Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

SUBMISSION

NHMRC Draft Infant Feeding Guidelines for Health Workers

Prepared by the Infant Nutrition Council – December 2011

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This submission has been prepared by the Infant Nutrition Council (INC).

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 products in Australia and New Zealand, including:

- Bayer Ltd
- Dairy Goat Co-operative (NZ) Ltd (Associate member)
- Fonterra Co-operative Group Ltd
- H. J. Heinz Company Ltd
- Murray Goulburn Co-operative Co Ltd (Associate member)
- Nestlé Australia Ltd & Nestlé New Zealand Limited
- Nutricia Pty Ltd
- Pfizer Nutrition

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

The Infant Nutrition Council 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 Infant Nutrition Council believes that breast milk provides an infant with the best source of nutrition, that breastfeeding is the normal way to feed an infant and it has numerous benefits for both mothers and babies. The Infant Nutrition Council is committed to supporting both breastfeeding and infant formula feeding.

The Infant Nutrition Council would like to thank the Infant Feeding Sub-Committee of the Dietary Guidelines Working Committee; the NHMRC Project Team; the Department of Health and Ageing Project Team and the Technical writers for preparing this document.

We welcome the opportunity to provide written comment to the Public Consultation on the Draft Infant Feeding Guidelines for Health Workers (October 2011) (the Draft Guidelines). The Infant Nutrition Council would welcome the opportunity for further discussion on our submission and any other aspects of the Draft Guidelines.

EXECUTIVE SUMMARY

The Infant Nutrition Council believes that breast milk provides an infant with the best source of nutrition, that breastfeeding is the normal way to feed an infant and it has numerous benefits for both mothers and babies. We fully support the importance of encouraging and maintaining breast feeding for as long as possible.

While there is no dispute that breastfeeding is best, there is a legitimate place for infant formula. When an infant is not breastfed the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition until solids are introduced.

The Infant Nutrition Council has a high regard for the important role that health workers play in infant feeding and fully support the purpose of the Draft Guidelines:

> *"The purpose of this document is to support optimum infant nutrition by providing a review of the evidence, and clear evidence-based recommendations on infant feeding for health workers."*

We do not, however, support the Draft Guidelines in their current format and content. They do not meet the stated purpose as they lack comprehensive advice and support for the non breastfed infant and their carer.

Throughout our submission we have identified our concerns and opportunities to strengthen the Draft Guidelines to ensure health workers are provided with a useful and practical evidence-based reference resource to enable them to support families with infants.

The principle concerns and opportunities that the Infant Nutrition Council has identified during our review of the Draft Guidelines are as follows:

1 Content and Scope of the Draft Guidelines;

2 Information should focus on the local (Australian) context with respect to marketing practices and regulations;

3 Information provided should be evidence-based and scientifically sound and the evidence-base for recommendations should be applied systematically across all aspects of infant feeding; and

4 Information provided has regard for promoting consistency.

The Draft Guidelines illustrate that there is a continuum of infant feeding. The optimum is breastfeeding however there are a number of possible combinations through a spectrum from exclusive breastfeeding, to partial breastfeeding, to exclusive feeding with infant formula, and the introduction of solids.

The Infant Nutrition Council believes that the Draft Guidelines are incomplete as they do not provide comprehensive guidance on the principles and options for infant formula feeding. While these guidelines provide an adequate review on the "technical" aspects of infant formula they do not address the role of these products in the broader context of Infant Feeding. For example - it is important that the Draft Guidelines state why infant formula is the only suitable and safe alternative and that is because it is the only food apart from breastmilk that is able to meet the whole of an infant's nutritional needs.

While the title of the Draft Guidelines is “Infant Feeding Guidelines for Health Workers” and the purpose and scope clearly state the intent “*to support optimum infant nutrition by providing a review of the evidence, and clear evidence-based recommendations on infant feeding for health workers,”* it is the impression of the Infant Nutrition Council that while the document provides comprehensive information on breast feeding, this is not necessarily the case for infant formula products.

The information provided needs to be comprehensive to ensure health workers have good access to information and resources which assist in their understanding of the entire infant feeding spectrum, (which includes breastfeeding, formula-feeding, and complementary feeding (solids)) and have the ability to use this information to assist all carers seeking information on these topics.

The information provided in the Draft Guidelines should focus on the local (Australian) context with respect to the legal environment, regulations and marketing practices.

The Infant Nutrition Council considers that the Draft Guidelines should, but do not, clearly explain that the MAIF Agreement is the sole governing document with reference to the marketing of breast milk substitutes in Australia. Although the MAIF Agreement is an agreement between manufacturers and importers of infant formula, the Infant Nutrition Council believes it should be incorporated within the responsibilities of healthcare professionals to support the MAIF Agreement by understanding and applying the MAIF Agreement. This is particularly relevant as the Australian Government, the infant formula industry; breastfeeding advocates and other stakeholders have already developed the MAIF Agreement as a response to the WHO Code within the context of Australia’s legal and economic environment.

There is no proper explanation in the Draft Guidelines of the APMAIF and its role. The Draft Guidelines should describe the nature of the APMAIF as a non-statutory body established by the Australian government whose members are highly skilled professionals in their chosen field of expertise and who are appointed by the Commonwealth Parliamentary Secretary for Health.

The Infant Nutrition Council believes that information and recommendations within these guidelines should be supported by evidence based research. We understand that the grading of evidence is applied only where systematic review has been conducted. Therefore we feel that this should be clearly communicated within the Draft Guidelines and where a review of the literature has not been conducted strong recommendations should not be concluded.

The Infant Nutrition Council believes that Information provided must have regard for promoting consistency in similar state-based guidelines/recommendations, industry recommendations, and consideration of the New Zealand infant feeding guidelines (specifically in areas related to harmonised food regulation).

In addition to these overarching comments, the Infant Nutrition Council has also identified specific areas requiring review in Chapter 8 of the Draft Guidelines.

The Infant Nutrition Council welcomes the opportunity to provide input on the Draft Infant Feeding Guidelines for Health Workers (October 2011) (the Draft Guidelines) and we would welcome the opportunity for further discussion on any aspects of the Draft Guidelines.

SUMMARY OF THE INFANT NUTRITION COUNCIL RECOMMENDATIONS

For ease of reference we have provided a summary of our recommendations here. Each of the recommendations is listed in the body of our submission with a discussion as to our reasoning.

OVERARCHING COMMENTS on NHMRC Infant Feeding Guidelines for Health Workers

Content and Scope of the Draft Guidelines

Recommendation 1: The "Introduction: Breastfeeding in Australia" (page 29) should be retitled "Introduction: Infant Feeding in Australia".

Recommendation 2: The Draft Guidelines should include a discussion on the subject of infant feeding and provision of advice and support across this range within the document.

Recommendation 3: that the wording in general in the Draft Guidelines be reviewed to ensure that they are consistent in meeting the intent of the scope and purpose and achieve objectivity and balance between information about breastfeeding and feeding with an infant formula product.

