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Commonwealth of Australia

Competition and Consumer Act 2010 — subsection 91C (1)

APPLICATION FOR REVOCATION OF A NON-MERGER AUTHORISATION AND SUBSTITUTION OF A NEW AUTHORISATION

To the Australian Competition and Consumer Commission:

Application is hereby made under subsection 91C (1) of the *Competition and Consumer Act 2010* for the revocation of an authorisation and the substitution of a new authorisation for the one revoked.

PLEASE FOLLOW DIRECTIONS ON BACK OF THIS FORM

1. Applicant

(a) Name of applicant:

A91506 & A91507 Infant Nutrition Council Limited (***INC***).

(b) Description of business carried on by applicant:

The INC is the association for the infant formula industry in Australia and New Zealand and the key industry stakeholder in the advancement of infant nutrition. The INC represents manufacturers, marketers and brand owners of infant formula and infant milk substitutes.

(c) Address in Australia for service of documents on the applicant:

Infant Nutrition Council Limited
Level 2, Salvation Army Building
2-4 Brisbane Ave
Barton ACT 2600

2. Revocation of authorisation

(a) Description of the authorisation, for which revocation is sought, including but not limited to the registration number assigned to that authorisation:

Determination of the Trade Practices Commission (***TPC***) dated 23 September 1992 granting authorisation to applications A30146, A90539 and A90540 and determination of the Australian Competition and Consumer Commission dated 30 August 2007 varying authorisations A90539 and A90540. The authorisations and variation were made in relation to the Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement (***MAIF Agreement***) dated May 1992.

(b) Provide details of the basis upon which revocation is sought:

Revocation of authorisations A90539 and A90540 is sought because these authorisations will expire on 31 December 2015. The INC seeks to substitute in their place new authorisations of the MAIF Agreement (as amended or to be amended), on the same terms as the original authorisations (as amended). The INC seeks authorisation of the MAIF Agreement for a period of 10 years and that the authorisation apply to current and future manufacturers in, and importers into, Australia of infant formula that are or become parties to the MAIF Agreement.

The INC submits that the benefits which flow from the MAIF Agreement outweigh any 'detriment' to the public which may result from the restrictions set out in the MAIF Agreement.

Please see attached submission for further detail.

3. Substitution of authorisation

(a) Provide a description of the contract, arrangement, understanding or conduct whether proposed or actual, for which substitution of authorisation is sought:

The provisions of the MAIF Agreement (a copy of which is annexed to the attached submission).

(b) Description of the goods or services to which the contract, arrangement, understanding or conduct (whether proposed or actual) relate:

Infant formula for the feeding of infants up to the age of 12 months.

(c) The term for which substitute authorisation of the contract, arrangement or understanding (whether proposed or actual), or conduct, is being sought and grounds supporting this period of authorisation:

Ten years. The MAIF Agreement has been in place for a considerable period of time. The original authorisations relating to the MAIF Agreement were not time limited. The ACCC varied the authorisations on 30 August 2007 and proposed a time limit of approximately eight years, allowing the authorisations to expire on 31 December 2015.

Since that time, only minor amendments to the MAIF Agreement have been proposed. Accordingly, the INC submits that a period of not less than ten years is an appropriate time frame which will allow for regular review of the authorisation.

Please see attached submission for further detail.

4. Parties to the contract, arrangement or understanding (whether proposed or actual), or relevant conduct, for which substitution of authorisation is sought

(a) Names, addresses and description of business carried on by those other parties to the contract, arrangement or understanding (whether proposed or actual), or the relevant conduct:

Current and future manufacturers in, and importers into, Australia of infant formula that are or become parties to the MAIF Agreement. The relevant business carried on by those parties is the marketing and sale of infant formula. The current signatories to the MAIF Agreement:

Abbott Australasia Pty Ltd
Sir Joseph Banks Corporate Park
32-34 Lord St
Botany NSW 2019

Aspen Nutritionals Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065

Australian Dairy Park Pty Ltd
(application pending)
120 Frankston Gardens Drive
Carrum Downs VIC 3201

Bayer Australia Ltd
875 Pacific Highway
Pymble NSW 2073

H J Heinz Company Australia Ltd
2 Southbank Boulevard
South Melbourne VIC 3205

Nestlé Australia Ltd
1 Homebush Bay Drive
Rhodes NSW 2138

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

The a2 Milk Company Limited
Level 11
80 Mount St
North Sydney NSW 2059

The Infant Food Co Pty Ltd
12 Clearview Place
Brookvale NSW 2101

(b) Names, addresses and descriptions of business carried on by parties and other persons on whose behalf this application is made:
(Refer to direction 5)

Not applicable.

(c) Where those parties on whose behalf the application is made are not known - description of the class of business carried on by those possible parties to the contract or proposed contract, arrangement or understanding:

Not applicable.

5. Public benefit claims

(a) Arguments in support of application for substitution of authorisation:

The INC submits that the MAIF Agreement will continue to provide public benefits if re-authorised.

Please see attached submission.

