of evidence in a policy document. As discussed previously trials to demonstrate effectiveness are not possible until after a product is in the market and being generally consumed by a population of infants.

Alignment with global standards and existing permissions in other markets is important to reduce regulatory burden, decrease cost and improve health outcomes for Australian and New Zealand infants.

¹² CCFL 2008 Alinorm: The Delegation of Australia noted that, in their opinion, clarification of the intent of "commercial communication to the public" may be required and requested that this clarification be noted as "Examples of commercial communications to the public would not include: communications in the form of academic papers, news, editorials, articles of public interest, text book information, website, educational material or professional advice from any source including government agencies and professional bodies". Other delegations and one Observer also identified the need for clarification of the term "commercial communication to the public".

Question 16 (p34): Does post-market surveillance have a place in the regulatory framework for infant formula products?

INC is of the opinion that post market surveillance is not appropriate for inclusion in the regulatory framework. Post market surveillance is difficult from a practical stand point and expensive. It may be expected that post market surveillance would need to be carried out by a third party or by industry. The additional expense of post market surveillance would be passed on to consumers.

Question 17 (p34): Do you think conditional approvals should be given so long as post-market surveillance is undertaken?

No. Conditional approvals should not be given.

The compliance with post-market surveillance requirements would be nearly impossible to implement and monitor and increase burden on industry and government departments.

INC is not aware of precedence in any of the listed key markets that active surveillance (as compared to passive) is the main methodology employed to measure the public health impact of a new ingredient in infant formula products beyond the clinical evidence that might have served in the application process. Passive surveillance is already in existence (formula companies offer 0800 lines that would capture post marketing issues with products) with no demonstration of market failure as yet.

Question 18 (p34): What do you consider would be a major formulation change to an infant formula? Please provide details.

As clarified at stakeholder meeting question 18 is not independent of question 17. INC is not in support of post market surveillance for major formulation changes.

Question 19 (p35): Do existing guidelines, standards and other regulatory measures deal effectively with labelling and advertising in relation to infant formula products?

The INC **does not** believe that existing guidelines, standards and other regulatory measures deal effectively with labelling of infant formula, however **does** believe that existing guidelines and codes deal effectively with advertising of infant formula products. The focus of this response will be on the former.

The INC **CONTENDS** that the current labelling permissions within the Food Standards Code Standard 2.9.1:

- 1) Do not support the FSANZ objective or the proposed FRSC High Order Principle c) in the provision of adequate information to enable consumers to make an informed choice.

2) Discourage innovation

Informed Choices for Consumers

One of the FSANZ primary objectives is:

- The provision of adequate information relating to food to enable consumers to make informed choices [*Section 18 of the Food Standards Australia New Zealand Act 1991 (the FSANZ Act)*].

The High Order Principle stated in the FRSC consultation paper is that:

- There are other priorities as set out in the Food Regulation Overarching Strategic Statement²⁸ (prepared by the Food Regulation Standing Committee and endorsed by the Ministerial Council) which are intended to make clear the context within which food regulation is undertaken in Australia and within the joint Australia-New Zealand food standards system and these are to: – enable consumers to make informed choices about food by ensuring that they have sufficient information and by preventing them from being misled;

Under consumer impacts, it is further stated the consideration of:

- The availability of sufficient labelling information so that consumers are not misled and can make appropriate choices to reflect their preferences, and can use the products appropriately. [*Pg 18, Food Regulation Policy Options Consultation Paper for The Regulation of Infant Formula Products, June 2009*]

In the INC's view, consumers are best able to make informed choices about alternative formula products if those nutrient references are permitted to be included on a pack in a format more readily communicated to consumers than via a statement of ingredients or nutrition information panel.

Nutrient information is fundamentally important to the consumer and this potentially benefits them in making an informed choice of the appropriate formula product for their infant. This is consistent with the World Health Assembly Expert Consultation Committee on the Optimal Duration of Breast feeding which highlights the need for mothers who choose to bottle feed to be supported in their choice to 'optimize their infant's nutrition'.

Labelling restrictions on infant formula currently do not allow sufficient communication to allow consumers to make an informed decision about which type of infant formula to choose or that is best for their infant, once they have made the decision to purchase. Therefore, much of the key/critical information regarding formula types and ingredients can only be communicated to carers via healthcare professionals. Industry currently relies on health care professionals to pass on the factual information on infant formula, and the differences between them to mothers who have made the decision to use infant formula. However, health care professionals are practically bound by their own internal feeding guidelines to discourage contact with infant formula companies, which has the effect of reducing flow of essential information to those carer's that require it. This is stated in the summary text from *Qualitative Research on Information Sources and Practices-Preparation of Powdered Infant Formula in New Zealand (2008)*: "Caregivers are typically information hungry and access to information on infant formula, in general, and in preparation, in particular, was usually less than caregivers required. Information on infant formula

tins was viewed as available, authoritative and trusted and was the major information source for most caregivers. Information from health professionals was valued and trusted, when it was provided, but in many cases the health professional available at the time were unwilling or unable to provide the necessary information. According to caregivers involved in the current study, a number of health professionals believed they were ‘not allowed’ to provide information on infant feeding.” (Winstanley and Cressey, 2008).¹³