Information should focus on the local (Australian) context

Recommendation 4: all references to the WHO Code in the context of Australia should be replaced with the MAIF Agreement. This would extend to listed definitions and interpretation of the MAIF Agreement for healthcare professionals.

Recommendation 5: Practical guidance about the roles and responsibilities of health workers and health care practitioners as set out in the MAIF Agreement should be provided in the draft guidelines to ensure they are aware of their responsibility to ensure that all mothers are informed and supported in their infant feeding choices.

Recommendation 6:
Chapter 11 should be renamed: *"Interpretation of the MAIF Agreement for Health Care Professionals in Australia*" and this section should clearly outline aspects of the MAIF Agreement that are relevant to health care professionals and health workers in Australia, and NOT aspects of the WHO Code or WHA resolutions.

Recommendation 7: section (11.1) of the Draft Guidelines should be revised to make it clear that the MAIF Agreement is the official application of the WHO Code in Australia. References to the WHO Code should be minimised to avoid confusion and duplication.

Recommendation 8: section (11.1.1) of the Draft Guidelines should be revised to include a proper explanation of the APMAIF and its role.

Recommendation 9: delete section (11.1.4) as the summary can be incorporated, simply, in the following section (11.1.5).

Recommendation 10: References to distribution of samples should be deleted and replaced with instructions to assist the health care professional regarding their obligation to ensure any distribution of samples is in line with the requirements of the MAIF Agreement.

Recommendation 11: Include reference to the Infant Nutrition Council Policy and Template Infant Formula Samples Request Form in the Draft Guidelines.

Recommendation 12: Reword Section 11.1.5 - *Differences between the MAIF Agreement and the WHO Code.* Revised wording provided within our submission.

Recommendation 13: Delete Section 11.1.6 as this information is not relevant in the Australian context with the exception of Distribution of Samples (refer Recommendations 10 and 11).

Recommendation 14: section 11.1.7 be reviewed and expanded as it appears to be a key section to clearly outline the responsibilities of the health care professional based on the MAIF Agreement.

Recommendation 15: the sentence on p114, (para 4) should be reworded to indicate the requirement to meet compositional criteria under FSANZ Code Standard 2.9.1 in Australia – i.e. the words "international and" should be deleted.

Information provided is evidence-based and scientifically sound

Recommendation 16: all factors listed to be reviewed and evidence graded in order to provide a level of association. In addition these factors should be specific to the disease state. For example 'some childhood cancers' should be specified.

Recommendation 17: The Infant Nutrition Council requests NHMRC review conflicting statements in the literature review to support final recommendation.

Recommendation 18: revise the wording (Box 1.2 p 42) - "exclusive" should be replaced with "any".

Recommendation 19: the statements identified on Feed Thickening (p 90) are reviewed to ensure they are an accurate reflection of the quoted literature.

Information provided has regard for promoting consistency.

Recommendation 20: review the Draft Guidelines (section 4.1) to ensure consistency in recommendation for storage time for breastmilk.

SPECIFIC COMMENTS on NHMRC Infant Feeding Guidelines for Health Workers (Chapter 8)

Recommendation 21: Statements on price, quality and nutritional value in Chapter 8 are reviewed to reflect factually correct advice.

Recommendation 22: This statement: "*their use is not considered necessary for most older infants and there have been no studies showing advantages over the infant formula they are already having."* (Chapter 8, p 114/115) should be deleted.

Recommendation 23: Review the wording in this section (8.1) to reflect the shared responsibilities between different stakeholders (e.g. industry, government, scientific community) for improving the quality of protein in infant formula.

Recommendation 24: revise the heading and content for this section to inform health workers of the process by which safety matters are dealt with and where to access up to date information on these matters

Recommendation 25: advice on transportation of infant formula is included in the Draft Guidelines.

Recommendation 26: advice on *Handling and Storage of 'Ready to Drink' Liquid Infant Formula* is included in the Draft Guidelines.

Recommendation 27: the following statement from the 2003 Infant Feeding Guidelines should be included in the current draft:

"...health workers should be mindful that mothers who do not breastfeed need information about infant formula and instruction about its use and preparation…All mothers are entitled to support and advice, so that they can feed their infants well."

1. INTRODUCTION

For the purpose of this submission, the Infant Nutrition Council has provided overarching comments and recommendations regarding the content and approach of the Draft Guidelines as well as specific comments and recommendations for some chapters. We have also provided comment on some of the recommendations. Throughout our submission we have referenced our comments back to the Chapter/Section we are addressing.

As the scope of the Infant Nutrition Council is infant formula feeding, we have only provided comments relating to this area of infant feeding (that is 0-12 months) and not on complementary feeding with solids.

2. INFANT NUTRITION COUNCIL POSITION on NHMRC Infant Feeding Guidelines for Health Workers

The Infant Nutrition Council has a high regard for the important role that health workers play in infant feeding and fully support the purpose of the Draft Guidelines:

> *"The purpose of this document is to support optimum infant nutrition by providing a review of the evidence, and clear evidence-based recommendations on infant feeding for health workers."(p 3)*

We do not, however, support the Draft Guidelines in their current format and content. They do not meet the stated purpose as they lack comprehensive advice and support for the non breastfed infant and their carer.

3. OVERARCHING COMMENTS on NHMRC Infant Feeding Guidelines for Health Workers

The principle concerns and opportunities that the Infant Nutrition Council has identified during our review of the Draft Guidelines are as follows:

1 Content and Scope of the Draft Guidelines;

2 Information should focus on the local (Australian) context with respect to marketing practices and regulations;

3 Information provided should be evidence-based and scientifically sound and the evidence-base for recommendations should be applied systematically across all aspects of infant feeding; and

4 Information provided has regard for promoting consistency.

In the following sections we address our concerns around each of these areas in further detail with reference to specific sections of the Draft Guidelines.

3.1 Content and Scope of the Draft Guidelines

The information provided needs to be comprehensive to ensure health workers have good access to information and resources which assist in their understanding of the entire infant feeding spectrum, (which includes breastfeeding, formula-feeding, and complementary feeding (solids)) and have the ability to use this information to assist all carers seeking information on these topics.

The Draft Guidelines illustrate that there is a continuum of infant feeding. The optimum is breastfeeding however there are a number of possible combinations through a spectrum from exclusive breastfeeding, to partial breastfeeding, to exclusive feeding with infant formula, and the introduction of solids.

The Infant Nutrition Council believes that the Draft Guidelines are incomplete as they do not provide comprehensive guidance on the principles and options for infant formula feeding. While these guidelines provide an adequate review on the "technical" aspects of infant formula they do not address the role of these products in the broader context of Infant Feeding.

Both the World Health Organisation International Code of Marketing of Breast Milk Substitutes (WHO 1981) (WHO Code) and Australia's official application of it, the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement 1992 (MAIF Agreement) have the same aim. The aim of the MAIF Agreement is:

> *"to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary[1], on the basis of adequate information and through appropriate marketing and distribution"*

Health care professionals and the health care system are participants in the process of achieving the aims of the MAIF Agreement and their role is directly referenced in Clauses 3 to 7 of the Agreement.