(b) Facts and evidence relied upon in support of these claims:

Please see attached submission.

6. Market definition

Provide a description of the market(s) in which the goods or services described at 3 (b) are supplied or acquired and other affected markets including: significant suppliers and acquirers; substitutes available for the relevant goods or services; any restriction on the supply or acquisition of the relevant goods or services (for example geographic or legal restrictions):

The relevant market is the Australian market for the supply of infant formula for the feeding of infants up to the age of 12 months. Infant formula is product that meets the applicable requirements of the Australia and New Zealand Food Standards Code for Infant Formula Products (Standard 2.9.1).

Please see attached submission.

7. Public detriments

(a) Detriments to the public resulting or likely to result from the substitute authorisation, in particular the likely effect of the conduct on the prices of the goods or services described at 3 (b) above and the prices of goods or services in other affected markets:

The MAIF Agreement restricts the promotional activities of signatories. However, for the reasons set out in the submission, this should not be characterised as a public detriment. The INC submits that the benefits which flow from the MAIF Agreement outweigh any 'detriment' to the public which may result from these restrictions.

Please see attached submission.

(b) Facts and evidence relevant to these detriments:

Please see attached submission.

8. Contracts, arrangements or understandings in similar terms

This application for substitute authorisation may also be expressed to be made in relation to other contracts, arrangements or understandings (whether proposed

or actual) that are, or will be, in similar terms to the abovementioned contract, arrangement or understanding

(a) Is this application to be so expressed?

No. However, as set out in the submission, there are a number of policies and guidelines which assist members to interpret and implement the MAIF Agreement.

(b) If so, the following information is to be furnished:

(i) description of any variations between the contract, arrangement or understanding for which substitute authorisation has been sought and those contracts, arrangements or understandings that are stated to be in similar terms:

Not applicable.

(ii) Where the parties to the similar term contract, arrangement or understanding(s) are known - names, addresses and description of business carried on by those other parties:

Not applicable.

(iii) Where the parties to the similar term contract, arrangement or understanding(s) are not known — description of the class of business carried on by those possible parties:

Not applicable.

9. Joint Ventures

(a) Does this application deal with a matter relating to a joint venture (See section 4J of the *Competition and Consumer Act 2010*)?

No.

(b) If so, are any other applications being made simultaneously with this application in relation to that joint venture?

Not applicable.

(c) If so, by whom or on whose behalf are those other applications being made?

Not applicable.

DIRECTIONS

1. Where there is insufficient space on this form to furnish the required information, the information is to be shown on separate sheets, numbered consecutively and signed by or on behalf of the applicant.

2. Where the application is made by or on behalf of a corporation, the name of the corporation is to be inserted in item 1 (a), not the name of the person signing the application and the application is to be signed by a person authorised by the corporation to do so.

3. In item 1 (b), describe that part of the applicant's business relating to the subject matter of the contract, arrangement or understanding, or the relevant conduct, in respect of which substitute authorisation is sought.

4. In completing this form, provide details of the contract, arrangement or understanding (whether proposed or actual), or the relevant conduct, in respect of which substitute authorisation is sought.

   (a) to the extent that the contract, arrangement or understanding, or the relevant conduct, has been reduced to writing — provide a true copy of the writing; and

   (b) to the extent that the contract, arrangement or understanding, or the relevant conduct, has not been reduced to writing — provide a full and correct description of the particulars that have not been reduced to writing; and

   (c) If substitute authorisation is sought for a contract, arrangement or understanding (whether proposed or actual) which may contain an exclusionary provision — provide details of that provision.

5. Where substitute authorisation is sought on behalf of other parties provide details of each of those parties including names, addresses, descriptions of the business activities engaged in relating to the subject matter of the authorisation, and evidence of the party's consent to authorisation being sought on their behalf.

6. Provide details of those public benefits claimed to result or to be likely to result from the contract, arrangement or understanding (whether proposed or actual), or the relevant conduct, including quantification of those benefits where possible.

7. Provide details of the market(s) likely to be affected by the contract, arrangement or understanding (whether proposed or actual), in particular having regard to goods or services that may be substitutes for the good or service that is the subject matter of the application for substitute authorisation.

8. Provide details of the detriments to the public, including those resulting from the lessening of competition, which may result from the contract, arrangement or understanding (whether proposed or actual). Provide quantification of those detriments where possible.

9. Where the application is made also in respect of other contracts, arrangements or understandings, which are or will be in similar terms to the contract, arrangement or understanding referred to in item 2, furnish with the application details of the manner in which those contracts, arrangements or understandings vary in their terms from the contract, arrangements or understanding referred to in item 2.