The fact remains that not all parents consult a health care professional to obtain advice about suitable formulas and these parents are less able to make an informed choice. It is important to consider that for those groups of mothers who cannot breastfeed and are walking into a store to make a decision at purchase, that they are presented with a retail environment in which general foods are permitted to communicate information on labels. Infant formula and general food are both available in Grocery stores – and it is important that our sector continues to communicate to ensure that the mother will give the **right** products that are specifically designed to meet the nutritional needs of her infant to avoid inappropriate choices being made.

The INC considers that properly formulated communication of product information on labels is consistent with the International Code for the Marketing of Breastmilk Substitutes (WHO Code) which does not specifically prohibit nutrition claims, and in fact encourages provision of adequate information: Article 9.1 “Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding.” Provisions for the latter are clear in the mandated “Breastmilk is best for babies” in the FSANZ Standard 2.9.1 for Infant formula.

INC also notes that a number of countries who are signatories of the WHO code (for example those listed in the FRSC policy consultation paper) permit nutrient content or nutrient function claims, regulated under specific conditions (specified categories, or those needing pre-market clearance). A key difference between Australia/New Zealand and most other markets is that Follow-On formula is not classed as a breastmilk substitute. Hence labelling of Follow-On formula can differ significantly from a starter infant formula.

This is relevant particularly in context of Follow-On formula being part of an increasingly diverse diet as the infant gets older, not the sole source of nutrition. Communication of nutrition information about the role of Follow-on formula in the early phase of infant’s total feeding is important. Properly communicated, this information provides key facts about the product and its use which is important for parents and is not a discouragement to breastfeeding.

INC believes that the promotion of breastfeeding and provision of information about infant formula need not be mutually exclusive. There is no evidence to support the hypothesis that informative labelling on infant formula would negatively impact

¹³ Winstanley A. and Cressey P. 2008. Information Sources and Practices-Preparation of Powdered Infant Formula in New Zealand –Qualitative Research. Report prepared as part of a New Zealand Food Safety Authority contract for Scientific Services by Institute of Environmental Science & Research Limited.

breast feeding rates. The recent Parliamentary Inquiry ‘The Best Start’ into the reason why breastfeeding rates are not higher in Australia did not find the presence of infant formula to be a barrier to initiation of or continuance of breastfeeding (House of Representatives Standing Committee on Health and Ageing, 2007).¹⁴

The legitimate interest of the consumer must be stressed, and Policy needs to consider the real needs of the consumer, and not be influenced by emotional arguments. The INC believes that there should be permission for the labels of infant formula products to be able to display clear information relating to the presence of ingredients and sufficient substantiated information about the nature of these ingredients to enable consumers to make an informed decision about whether that product is suitable. This is in line with FSANZ objectives and Policy principles, but these permissions need not contravene any prohibition on health claims or advertising of infant formula.

Question 20 (p50): Are there any policy options that have not been considered here? If so, please provide details.

Option 4 (current status) with modification

Specified categories of ingredients proposed to be used in infant formula products require a pre-market assessment assessing safety and where applicable: comparison with breast milk and equivalence of physiological outcomes to exclusively breast-fed infants. The pre-market assessment does not include health benefit except where the ingredient proposed is being added for the purpose of a health benefit. In which case industry is required to have some level of evidence in order to demonstrate efficacy and also be able to communicate the demonstrated benefit to the consumer.

Question 21(p50): Can you provide data to support the potential costs and/or benefits of impacts of policy options? If so please provide this in relation to comments on the key issues and relevant options.

The INC requests that any specific questions about data to support the potential costs and/or benefits of impacts of policy options be addressed to individual companies. Companies will provide the information on a commercial in confidence basis.

Question 22 (p51): Please indicate your preferred option (as stated or otherwise) and provide details as to why you consider this option is suitable.

Option 4 (current status) with modification

Specified categories of ingredients proposed to be used in infant formula products require a pre-market assessment assessing safety and where applicable: comparison with breast milk and equivalence of physiological outcomes to exclusively breast-fed infants. The pre-market assessment does not include health benefit except where the

¹⁴ House of Representatives Standing Committee on Health and Ageing; August 2007 *The Best Start – Report on the Inquiry into the Health Benefits of Breastfeeding*

ingredient proposed is being added for the purpose of a health benefit. In which case industry is required to have some level of evidence in order to demonstrate efficacy and also be able to communicate the demonstrated benefit to the consumer.