It is important that the Draft Guidelines assist health care professionals and the health care system to fulfil their role under the MAIF Agreement including that of enabling parents to make informed choices around infant feeding, providing information about infant formula when required and supporting parents in their choice.

Recommendation 1: The "Introduction: Breastfeeding in Australia" (page 29) should be retitled "Introduction: Infant Feeding in Australia".

The Draft Guidelines should include a discussion on the subject of infant feeding and provision of advice and support across this range within the document. For example, discussion on the optional ingredients in formula as well as discussion around proper use of foods for special dietary uses (e.g. formulas available for formula-fed infants suffering lactose intolerance, cow's milk protein allergy or regurgitation).

Recommendation 2: The Draft Guidelines should include a discussion on the subject of infant feeding and provision of advice and support across this range within the document.

While the title of the Draft Guidelines is "Infant Feeding Guidelines for Health Workers" and the purpose and scope clearly state the intent "*to support optimum infant nutrition by providing a review of the evidence, and clear evidence-based recommendations on infant feeding for health workers,"* it is the impression of the Infant Nutrition Council that while the document provides comprehensive information on breast feeding, this is not necessarily the case for infant formula products.

While there is no dispute breastfeeding is best, there is a legitimate place for infant formula products. When an infant is not given breastmilk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition until solids are introduced.

[1] For the purposes of the Aim, 'necessary' includes mothers who make an informed choice to use breast milk substitutes (The MAIF Agreement)

The Infant Nutrition Council believes that it is important that the Draft Guidelines state why infant formula is the only suitable and safe alternative and that is because it is the only food apart from breastmilk that is able to meet the whole of an infant's nutritional needs.

The guidelines provide detailed information about why breastmilk is best and this is important to inform health practitioners about why they should promote breastmilk first over any other infant food. However, the Infant Nutrition Council believes that it is also important that health practitioners be informed about why infant formula should be used when a baby is not being breastfed in preference to other unsuitable breastmilk substitutes such as instant milk powders.

The Infant Nutrition Council does not consider that the Draft Guidelines achieve their stated purpose and scope for those infants who are not being breastfed. Further, we consider that in some areas, the Draft Guideline use language and wording which position the option or choice to use infant formula as a negative in the context of delivering *optimum infant nutrition.*

Indeed, the way that the recommendations are set out illustrates this point. The two key headings are:

- Breastfeeding; and
- Promotion of supportive social and physical environments for breastfeeding.

We believe that the intent of the second heading should be to address:

*"Promotion of supportive social and physical environments for **infant** feeding**."***

The Draft Guidelines specifically state that:

> *"All health workers should promote breastfeeding in the community and ensure that best practice in breastfeeding is followed."(p 4)*

We would propose that this sentence is amended to read:

> *"All health workers should promote breastfeeding in the community and ensure that best practice in **infant feeding** is followed."*

The Draft Guidelines are referenced as breastfeeding guidelines on occasion (p 45) and the language and wording may not consider the non-breastfeeding mother. For example:

- p 51/52 – physiologically almost all women can breastfeed – there is no mention of women who make an informed choice not to breastfeed; and

- p 87 – postnatal depression – there is no mention of mothers who formula feed their infants.

Recommendation 3: that the wording in general in the Draft Guidelines be reviewed to ensure that they are consistent in meeting the intent of the scope and purpose and achieve objectivity and balance between information about breastfeeding and feeding with an infant formula product.

3.2 Information should focus on the local (Australian) context

The information provided in the Draft Guidelines should focus on the local (Australian) context with respect to the legal environment, regulations and marketing practices.

3.2.1 The MAIF Agreement and the WHO Code (Chapter 11, p 139)

The Infant Nutrition Council considers that the Draft Guidelines should, but do not, clearly explain that the MAIF Agreement is the sole governing document with reference to the marketing of breast milk substitutes in Australia.

Article 11.1 of the WHO Code states:

> *"Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework."*

The Australian government's response to Article 11.1 is the MAIF Agreement. This is a voluntary self-regulatory code of conduct between manufacturers and importers of infant formula in Australia. Distributors are not included in the MAIF Agreement and the Infant Nutrition Council does not agree with the inclusion of distributors as a party to the MAIF Agreement.

Both the MAIF Agreement and the WHO Code have the same aim and this is not stated anywhere in the draft guidelines.

> *"…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 Infant Nutrition Council considers that the referencing throughout the Draft Guidelines to the WHO Code is unnecessary and confusing and may lead health workers to think the WHO Code applies in addition to the MAIF Agreement. Some examples of how this may be confusing include:

- p 6 "recommendations for creating a supportive environment" include reference to implementing the WHO Code; and
- p 148 – "areas where the WHO Code is out of date" – given the WHO Code is not relevant in Australia – the reference should be deleted as inclusion is confusing given:
    - 'Home prepared formula' is not contained in the MAIF Agreement. Whether the WHO Code in this respect is out of date is not relevant in Australia; and
    - 'Distribution of Samples' - this is a point of difference between the WHO Code and the MAIF Agreement and reference to the WHO Code position on samples is confusing; and
    - The title of the Draft Guidelines "for Health Workers" references the WHO Code and not the MAIF Agreement.

The Draft Guidelines are also not the appropriate forum to outline areas of the WHO Code or MAIF Agreement which might be out of date. Members of the Infant Nutrition Council are signatories to the MAIF Agreement as currently worded and the Infant Nutrition Council considers that discussion of where it is out of date should be left to a review of the MAIF Agreement.

The WHO Code applies to "Health Workers" who may or may not have a professional qualification whereas the MAIF Agreement refers to "Health Care Professionals" who must have a professional health qualification or be trained appropriately. In the Australian context, information and guidance about infant feeding would be provided to carers by professionally qualified or trained health practitioners.

Recommendation 4: all references to the WHO Code in the context of Australia should be replaced with the MAIF Agreement. This would extend to listed definitions and interpretation of the MAIF Agreement for healthcare professionals.

3.2.2 Health Workers

Under the MAIF Agreement, health care professionals are the only group authorised to demonstrate feeding with breastmilk substitutes and this should be a more prominent focus of the guidelines.

The summary does not state that Health Workers have a responsibility to:

- assist mothers to make an informed choice;
- provide information about infant formula when necessary; and
- support all mothers in their infant feeding choice.

These points are also not included in the Recommendations Table on p 18.

The definition of 'necessary' is not explored in the Draft Guidelines or anticipated at all (i.e. no anticipation the decision not to breastfeed might be through choice) – hence the requirement for all health workers to have sufficient working knowledge of infant formulas.

Recommendation 5: Practical guidance about the roles and responsibilities of health workers and health care practitioners as set out in the MAIF Agreement should be provided in the draft guidelines to ensure they are aware of their responsibility to ensure that all mothers are informed and supported in their infant feeding choices.