10. Further information

(a) Name, postal address and telephone contact details of the person authorised by the parties seeking revocation of authorisation and substitution of a replacement authorisation to provide additional information in relation to this application:

Fiona Crosbie
Partner, Allens
GPO Box 50
Sydney NSW 2001
Telephone: (02) 9230 4383

Dated 20.7.2015

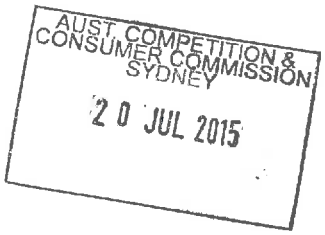
Signed by/on behalf of the applicant

Fiona Crosbie
.....
(Signature)

FIONA CROSBIE
.....
(Full Name)

ALLENS
.....
(Organisation)

PARTNER
.....
(Position in Organisation)



Allens › ‹ Linklaters

Infant Nutrition Council

Application to the Australian Competition and Consumer Commission for authorisation of the MAIF Agreement

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1 Executive Summary

The Infant Nutrition Council Limited (***INC***) seeks authorisation of the Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement (***MAIF Agreement***) and associated guidelines.

The INC was established in 2009 and is an amalgamation of the Infant Formula Manufacturers' Association of Australia and the New Zealand Infant Formula Marketers' Association. The INC represents the major manufacturers and marketers of infant formula in Australia and New Zealand as well as local manufacturers who are producing product for export. The members of the INC work with key stakeholders to support the public health goals of promoting breastfeeding and good nutrition for infants. The INC aims to:

- 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
- represent the infant formula industry in Australia and New Zealand.

All current signatories to the MAIF Agreement are members of the INC.

The MAIF Agreement was established in May 1992. It constitutes Australia's official application of the World Health Organization's International Code of Marketing of Breast Milk Substitutes (***WHO Code***). The MAIF Agreement is a voluntary self-regulatory code of conduct between manufacturers and importers to Australia of infant formula. It governs the marketing of infant formula for infants up to 12 months.

The INC proposes to make some minor amendments to the MAIF Agreement to ensure it reflects the current regulatory regime. The amendments are not substantive in nature and are set out in section 4 below.

The Trade Practices Commission (***TPC***) authorised the MAIF Agreement on 23 September 1992.[1] The authorisation was varied by the Australian Competition and Consumer Commission (***ACCC***) on 30 August 2007.[2] The effect of the variation was that the authorisation applied to current and future Australian manufacturers and importers of infant formula that are or become parties to the MAIF Agreement. The authorisation expires on 31 December 2015.

This application for re-authorisation is structured as follows:

- Section 2 outlines the authorisation that the INC is seeking and the legislative basis for the authorisation application.
- Section 3 defines the relevant market.
- Section 4 provides an overview of the MAIF Agreement and its scope, outlines the guidelines for the interpretation of the MAIF Agreement, and explains the role of the MAIF Complaints Tribunal in monitoring compliance with the MAIF Agreement.

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[1] TPC: Determination in relation to an arrangement for the Marketing in Australia of Infant Formula: Manufacturers and Importers on behalf of Abbott Australasia Pty Limited and Nestle Australia Limited (***TPC Determination***), 23 September 1992.

[2] ACCC: Determination in respect of application for Minor Variations of Authorisations A90539 and A90540 in respect of Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement (***ACCC Determination***), 30 August 2007.

- Section 5 outlines the public benefits arising from the MAIF Agreement, including why the MAIF Agreement is desirable as a matter of policy and is an effective voluntary code.
- Section 6 sets out the reasons that the public benefits arising from the MAIF Agreement outweigh any public detriments.

2 Authorisation of the MAIF Agreement

2.1 Terms of authorisation

The INC seeks revocation of authorisations A90539 and A90540 in respect of the MAIF Agreement (these authorisations will expire on 31 December 2015) and substitution of a replacement authorisation of the MAIF Agreement.

The INC is seeking authorisation of the MAIF Agreement for a period of 10 years without condition, in the same or similar terms to the original authorisations as amended. That is, the authorisation should apply to current and future Australian manufacturers and importers of infant formula that are or that have become parties to the MAIF Agreement. The INC sets out the reasons for the proposed term and application:

(a) *Ten year term*

The INC submits that the period of authorisation sought is appropriate, and is consistent with the view previously taken by the ACCC. The original authorisations granted by the TPC were not time limited. In 2007, on application from Nestlé, the ACCC amended the authorisations to introduce a circa 8 year time limit. The ACCC was satisfied that the benefit to the public was likely to increase upon the introduction of a review in light of possible changing circumstances.[3] Given the very few changes that have been made to the MAIF Agreement in those 8 years, the INC considers that a 10 year term is appropriate.

(b) *Application to both current and future members*

Previously, the ACCC considered it important to maintain the level of certainty afforded by the original authorisations by ensuring that new parties who signed the MAIF Agreement are covered by the authorisations. The ACCC concluded that this would maintain the industry-wide participation in the MAIF Agreement, and therefore the benefits from the authorisations would continue to be realised.[4] The INC submits that this authorisation should continue to provide for the addition of future parties, to encourage new parties to sign the MAIF Agreement. In this way, market participants would be less inclined to operate outside the terms of the MAIF Agreement and thereby result in the erosion of the public benefit resulting from the MAIF Agreement.