3.2.3 Interpretation of the WHO Code for Health Workers in Australia (Chapter 11, p 139)

As Australia's response to the WHO Code was the development of the MAIF Agreement, The Infant Nutrition Council recommends that the title and introduction of Chapter 11 should clearly relate to the aim and purpose of the MAIF Agreement. An explanation of how Australia implements the WHO Code is relevant here as well as the development of the MAIF Agreement.

Although the MAIF Agreement is an agreement between manufacturers and importers of infant formula, the Infant Nutrition Council believes it should be incorporated within the responsibilities of healthcare professionals to support the MAIF Agreement by understanding and applying the MAIF Agreement. This is particularly relevant as the Australian Government, the infant formula industry; breastfeeding advocates and other stakeholders have already developed the MAIF Agreement as a response to the WHO Code within the context of Australia's legal and economic environment.

The Infant Nutrition Council seeks alignment and support from Australian healthcare professionals to understand the responsibilities relevant to them within the MAIF Agreement.

Recommendation 6:
Chapter 11 should be renamed: *"Interpretation of the MAIF Agreement for Health Care Professionals in Australia*" and this section should clearly outline aspects of the MAIF Agreement that are relevant to health care professionals and health workers in Australia, and NOT aspects of the WHO Code or WHA resolutions.

3.2.4 The Marketing in Australia of Infant Formulas Agreement: Status (Section 11., p 140)

Recommendation 7: this section (11.1) of the Draft Guidelines should be revised to make it clear that the MAIF Agreement is the official application of the WHO Code in Australia. References to the WHO Code should be minimised to avoid confusion and duplication.

3.2.5 The Advisory Panel on the Marketing in Australia of Infant Formula (the APMAIF) (Section 11.1.1, p 141)

There is no proper explanation in the Draft Guidelines of the APMAIF and its role. The Draft Guidelines should describe the nature of the APMAIF as a non-statutory body established by the Australian government whose members are highly skilled professionals in their chosen field of expertise and who are appointed by the Commonwealth Parliamentary Secretary for Health.

While it is true that the MAIF Agreement is a voluntary agreement between the manufacturers and importers of infant formula, there is no mention of the APMAIF imposed sanctions when a signatory to the MAIF Agreement breaches the MAIF Agreement. The Draft Guidelines should explain that the APMAIF's Annual Report is tabled in Parliament and any breaches of the MAIF Agreement are recorded in the Annual Report. This public reporting receives global publicity and could potentially damage the reputation of the company involved.

The APMAIF's role of investigating complaints regarding the marketing of infant formula is applied through a robust process and the Infant Nutrition Council considers that this should be highlighted in the Draft Guidelines.

Recommendation 8: this section (11.1.1) of the Draft Guidelines should be revised to include a proper explanation of the APMAIF and its role.

3.2.6 Summary of the International Code of Marketing of Breast Milk substitutes (WHO Code) (Section 11.1.4, p 146)

Recommendation 9: delete this section (11.1.4) as the summary can be incorporated, simply, in the following section (11.1.5).

3.2.7 Differences between the MAIF Agreement and the WHO Code (Section 11.1.5, p 147)

The Infant Nutrition Council suggests including an explanation in the Draft Guidelines as to why there are differences between the WHO Code and the MAIF Agreement. Article 11.1 of the WHO Code should be referenced here as well as why these differences exist under the Competition and Consumer Act 2010 (formerly known as The Trade Practices Act 1974).

The current wording and explanation of differences between the two documents as provided is confusing especially given that the WHO Code and the MAIF Agreement both have the same aim. At the same time there is no acknowledgement that the scope of the MAIF Agreement is broader than the WHO Code in that it restricts the marketing of infant formula to beyond 6 months and includes infant formula product up to 12 months.

The MAIF Agreement does not restrict the distribution of samples to consumers through health care professionals including pharmacists directly because the MAIF Agreement only applies to health care professionals and not to potentially unqualified health workers. The MAIF Agreement was developed by the Australian Government, the infant formula industry, breastfeeding advocates and other stakeholders where provision of samples to health care professionals for the purposes of professional evaluation was deemed acceptable to all key stakeholders.

Page 45 of the Draft Guidelines outlines a Cochrane review regarding the distribution of samples and adverse effect on breastfeeding. This discussion point is inappropriate given, as outlined above; the distribution of samples is tightly governed under the MAIF Agreement and at the discretion of the health care professional. The Infant Nutrition Council would like to see a reference to The Infant Nutrition Council's "Samples Request Template" included in this section (copy provided with our submission). Health practitioners need to understand that samples may only be provided by infant formula manufacturers on their written request and use must be monitored, that is, they may only be used under their professional guidance.

Recommendation 10: References to distribution of samples should be deleted and replaced with instructions to assist the health care professional regarding their obligation to ensure any distribution of samples is in line with the requirements of the MAIF Agreement.

Recommendation 11: include reference to the Infant Nutrition Council Policy and Template Infant Formula Samples Request Form in the Draft Guidelines.

The Infant Nutrition Council proposes the following revised wording for Section 11.1.5:

"Differences between the MAIF Agreement and the WHO Code

The MAIF Agreement is Australia's response to becoming a signatory to the WHO Code. The MAIF Agreement implements those aspects of the WHO Code that are appropriate to Australia's legal and economic environment. The MAIF Agreement was authorised by the then Trade Practices Commission (now the Australian Competition and Consumer Commission) in 1992. Authorisation of the MAIF Agreement was necessary because it contains marketing restrictions limiting competition and was granted on the basis that public benefit outweighed any anti-competitive detriment.

Overall, the WHO Code applies to the marketing and related practices of the following products:

- *breastmilk substitutes including infant formula;*
- *other milk products;*
- *feeding bottles and teats; and*
- *foods and beverages – including bottle-fed complementary food*

When marketed to be suitable for use as a partial or total replacement for breastmilk. It also applies to retailers and health professionals.

In contrast, the MAIF Agreement applies only to manufacturers and importers of formulas and covers only infant formula products for infants up to 12 months of age. In this respect it differs from the WHO Code which only applies to infant formula products up to the age of 6 months.

The MAIF Agreement does not include other milk products, foods, beverages or feeding bottles and teats. The activities of retailers of infant formula are specifically excluded from the MAIF Agreement.

The WHO Code applies to "Health Workers" who may or may not have a professional qualification whereas the MAIF Agreement refers to "Health Care Professionals" who must have a professional health qualification (appropriately trained person working in a component of the health care system).

Distribution of Samples

The MAIF Agreement allows the distribution of infant formula samples to health care professionals for the purposes of professional evaluation or research at the institutional level. Guidelines on the definition of professional evaluation were acknowledged by the APMAIF in 2010 and includes analysis of products (ingredients, taste, nutritional profile); trial preparation and mixing of infant formula products (includes preparation and mixing instructions to mothers); investigative or development projects, using sound methodology and involving a number of infants; a thorough assessment of the suitability of a product for an individual infant, including acceptance by the infant, when mothers have made the informed choice to use infant formula; an individual patient assessment including a follow-up meeting between the health professional and the mother of the infant.

The Infant Nutrition Council has developed a Policy on Distribution of Infant Formula Samples to Health Care Professionals and Template Infant Formula Samples Request Form for use by member companies.

The Aim of the Policy is:

- *to ensure the proper use of infant formula samples under the terms of the MAIF Agreement and the Infant Nutrition Council Code of Practice for the Marketing of Infant Formula;*

- *to define the role and responsibility of manufacturers and importers of infant formulas in the provision of infant formula samples; and*

- *to discourage infant formula samples from being seen as a general resource for all Health Care Professionals.*

Healthcare professionals need to know that samples may only be acquired from infant formula manufacturers at their request and may only be provided and used under their professional guidance."

Recommendation 12: reword Section 11.1.5 - *Differences between the MAIF Agreement and the WHO Code.*

3.2.8 Areas in which the WHO Code is out of date (Section 11.1.6, p 148)

Recommendation 13: delete Section 11.1.6 as this information is not relevant in the Australian context with the exception of Distribution of Samples.

3.2.9 Practical Points (Section 11.1.7, p 149)

The Infant Nutrition Council believes that this section should be reviewed and expanded as it appears to be a key section to clearly outline the responsibilities of the health care professional based on the MAIF Agreement.

We suggest:

- adding a practical point about clause 6(d) of the MAIF Agreement where feeding with infant formulas should be demonstrated only by health care professionals; and
- using the wording of the MAIF Agreement to outline the distribution of samples, that is "...for the purpose of professional evaluation or research."

Recommendation 14: section 11.1.7 be reviewed and expanded as it appears to be a key section to clearly outline the responsibilities of the health care professional based on the MAIF Agreement.

3.2.10 Local Regulations

The Draft Guidelines state:

> *"Almost all infant formulas sold in Australia are imported and meet international and Australian nutritional and quality-control standards."* (p 114, paragraph 4, 2nd sentence)

Under the Food Standards Australia New Zealand (FSANZ) Code Standard 2.9.1 on Infant Formula Products there are specific compositional criteria for infant formula sold within Australia. These should not be considered to 'meet **international** … nutritional and quality-control standards' as in most cases the FSANZ Code requires a specific and different formulation for the Australian market which may not comply with International standards.

Recommendation 15: the sentence on p114, (para 4) should be reworded to indicate the requirement to meet compositional criteria under FSANZ Code Standard 2.9.1 in Australia – i.e. the words "international and" should be deleted.

3.3 Information provided is evidence-based and scientifically sound

The Infant Nutrition Council believes that information and recommendations within these guidelines should be supported by evidence based research. We understand that the grading of evidence is applied only where systematic review has been conducted. Therefore we feel that this should be clearly communicated within the Draft Guidelines and where a review of the literature has not been conducted strong recommendations should not be concluded.

We highlight the following examples to illustrate this point.

3.3.1 Health (Section 1.1.1.3, p 34)

The Infant Nutrition Council support the need to provide evidence to promote the benefits of breastfeeding as set out in this section of the Draft Guidelines.

As infant formula delivers the sole source of nutrition for some infants, we believe the benefits of breastfeeding should be evidence-based and should not undermine the importance of a safe alternative where there is inconclusive evidence.

We believe the following statement in section 1.1.1.3 implies a strong association for all the disease states listed in this section.

"*Studies have shown that breastfeeding reduces the risk of severity of a number of diseases states in infancy and later life*" (p 34)

The Infant Nutrition Council would like to see the NHMRC review the level of evidence so that the evidence is categorised into separate groups according to the strength of the association between breastfeeding and the disease state.

> **Recommendation 16:** all factors listed to be reviewed and evidence graded in order to provide a level of association. In addition these factors should be specific to the disease state. For example 'some childhood cancers' should be specified.

Further to this, the Infant Nutrition Council would also like to express concern over conflicting statements regarding the quality of evidence within the literature review. An example of this is:

3.3.2 Maternity care practices (Section 1.2.3, p 45)

"Evidence also suggests that the use of prelacteral feeds negatively affects breastfeeding duration (Evidence Grade C)" (p 46).

The draft evidence statement on p 35 states;

"There is consistent evidence to support the hypothesis that the use of prelacteal feeds negatively affects breastfeeding duration (Grade C)".

However, immediately below that statement, the "consistency" of the evidence is ranked as "*poor*". From the literature review there were a total of 4 studies included, with 2 (including the only Australian study) showing no effect of prelacteal feeds on breastfeeding duration whilst the other 2 showed a negative effect.

Additionally p 36 of the literature review also states:

"Overall, there is insufficient evidence to support or refute the hypothesis that the use of prelacteal feeds or the brief exposure of supplements in the early post partum period, negatively affect breastfeeding duration".

Recommendation 17: The Infant Nutrition Council requests NHMRC review conflicting statements in the literature review to support final recommendations.

3.3.3 Obesity (Section 1.1.1.10)

On the topic of obesity in infants who are either breast-fed or formula fed, the following statement is not referenced in the Draft Guidelines and we query the evidence base which substantiates this statement.

"Exclusive breastfeeding for around six months is associated with the lowest risk of later obesity" (Box 1.2, p41-42).

The Infant Nutrition Council request that the wording of this statement is revised to reflect what the meta-analyses in this area have examined. The discussion on p 41 and the literature review is all related to "any" breastfeeding as opposed to "exclusive".

Recommendation 18: revise the wording (Box 1.2 p 42) - "exclusive" should be replaced with "any".

3.3.4 Breastfeeding: Common Problems and their Management (Chapter 4, p 72)

Feed Thickening (p 90)

In the section on thickening feeds, the Draft Guidelines make the following statement:

"Thickening of feeds has some benefit in decreasing the amount regurgitated, but has no efficacy in decreasing the number of episodes of GOR or acid exposure, and thus has no real place in the management of complicated GOR."

The Draft Guidelines reference the 2008 meta-analysis conducted by Horvath et al (2008) to support this statement. Review of the actual Horvath paper, reveals the following concluding statement:

"This meta-analysis shows that thickened food is only moderately effective in treating gastroesophageal reflux in healthy infants."

Therefore the Horvath paper is supportive of thickeners, yet the Draft Guidelines appear to have mis-interpreted the conclusions of Horvath et al.

Additionally, the Draft Guidelines state that

"*…feed thickeners cannot be utilized in breastfeeding"*.

Whilst this may be true for the strict definition of "exclusive breastfeeding", it is possible for breast milk to be expressed, thickened, and then fed to an infant immediately if the need arises.

Recommendation 19: the statements identified on feed thickening (p 90) are reviewed to ensure they are an accurate reflection of the quoted literature.

3.4 Information provided has regard for promoting consistency.

The Infant Nutrition Council believe that Information provided must have regard for promoting consistency in similar state-based guidelines/recommendations, industry recommendations, and consideration of the New Zealand infant feeding guidelines (specifically in areas related to harmonised food regulation).