2.2 Legislative bases for the authorisation application

The INC requests that the authorisations granted by the TPC on 23 September 1992, and varied by the ACCC on 30 August 2007, in respect of the MAIF Agreement be substituted under subsection 91C(1) of the *Competition and Consumer Act 2010* (Cth) (***CCA***). Specifically, those applications for substitute authorisation in respect of the MAIF Agreement are:

[3] ACCC Determination, paragraph 6.9.

[4] ACCC Determination, paragraph 6.6.

- an application under subsection 88(1A) of the CCA for an authorisation under that subsection:
  - to make a contract or arrangement, or to arrive at an understanding, if a provision of the proposed contract, arrangement or understanding would be, or might be, a cartel provision; or
  - to give effect to a provision of a contract, arrangement or understanding if the provision is, or may be, a cartel provision; and
- an application under subsection 88(1) of the CCA for an authorisation under that subsection:
  - to make a contract or arrangement, or to arrive at an understanding, where a provision of the proposed contract, arrangement or understanding would be, or might be, an exclusionary provision within the meaning of section 45 of the CCA; and
  - to give effect to a provision of a contract, arrangement or understanding where the provision is or may be an exclusionary provision within the meaning of section 45 of the CCA; and
- an application under subsection 88(1) of the CCA for an authorisation under that subsection:
  - to make a contract or arrangement, or to arrive at an understanding, where a provision of the proposed contract, arrangement or understanding may have the purpose, or may have the effect of, substantially lessening competition within the meaning of section 45 of the CCA; and
  - to give effect to a provision of a contract, arrangement or understanding where the provision may have the purpose, or may have the effect, of substantially lessening competition within the meaning of section 45 of the CCA.

3 The Infant Formula Market

The INC submits that, consistent with the ACCC's approach in its review of the acquisition by Nestlé of Pfizer Nutrition,[5] the relevant market for the purposes of this authorisation is the Australian market for the supply of Starter Infant Formula and Follow-On Formula (***IFFO Formula***).

Regulations in Australia applicable to nutritional milk formulas for infants and toddlers generally distinguish between two types of products:

- IFFO Formula; and
- Growing-Up Milks (***GUMs***).

IFFO Formula has a special dietary use and is intended as a substitute for human breast-milk. IFFO Formula is formulated for infants aged between 0 and 12 months and is typically available in two compositions:

[5] ACCC: Public Competition Assessment – Nestle – proposed acquisition of Pfizer Nutrition, 3 May 2013, p5.

- Stage 1: starter infant formula – for infants aged 0 to 6 months; and
- Stage 2: follow-on formula – for infants aged 6 to 12 months.

Infant formula is a product that meets the applicable requirements of the Australia New Zealand Food Standards Code for Infant Formula Products.[6]

GUMs, also referred to as 'toddler milks', are formulated for children aged between 1 and 5 years (**Stage 3**). There are also **specialty formulas** (such as anti-reflux and lactose intolerance formulas) which are specifically formulated to address digestive problems or designed for infants and toddlers with special needs and are made available across all stages.

Infant formula products by their very nature are substitutes for human breast-milk. The INC submits that infant formula is the only suitable alternative to breast-milk. WHO guidelines suggest liquid animal milk (cow or goat), powdered animal milk and evaporated milk are also possible breast-milk substitutes; however, these are suggested as alternatives in emergency situations only.[7] Other infant food products include baby cereals and baby foods and drinks, however the INC does not consider these to be appropriate substitutes for breast-milk, and for that reason, not substitutable for infant formula.

The MAIF Agreement relates only to IFFO Formula and prohibits manufacturers and importers of IFFO Formula from advertising or promoting IFFO Formula directly to the general public. The MAIF Agreement does not apply to GUMs/toddler milks nor to retailers (such as supermarkets) or distributors of infant formula.

Infant formula products are traded globally, with products on the Australian market either made locally or imported. Food Standards Australia New Zealand (***FSANZ***) estimates that most infant formula products are imported into Australia, predominantly from either the European Union, or New Zealand, as there is a relatively small (in global terms) domestic market for these products.[8]

There are several companies marketing, and manufacturing or importing infant formula products in Australia. The major companies include a2 Nutrition, Abbott, Aspen Nutrition, Bayer, Bellamy's Organic, Heinz, Nestlé, Nutricia Australia and The Infant Food Co. In addition, some pharmacies and supermarkets supply their own private label infant formula. The signatories to the MAIF Agreement account for the majority of sales in Australia.[9]

The major retail outlets for selling infant formula products are supermarkets and pharmacies. According to IBISWorld:[10]

> ... Supermarket giants account for almost all domestic sales of infant formulas, with large chains like Coles and Woolworths typically stocking a large variety of different specialty baby formulas. However, there is competition from imported infant formula, which has limited the growth of this

[6] Australia New Zealand Food Standards Code, Standard 2.9.1.

[7] WHO, Guidelines for use of breast-milk substitutes in emergency situations (http://www.who.int/hac/crises/international/middle_east/Lebanon_guidelines_for_breast_milk_substitutes.pdf).