3.4.1 Expressing and Storing Breastmilk (Section 4.1, p 72)

There are inconsistencies with – for example, NZ Ministry of Health guidelines and NSW Food Authority proposed web information guidelines. The Draft Guidelines states up to 5 days storage, however, other guidelines propose up to 48 hours. The maximum length of storage time of pre-prepared infant formula is 24 hours. This is because powdered infant formula is not sterile and can contain very low amounts of bacteria which can multiply over time. Given that breastmilk is also not sterile, the Infant Nutrition Council queries the large discrepancy on maximum storage times.

The Infant Nutrition Council also considers that some statements are potentially incorrect as follows:

Storing breastmilk at home (Section 5.3.2)

Breastmilk is a living substance which is incorrectly described in the Draft Guidelines as being:

"…sterile when it comes from the breast…" (p 98).

This statement has been shown to be inaccurate by numerous recent studies which have clearly shown that breastmilk contains bacteria (Heikkila & Saris, 2003; Martin et. al., 2009; Martin et. al., 2004; Olivares et. al., 2006; Gueimonde et. al., 2007). Indeed, it is thought that these bacteria (such as *lactobacilli* and *bifidobacteria*) play an important role in promoting the development of the healthy microbiota that is found in breastfed infants (Gueimonde 2007).

The Draft Guidelines are also inconsistent in their recommendation for the storage time for breastmilk. On p 97 the Draft Guidelines state:

"The literature review identified evidence suggesting that the optimum maximum storage time of breastmilk under clean conditions in a refrigerator at 0-4°C is around 96 hours."(p 97)

However, Table V.1 Length of time breastmilk can be stored (p 99) states that freshly expressed breastmilk can be stored for 3-5 days in the refrigerator. Please note the typo's in this Table - the degree part of the temperature needs to be superscripted (i.e. – it should be 26^{o}C rather than 260C; and 4^{o}C rather than 40C).

This discrepancy needs to be addressed to ensure consistent recommendations for health workers.

Recommendation 20: review the Draft Guidelines (section 4.1, p 72) to ensure consistency in recommendation for storage time for breastmilk.

4. SPECIFIC COMMENTS on NHMRC Infant Feeding Guidelines for Health Workers (Chapter 8)

The following sections provide some further comments and feedback on the Draft Guidelines.

4.1 Pricing and Quality of Infant Formula

The Draft Guidelines state:

"The prices of different infant formulas and the types of retail outlets that sell the formulas are not related to quality or nutritional value." (pg 114)

"Interchange between formulas within the same generic group is optional and can be decided on the basis of cost." (pg 114)

The Infant Nutrition Council wishes to advise these statements in the Draft Guidelines are incorrect. Whilst all infant formulas in compliance with the ANZ Food Standards Code are of the same quality with regard to safety, the nutritional value (composition and health benefit associated with optional ingredients) can vary across different brands of infant formulas in the market and this can be reflected in the price.

To ensure innovation and the continual improvement of infant formula products, substantial investment into clinical trials investigating safety and efficacy by infant formula manufacturers is required. The addition of optional ingredients added for the purpose of achieving a health benefit mean that the nutritional value of infant formula products can vary. These factors are reflected in the price of the product.

The Infant Nutrition Council recommends that the interchange of formulas across the range of formulas that are suitable for the age of the infant should not be decided on cost, but rather, on the health and optimum growth and development of the infant. As noted above, significant investment is made into ensuring the substantiation of health benefits of optional ingredients that are added to infant formula. This investment is reflected in the nutritional value and cost of the product. Therefore, while interchange may be optional, it should not be decided on cost, but rather on what health outcome is of most importance for the optimum growth and development of the infant, whether that be, for example, an immune system benefit or for digestive comfort.

The Infant Nutrition Council considers that the Draft Guidelines for health workers need to stay focused on achieving the optimum growth and development of the infant as the paramount consideration, and not extend into a commercial context. While it may be appropriate to comment on the price, quality and nutritional value of different infant formula, the existing information is not correct. The Infant Nutrition Council would welcome the opportunity to provide information to support this topic in the Draft Guidelines.

Recommendation 21: Statements on price, quality and nutritional value in Chapter 8 are reviewed to reflect factually correct advice.

4.2 Starter verses Follow-on formula (Chapter 8)

Follow-on formulas are suitable for infants over 6 months of age. The Draft Guidelines state:

"*their use is not considered necessary for most older infants and there have been no studies showing advantages over the infant formula they are already having."* (p 114/115).

The Infant Nutrition Council believes this needs to be reviewed further, and that potentially, the composition of follow-on formula needs to be reviewed to address different physiological needs of the older infant, and as such, is indeed considered necessary. According to the Nutrient Reference Values (NRV) in Australia and New Zealand infants' requirements increase for a number of nutrients including protein, carbohydrate, folate, vitamin A , choline, calcium, phosphorous, iron, magnesium and iodine, once they reach seven (7) months of age. (NRV's ANZ, 2006)

The New Zealand Food and Nutrition Guidelines for Healthy Infants and Toddlers (2008) state:

"Follow-on formula generally has a higher protein, iron and mineral content and a higher renal solute load than in standard infant formula, although these nutrient levels vary between products. Follow-on formula may be useful in preventing and treating iron deficiency in an infant. A health practitioner's advice should be sought regarding the use of follow-on formula for treating iron deficiency. Iron-fortified infant formula is one of several options for preventing and treating iron deficiency in infants unable to have a normal varied diet."

At the time of solids introduction, infant formula is no longer a sole source of nutrition. Follow-on formulas provide a principal liquid source of nourishment in a progressively diversified diet as infants' transition to solids.

> **Recommendation 22:** *This statement:* "*their use is not considered necessary for most older infants and there have been no studies showing advantages over the infant formula they are already having."* (Chapter 8, p 114/115) *should be deleted.*

4.3 Infant Formula and reference to "Toddler Formula Milks"

The product scope of interest to the Infant Nutrition Council is infant formula products for the 0-12 month aged infant and so generally, we would not make comment on topics beyond this scope. However, we would like to make some editorial comment on the last sentence of the section:

4.3.1 "Toddler's formula milks are not necessary". (p 115)

Chapter 8 is specific to infant formula; which is defined as:

"a product represented as a breastmilk substitute for infants and which satisfies the nutritional requirements of infants until solids are introduced." (ANZ Food Standards Code).

What are referred to as "toddler formula milks" are specifically formulated to the requirements of young children over the age 1-3 years. This product category are not formula products and should not be referred to as "formula products"; they are manufactured and sold as formulated supplementary foods for young children as per the ANZ Food Standards Code and are regulated under a different standard.

4.3.2 Protein levels in infant formula (for infants 0-12 months of age) (Chapter 8, p 114)

The Draft Guidelines state that

"…many brands of infant formula in Europe have improved the quality of the protein they contain enabling the overall protein levels to be reduced", (p 115) and

"It is anticipated that infant formula manufacturers will work towards improving the quality of protein". (p 115)

The Infant Nutrition Council suggests that this section is re-worded to reflect that the onus of improving the quality of protein in infant formula does not lie solely with manufacturers. This responsibility should also lie with the regulatory bodies who, in conjunction with interested stakeholders; systematic reviews of the latest scientific evidence; and consideration of international standards of relevance (e.g. CODEX & EU) develop, implement and enforce these compositional criteria, which encompass minimum and maximum levels.