[8] Food Standards Australia New Zealand, Consultation Paper, *Regulation of Infant Formula Products in the Australia New Zealand Food Standards Code* (26 September 2012), p11.

[9] Department of Health, *Review of the effectiveness and validity of operations of the MAIF Agreement: Research Paper* (13 June 2012), p34.

[10] IBISWorld Industry Report C1133b, *Milk Powder Manufacturing in Australia* (February 2015), p14.

market for milk powder manufacturers. Supermarkets are estimated to account for 3.2% of industry revenue during 2015-16. The significant bargaining powers of large retail chains is pushing down the price that manufacturers receive. Revenue from sales to supermarkets have fallen as a share of industry revenue over the past five years.

4 The MAIF Agreement

4.1 Overview of the MAIF Agreement

The MAIF Agreement constitutes Australia's official application of the WHO Code. The MAIF Agreement was developed by the Australian Government, the infant formula industry, breastfeeding advocates and other stakeholders. The MAIF Agreement is a voluntary self-regulatory code of conduct between manufacturers and importers to Australia of infant formula and sets out the obligations of manufacturers and importers of infant formulas in Australia.

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, on the basis of adequate information through appropriate marketing and distribution (as per Article 11.1 of the WHO Code).

The MAIF Agreement applies to those Australian manufacturers and importers of infant formula who are signatories to the MAIF Agreement. A copy of the MAIF Agreement is provided at **Annexure 1**. A list of the current signatories to the MAIF Agreement is provided at **Annexure 2**.

In summary, the MAIF Agreement:

- applies to 'infant formula' that is suitable for babies from birth and follow-on formula that is suitable for babies from six months up to 12 months, or IFFO Formula;
- requires specified information to be contained in the educational material provided by manufacturers and importers which is intended for pregnant women or parents of young children and which relates to the feeding of infants;
- prohibits the advertising and promotion of infant formula by manufacturers and importers directly to the general public;
- restricts the information provided to health care professionals by manufacturers and importers regarding infant formulas to scientific and factual matters; and
- prohibits health care professionals and persons employed by manufacturers and importers from accepting or offering incentives to promote or sell infant formulas.

4.2 The scope of the MAIF Agreement

The WHO Code is broader in scope than the MAIF Agreement.[11] The TPC, in its original authorisation determination, noted that 'the voluntary implementation of a self-regulatory scheme, based on the full WHO Code, was not feasible', but that 'a workable self-regulatory arrangement,

[11] The WHO Code applies to all products marketed as partial or total substitutes for breast-milk for infants, including infant formula, other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented as suitable for use as a partial or total replacement of breast-milk, as well as feeding bottles and teats. The scope of the WHO Code extends to the manufacturers and importers of infant formula, feeding bottle and teats and to the retailing of these products.

short of the full WHO Code, could be implemented in the sectors of the industry which import and manufacture infant formula'.[12]

The MAIF Agreement applies to 'infant formula' that is suitable for babies from birth and follow-on formula that is suitable for babies from six months up to 12 months. It does not apply to toddler milk drinks suitable from 12 months,[13] complementary foods and feeding bottles and teats.

Retailers, such as supermarkets and pharmacies, and distributors of infant formula products are not signatories to the MAIF Agreement and are not bound by its terms. However, manufacturers and importers must not pursue or endorse promotional activities through retail channels unless those activities are allowed under the MAIF Agreement.

There are some retailers, primarily pharmacies, which supply their own private label infant formula. Typically, these retailers source infant formula from export manufacturers, brand the infant formula with their own company label and then sell it in the retail sector. Accordingly, these retailers do not manufacture or import infant formula themselves and therefore do not fall within the scope of the MAIF Agreement.[14]

The MAIF Agreement is complemented by other measures designed to implement the provisions of the WHO Code, including:

- Food Standards Australia New Zealand Standard 2.9.1, which is a mandatory labelling and composition standard for infant formula; and
- NHMRC Dietary Guidelines for Children and Adolescents in Australia incorporating the Infant Feeding Guidelines for Health Workers. These contain guidance for health workers on interpreting the WHO Code in Australia.

4.3 Amendments to the MAIF Agreement

In 2015 the following two minor amendments were made to the MAIF Agreement:

- the definition of 'infant formula' in clause 3 was amended so that it reflects the definition provided in Food Standards Australia New Zealand- Infant Formula Standard 2.9.1; and
- clause 10(b) has been deleted because it no longer applies.

4.4 Guidelines on the interpretation and application of the MAIF Agreement

Previously, the Advisory Panel on the Marketing in Australia of Infant Formula (***APMAIF***), a non-statutory advisory panel, was tasked with monitoring compliance with, and advising the Government on, the MAIF Agreement. The APMAIF ceased to operate from 8 November 2013. In considering complaints of alleged breaches of the MAIF Agreement, the APMAIF was required to make interpretations under the clauses of the MAIF Agreement and develop guidelines on the interpretation and application of the MAIF Agreement.

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[12] TPC Determination, paragraphs 2.3-2.7.

[13] In this respect, the MAIF Agreement differs from the WHO Code, which only applies to infant formula for use up to the age of 6 months.

[14] APMAIF, *Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) Submission to the Parliamentary Inquiry on the Benefits of Breastfeeding*, p10.

The interpretations were recorded in the *Guidelines on the interpretation and application of the MAIF Agreement by the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF)* (***Interpretation Guidelines***) which are available on the Department of Health website. A copy of the Interpretation Guidelines is provided at **Annexure 3**.

The Interpretation Guidelines continue to provide a reference point to companies and industry. However, the MAIF Complaints Tribunal (***Tribunal***) which is discussed in detail below, does not have to apply the Interpretation Guidelines when it makes a decision.

The INC also actively promotes understanding of the MAIF Agreement. The INC has developed guidelines to aid the interpretation of the MAIF Agreement in light of changes to the marketing environment and in community expectations over time. These guidelines are discussed below.

(a) Guidelines concerning the marketing of infant formula via electronic media

The INC developed guidelines on *Marketing of Infant Formulas via Electronic Media* to ensure that material displayed on manufacturers' websites and or communicated via other electronic media is consistent with the terms of the MAIF Agreement. These guidelines were adopted by the INC and endorsed by the Department of Health and the APMAIF on 10 September 2012.

A copy of *Marketing of Infant Formulas via Electronic Media* is provided at **Annexure 4**.

(b) Guidelines relating to interactions with health care professionals

The MAIF Agreement imposes limitations on the interaction between infant formula manufacturers and health care professionals.[15] The MAIF Agreement stipulates that information provided to health care professionals be restricted to scientific and factual matters, that manufactures and importers should not offer any financial or material inducement to promote infant formulas, and should not provide samples of infant formulas, or equipment or utensils for their preparation or use, to health care professionals, except when necessary for the purpose of professional evaluation or research.[16]

To ensure that interactions between manufacturers and importers of infant formula and health care professionals are appropriate, the INC developed *Guidance on Interactions with Healthcare Professionals*. The guidelines were approved by the INC Board on 31 January 2012.

The *Guidance on Interactions with Healthcare Professionals* was presented to the APMAIF at their meeting on 16 February 2012. The Panel members noted the guidelines appeared to have a 'common sense' approach.

A copy of *Guidance on Interactions with Healthcare Professionals* is provided at **Annexure 5**.

In addition to these guidelines, the Department of Health has published *Principles for the consideration of interactions with health care professionals for the purpose of interpreting*

[15] MAIF Agreement, clauses 4, 5 and 7.

[16] MAIF Agreement, clause 7.

the MAIF Agreement.[17] The INC considers that its guidelines embody these principles and operate as a guidance on how to put the principles into practice.

(c) Policy on the provision of samples of infant formula to health care professionals

The MAIF Agreement allows for the provision of samples of infant formula products to healthcare professionals only for the purposes of professional evaluation or research at the institutional level.[18] To ensure that samples are used properly under the terms of the MAIF Agreement, the INC developed a policy on *Distribution of Infant Formula Samples to Health Care Professionals*. The policy was approved by the INC Board on 19 May 2010 and was amended on 15 May 2012. The policy requires that no infant formula samples may be distributed unless they are first requested by a health care professional. The INC worked with the Australian Government and APMAIF to develop a template for a Samples Request Form that must be used before any samples are distributed. The Samples Request Form and the INC Samples Policy were accepted by the Department of Health and the APMAIF on 12 August 2010.

All members of the INC adhere to this policy and will only provide samples at the request of health care professionals. Before receiving the requested samples, health care professionals are required to sign an Infant Formula Sample Request Form stating that it is understood that the samples will only be used in accordance with the definitions of 'professional evaluation' or 'research'. The form also has information about the responsible use of samples including the condition that samples must never be left in public view.

A copy of *Distribution of Infant Formula Samples to Health Care Professionals* is provided at **Annexure 6**.

4.5 Compliance with the MAIF Agreement

The INC actively seeks to reduce non-compliance. Under the current MAIF Agreement, signatories are required to take responsibility for monitoring their own marketing practices in accordance with the arrangement.[19] In addition, previously the APMAIF, a non-statutory advisory panel, was tasked with monitoring compliance with, and advising the Government on, the MAIF Agreement. The APMAIF ceased to operate from 8 November 2013.

The Department of Health is responsible for monitoring compliance by receiving complaints about potential breaches of the MAIF Agreement, which are then referred to the MAIF Complaints Tribunal.

(a) The MAIF Complaints Tribunal

As a result of the APMAIF becoming inoperative on 8 November 2013, the MAIF Complaints Tribunal (***Tribunal***) was established by MAIF signatories in 2014 and is responsible for:

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[17] Available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/C071F9594B840C3CCA257BF00020A826/$File/General%20Principles%20final_endorsed%20by%20panel.pdf.

[18] MAIF Agreement, clause 7(d).

[19] MAIF Agreement, clause 10(a).