The Infant Nutrition Council wish to advise the NHMRC that voluntary reduction in protein levels by some manufacturers occurred as far back as 2008 in Australia. These reductions have been done to the absolute minimum levels to comply with Standard 2.9.1.

Recommendation 23: Review the wording in this section (8.1) to reflect the shared responsibilities between different stakeholders (e.g. industry, government, scientific community) for improving the quality of protein in infant formula.

4.4 Preparation of infant formula (Section 8.3, p 116)

The Infant Nutrition Council endorses the NHMRC guidelines on the correct preparation of infant formula.

Scoop sizes and reconstitution instructions do vary between brands so it is important to follow the manufacturer's instructions on preparation and storage of infant formula. To minimise errors in preparation of infant formula the Infant Nutrition Council also endorses the recommendation that it is important that health workers know how to demonstrate the reconstitution of infant formula and how to feed an infant with a bottle. This information is readily available on the product packaging.

4.5 Contamination of infant formula (Section 8.7, p 124)

The Infant Nutrition Council believes the heading and content of this section of the Draft Guidelines may cause unnecessary concern and potential confusion with respect to the overall safety of infant formula. The heading, in particular is quite "alarmist" and unnecessary.

The information contained in this section, while current at the time of writing the Draft Guidelines, will date over their life.

We would recommend that this intent of this section should be to inform health workers of the process by which safety matters are dealt with and where to access information on these matters. This will then insure that they have up to date information and are not acting on out of date and potentially incorrect materials.

There are a number of sources of up to date and accurate information which are easily available to health workers, for example:

- Food Standards Australia New Zealand website – Consumer Information

http://www.foodstandards.gov.au/consumerinformation/

- Food Standards Australia New Zealand website – Food Recalls

http://www.foodstandards.gov.au/consumerinformation/foodrecalls/

- The Infant Nutrition Council website

http://infantnutritioncouncil.com/

Recommendation 24: revise the heading and content for this section to inform health workers of the process by which safety matters are dealt with and where to access up to date information on these matters.

4.6 Additional Comments for Chapter 8

The Infant Nutrition Council suggests inclusion of 2 other topic areas in this section: –

- transportation of infant formula; and
- storage of ready to drink liquid infant formula.

The advice provided within these 2 topic areas is proposed by the Infant Nutrition Council as follows:

4.6.1 Transportation of infant formula

It is not recommended to take made up bottles of infant formula out of the home. It is much safer to prepare bottles of infant formula at the destination, rather than transporting bottles of prepared formula made up at home prior to departure. Harmful bacteria thrive in warm, moist conditions. Ready-made bottles of prepared formula can be a breeding ground for bacteria particularly if the bottles have been sitting in a car or baby bag for several hours, especially on a warm day.

There a number of special containers available designed to carry single serves of infant formula. It is also recommended to take a separate sterilized bottle (or numerous sterilized bottles) of cooled boiled water at the correct volume, so the formula can be prepared at the destination. Alternatively, single-serve sachets of infant formula powder or ready-to-drink servings of liquid formula are available. Ensure to check the manufacturer's instructions.

Recommendation 25: advice on transportation of infant formula is included in the Draft Guidelines.

4.6.2 Handling and Storage of 'Ready to Drink' Infant Formula

The Infant Nutrition Council recommends where possible that each infant feed be prepared individually just prior to use. Always follow manufacturers' instructions about how to prepare and store infant feeds.

'Ready to Drink' infant formula products are available in aseptically packed glass bottles for hospital use only or in aseptically packed tetrapaks for domestic use. However once opened, prior to use either "Ready to Drink' formats (glass bottle or tetrapak) may be prepared into numerous sterilized bottles provided that these bottles are refrigerated below 4 °C continuously and used within 24 hours.

Any unfinished formula left in the bottle after a feed must be discarded and never kept for use in a later feed.

Recommendation 26: advice on *Handling and Storage of 'Ready to Drink' Infant Formula* is included in the Draft Guidelines.

5. SPECIFIC COMMENTS on NHMRC Infant Feeding Guidelines for Health Workers - Recommendations (p 18)

As the recommendations are not numbered in the document (or indeed listed in the body of the document) we have used the headings in the consultation document. Please note – we have not provided comments on all recommendations.

Draft Guidelines Recommendation	Infant Nutrition Council Comment	Infant Nutrition Council Recommendation
Promotion of supportive social and physical environments for breastfeeding	That this heading should reflect the continuum of infant feeding as per our comments under Content and Scope of the Draft Guidelines.	# 28: Suggested Heading: *Promotion of supportive social and physical environments for infant feeding.*
Recommendations for Individuals *Chapters 1.2.3; 2.1; 3.3.1; 4;*	The Infant Nutrition Council is concerned that none of these recommendations include support for the non breast feeding mother.	Recommendations under this heading need to include recognition and support for the non breast feed infant and their mother.
Recommendations for Creating a Supportive Environment Chapters: 1.2.3; 5; 6.5; 11	The Infant Nutrition Council is concerned that none of these recommendations include support for the non breast feeding mother.	Recommendations under this heading need to include recognition and support for the non breast feed infant and their mother. *Refer to recommendation #27*
Continue to implement the WHO International Code of Marketing of Breast-milk Substitutes and the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement and ensure that all health workers understand their related obligations. *Chapter 11*	The Draft Guidelines should be revised to make it clear that the MAIF Agreement is the official application of the WHO Code in Australia. References to the WHO Code should be minimised to avoid confusion and duplication.	As per our recommendations under the heading "Information should focus on the local (Australian) context."
When an infant is not receiving breastmilk Chapters: 1; 3.3.2; 7; 8		Additional comment needs to be included under this section such as: *"Infant Formula is the only suitable and safe alternative' to breast milk – it is important to ensure no other substitutes are given."*

Recommendations for Creating a Supportive Environment

If a parent makes the decision to not breastfeed, this decision must be respected and supported by the health worker and any Infant Feeding Guidelines. Infant feeding is an emotive topic and parents who do not breastfeed their infant can experience guilt, anger, worry, and a sense of failure (Wirihana et al 2011),

in addition to increased risk of developing post-natal depression (Lee 2007). As a result, it is critical that health workers support these parents and infants who, for whatever reason, are not breastfeeding.

The 2003 Infant Feeding Guidelines included the statement that:

"…health workers should be mindful that mothers who do not breastfeed need information about infant formula and instruction about its use and preparation…All mothers are entitled to support and advice, so that they can feed their infants well" (2003: p313).

This statement is not in the 2011 Draft Guidelines.

Recommendation 27: the following statement from the 2003 Infant Feeding Guidelines should be included in the current draft:

"...health workers should be mindful that mothers who do not breastfeed need information about infant formula and instruction about its use and preparation…All mothers are entitled to support and advice, so that they can feed their infants well."

6. REFERENCES

Australia New Zealand Food Standards Code –
http://www.comlaw.gov.au/Details/F2011C00547
Standard 2.9.1 Infant Formula Products, 11 July 2011.