- receiving and investigating complaints regarding the marketing in Australia of infant formulas; and
- developing guidelines on the interpretation and application of the MAIF Agreement.

On 18 December 2014, the Assistant Minister for Health, Senator the Honourable Fiona Nash, stated that this tribunal 'meets Australia's obligations under the World Health Organization's International Code of Marketing of Breast-milk Substitutes (WHO Code)'. The Department of Health receives all complaints and refers in-scope complaints to the Tribunal.

The Tribunal is composed of three members. The current members are:

- Graeme Innes AM, Chair. Mr Innes has legal qualifications and experience in hearing and determining complaints that have involved both private and public interests;
- Dr Jacqui Dalby-Payne, a Public Health and Nutrition Expert with scientific and technical expertise in public health, nutrition, regulation around therapeutic goods and the food/drug interface; and
- Gillian Calvert AO, a community representative.

(b) The complaints process

The complaints process is set out in sections 22 to 38 of MAIF Complaints Tribunal Terms of Reference, a copy of which is provided at **Annexure 7**.

In summary, complaints may be submitted to the Commonwealth Department of Health, which are assessed and classified as being within or outside the scope of the MAIF Agreement. Complaints that have been assessed as falling within the scope of the MAIF Agreement, along with any supporting documents, are submitted to the Tribunal. The Tribunal will consider the complaint and the response to the complaint from the MAIF Agreement signatory company concerned. The Tribunal may decide initially that it does not represent a breach of the MAIF Agreement or that further consideration is required before a determination can be made.

In cases where a breach of the MAIF Agreement has been found, the Tribunal may make recommendations as to how the breach might best be remedied. The decision will be reported to the Department and recorded in the Tribunal's Annual Report.

5 Significant Benefits to the Public

Proper nutrition is crucial to the long-term mental and physical development of infants. Ensuring infants receive proper nutrition is a major public health concern.

The INC recognises that breastfeeding provides the best nutritional start for infants. The WHO Code states that breastfeeding is an 'unequalled way of providing ideal food for the healthy growth and development of infants'.[20] Further, the Australian Institute of Health and Welfare has acknowledged:

[20] WHO Code, p10.

> There is growing evidence that breastfeeding improves mother–infant bonding and secure attachment between mother and child (Allen & Hector 2005), an important factor in early childhood development. In addition, research has shown that breastfeeding protects infants against infectious diseases. Other possible benefits include a reduced risk of SIDS, Type 1 diabetes and some childhood cancers. Breastfeeding has also been found to be protective against wheezing in infancy (AIHW 2009b). There is also evidence that being breastfed may reduce the incidence of high cholesterol, high blood pressure, obesity and diabetes later in life, as well as improve cognitive development (Horta et al. 2007; Kramer et al. 2008).[21]

The Australian Government recognises that there is a large existing body of research and systematic reviews documenting the association between breastfeeding and infant, maternal and longer term health and acknowledges the social and economic benefits associated with breastfeeding.[22]

Accordingly, the Australian Health Ministers endorsed the Australian National Breastfeeding Strategy (***ANBS***) 2010-2015 at their meeting on 13 November 2009. The ANBS was developed in response to a 2007 Parliamentary Inquiry into the Health Benefits of Breastfeeding. The ANBS affirms the commitment of the Australian and state and territory governments to promoting the value of breastfeeding and improving breastfeeding rates in Australia. The stated aim of the ANBS is to contribute to improving the health, nutrition and wellbeing of infants and young children, and the health and wellbeing of mothers, by protecting, promoting, supporting and monitoring breastfeeding.[23]

As foreshadowed by the ANBS, in 2012, the Australian Government's National Health and Medical Research Council published a revised version of the *Infant Feeding Guidelines: Information for health workers.* This guidance seeks to encourage, support and promote breastfeeding in the Australian community.[24] It also provides that when infants are not breastfed, infant formula is the only suitable and safe alternative to meeting their primary nutritional needs and that it is therefore necessary to educate and support parents about formula feeding.[25]

The INC submits that in view of this, it is in the public interest to promote and protect breastfeeding; whilst also ensuring that appropriate information is provided to women who are unable to (or make an informed choice not to) breastfeed. Accordingly, 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, on the basis of adequate information and through appropriate marketing and distribution'.[26]

6 The MAIF Agreement is an Effective Voluntary Code

The ACCC and the Australian Government have accepted that an effective voluntary code that extends beyond the reach of statutory regulation is of significant public benefit.

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[21] Australian Institute of Health and Welfare *A picture of Australia's children 2012*, p30.

[22] Australian Government Response to *The Best Start: Report on the inquiry into the health benefits of breastfeeding*, p5.

[23] Australian National Breastfeeding Strategy 2010-2015, p3.

[24] Australian Government, National Health and Medical Research Council, *Infant Feeding Guidelines*, (2012).

[25] Australian Government, National Health and Medical Research Council, *Infant Feeding Guidelines*, (2012) p73.

[26] MAIF Agreement, cl 1.