Food and Nutrition Guidelines for Healthy Infants and Toddlers, A background paper (4th Edition). Ministry of Health New Zealand 2008.

Gueimonde M, et al. Breast milk: A source of bifidobacteria for infant gut development and maturation? *Neonatology* 2007; 92: 64-66.

Heikkila M, & Saris P. Inhibition of Staphylococcus aureus by the commensal bacteria of human milk. *Journal of Applied Microbiology* 2003; 95: 471-478.

Horvath A, et al. The Effect of Thickened Feed Interventions on Gastroesophageal Reflux in Infants: Systematic Review and Meta-Analysis of Randomized, Controlled Trials. *Pediatrics* 2008; 122: 1268-1277.

Lee E. Health, morality, and infant feeding: British mothers' experiences of formula milk use in the early weeks. *Sociol Health Ill* 2007; 29: 1075-1090.

Martin R, et al. The commensal microflora of human milk: new perspectives for food bacteriotherapy and probiotics. Trends in Food Science and Technology, 2004; 15: 121-127.

Martin R, et al. Isolation of Bifidobacteria from Breast Milk and Assessment of the Bifidobacterial Population by PCR-Denaturing Gradient Gel Electrophoresis and Quantitative Real-Time PCR. *Applied and Environmental Biology* 2009; 75(4): 965-969.

NHMRC 2003 Infant Feeding Guidelines -
http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n20.pdf
Nutrient Reference Values for Australia and New Zealand, 2006, Australian Government, DOHA, NHMRC.

Nutrient Reference Values for Australia and New Zealand. Ministry of Health. Australian Government. Department of Health and Aging. National Health and Medical Research Council 2006.

Olivares M, et al. Antimicrobial potential of four *Lactobacillus* strains isolated from breast milk. *J Appl Microbiol,* 2006; 101: 72-79.

Wirihana LA & Barnard A. Women's perceptions of their healthcare experience when they choose not to breastfeed. *Women Birth* 2011 Sep 6.

Policy – Distribution of Infant Formula Samples to Health Care Professionals

Aim

- to ensure the proper use of infant formula samples under the terms of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement) and the Infant Nutrition Council Code of Practice for the Marketing of Infant Formula
- to define the role and responsibility of manufacturers and importers of infant formulas in the provision of infant formula samples
- to discourage infant formula samples from being seen as a general resource for all Health Care Professionals

Scope

- to define the governance processes for the distribution of samples to Health Care Professionals
- to define the level of information regarding samples provided to Health Care Professionals from infant formula manufacturers

Definitions

'Samples'

- single or small quantities of an infant formula provided without cost *(MAIF Agreement)*

'Professional Evaluation' and 'Research'

The words *'professional evaluation'* apply to:

- Analysis of products (ingredients, taste, nutritional profile);
- Trial preparation and mixing of infant formula products (includes preparation and mixing instructions to mothers);
- Investigative or development projects, using sound methodology and involving a number of infants;
- A thorough assessment of the suitability of a product for an individual infant, including acceptance by the infant, when mothers have made the informed choice to use infant formula.
- An individual patient assessment includes a follow-up meeting between the health professional and the mother of the infant. (Note: This guideline was developed following discussions at the 46th meeting of the APMAIF Panel on 5 December 2002)

The word *'research'* applies to:

- Clinical research carried out at the institutional level.

'*Health Care System'*

- Governmental, non-governmental or private institutions engaged, directly or indirectly, in health care for mothers, infants and pregnant women. It also includes health workers in private practice.

For the purposes of this policy document, the health care system does not include voluntary workers, nurseries, social welfare agencies or childcare centres.

'*Health Care Professional*'

- A professional or other appropriately trained person working in a component of the health care system, including pharmacists and voluntary workers.

Policy

- Manufacturers and Importers may provide infant formula samples to health care professionals (as defined) only when requested to do so by health care professionals.

- Manufacturers and Importers should provide health care professionals with suitable educational material explaining the provisions of the MAIF Agreement or the INC Code of Practice and the responsible use of samples in the health care system including the condition that samples must never be left in public view.

- Manufacturers and Importers should only provide infant formula samples to health care professionals after their representative has signed for and received a signed Infant Formula Sample Request Form from the health care professional stating that the samples will only be used in accordance with the definitions of 'professional evaluation' or 'research'. (See attachment 1: Infant Formula Sample Request Form, which is a template form containing the minimum information required for such a form. Individual company forms do not have to use this format.)

- Manufacturers and Importers should inform health care professionals that an individual patient assessment includes a follow-up meeting between the health professional and the mother of the infant.

- All staff of infant formula manufacturers and Importers who are responsible for the ordering, management and tracking of sample stock will receive training in the provisions of the industry codes of practice, the processes for the distribution of samples and the requirements for completion of samples request forms.

- Manufacturers and Importers are required to retain all documentation authorising samples for a 12 month period.

- Manufacturers and Importers will conduct internal reviews on infant formula sample distribution to ensure that due process is being followed and that all paperwork has been completed.

«Company logo»

Template Infant Formula Samples Request Form (Australia)

(contains minimum information required, format is not mandatory)

Breast milk is the normal way to feed a baby and is important for baby's health. Professional advice should be followed before using an infant formula. Introducing partial bottle feeding could negatively affect breast feeding. Good maternal nutrition is preferred for breast feeding and reversing a decision not to breast feed may be difficult. Infant formula should be used as directed. Proper use of an infant formula is important to the health of the infant. Social and financial implications should be considered when selecting a method of feeding.

The Marketing in Australia of Infant Formula Agreement **(MAIF)**

"The aim is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of Breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution." (WHO Code Article 1)
For the purposes of the Aim, 'necessary' includes mothers who make an informed choice to use breast milk substitutes.

I hereby request from «Company name» the following infant formula samples for professional evaluation:

Product	Quantity	Batch Number & Expiry Date
«Company products listed here»		

I understand that these samples have been provided under the provisions of Clause 7 (d) of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement):

Manufacturers and importers of infant formulas should not provide samples of infant formulas, or equipment of utensils for their preparation or use, to health care professionals except when necessary for the purpose of professional evaluation or research at the institutional level.

I understand that *'professional evaluation'* applies to one or all of the following situations:

- Analysis of products (ingredients, taste, nutritional profile);
- Trial preparation and mixing of infant formula products (includes preparation and mixing instructions to mothers);
- Investigative or development projects, using sound methodology and involving a number of infants;
- A thorough assessment of the suitability of a product for an individual infant, including acceptance by the infant, when mothers have made the informed choice to use infant formula.

Where the suitability of a product is being assessed for an individual infant the professional evaluation will always include a follow-up meeting with the mother of the infant.

I understand that product samples should be kept out of public view.

Health Care Professional:	Position:
Signature:	
Address:	
Company Representative:	
	Date:

<Company name> is strongly committed to protecting your privacy and is committed to supporting the National Privacy Principles. Any information you provide us, including your personal information remains confidential