As the ACCC Guidelines for developing effective voluntary industry codes of conduct note, 'there are significant benefits in developing and complying with voluntary industry codes'.[27] The ACCC Guidelines outline the following benefits of such codes:

- greater transparency of the industry;
- greater stakeholder confidence in the industry/business; and
- ensuring compliance with the CCA to significantly minimise breaches.

The ACCC Guidelines also outline several other benefits to developing industry codes:

- codes are more flexible than government legislation and can be amended more efficiently to keep abreast of changes in industries' needs;
- industry participants have a greater sense of ownership of such codes, leading to a stronger commitment to comply with the CCA;
- codes act as a quality control within an industry; and
- complaint handling procedures under such codes are generally more cost effective, time efficient and user friendly in resolving complaints than government bodies.

A review of the economic literature by Victoria University of Wellington concluded that the marketing of infant formula is a strong candidate for self-regulation.[28] The review indicated that compliance is likely to be high under self-regulation for reasons which include:

- low monitoring costs as a result of the inherently public nature of advertising and promotion;
- that breastfeeding is acknowledged as being superior as an industry and interest group norm;
- over-reporting of complaints, as suggested by the high proportion of complaints in Australia that are not upheld ; and
- the industry is supplied by a number of companies that are large, multi-national product firms that are relatively vulnerable to retaliation by consumers for misbehaviour.

The effective operation of the MAIF Agreement is also evident from the fact that potential breaches of the agreement are over-reported. From 2002 to 2013, approximately 1450 complaints were received but a significant majority (approximately 1200 complaints) were determined by the APMAIF Secretariat from the Department of Health to be outside the scope of the MAIF Agreement. During the entire 11 year period, there have been only six findings of a breach of the MAIF Agreement.[29]

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[27] ACCC *Guidelines for developing effective voluntary industry codes of conduct* July 2011, p3.

[28] M Burgess and N Quigley, *Effectiveness, Implementation and Monitoring of the International Code of Breast-Milk Substitutes in New Zealand: A Literature and Interview-Based Review* (15 July 2011), Research Trust of Victoria University, Victoria University of Wellington, p59.

[29] Based on data reported in Advisory Panel on the Marketing in Australia of Infant Formula publications: *Submission to the Parliamentary Inquiry on Benefits of Breastfeeding*, 20 June 2007, p6; Annual Reports in the period 2004 – 2013; *'Australia – The WHO Code and Breastfeeding: An International Comparative Overview'*, 3 May 2012:

Further, the Department of Health engaged the Nous Group to conduct a review of the MAIF Agreement. The *Review of the effectiveness and validity of operations of the MAIF Agreement: Research Paper* was published on 13 June 2012. The Research Paper concluded that the voluntary, self-regulatory nature of the MAIF Agreement is the most cost effective regulatory mechanism and should continue provided that it continues to promote the achievement of the aim of the MAIF Agreement and industry coverage levels remain high.

6.1 TPC concluded that the MAIF Agreement was likely to result in public benefits

The TPC determined that the public benefits likely to result from the MAIF Agreement were also likely to outweigh any anti-competitive detriment or other public detriment.[30] The TPC accepted that the following public benefits were likely to arise from the MAIF Agreement:[31]

- the provision of safe and adequate nutrition for infants, which is a necessary precondition for their long-term development, through the protection and promotion of breastfeeding and by encouraging mothers to obtain the information of the nutritional needs of their children from healthcare professionals;
- allowing information on formula feeding from trained health care professionals and that the information which is available is accurate and balanced; and
- allowing the decision by women who chose to breastfeed not to be undermined by advertising and promotional efforts.

6.2 Continued public benefits will result under reauthorisation

As set out above, 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, on the basis of adequate information and through appropriate marketing and distribution'. This gives effect in Australia to Article 1 of the of the WHO Code.

A number of public benefits flow from this including:

- protecting and promoting breastfeeding, which is recognised as the best form of nutrition for the healthy growth and development of infants;
- ensuring adequate information and appropriate marketing and distribution of breast-milk substitutes when they are necessary;
- restricting promotional activities which could undermine these objectives;
- setting consistent standards for the information to be provided to health care professionals, facilitating a focus on appropriate scientific and factual matters and education about infant formula products and their use;

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http://www.health.gov.au/internet/publications/publishing.nsf/Content/int-comp-whocode-bf-init~int-comp-whocode-bf-init-ico~int-comp-whocode-bf-init-ico-aus.

[30] TPC Determination at [6.6].

[31] TPC Determination at [6.2].

- outlining the boundaries for appropriate relationships between manufacturers and importers of infant formula products and health care professionals to limit the potential for conflicts of interest; and
- requiring manufacturers and importers of infant formula products to have internal compliance procedures which promote compliance by all company employees.

7 Benefits Outweigh Any Public Detriments

The MAIF Agreement does not result in any material anti-competitive or other public detriment. The MAIF Agreement restricts the promotional activities of signatories. However, for the following reasons, this is not appropriately characterised as a public detriment:

- as set out above, the restrictions are directed to meeting the important public health goals of protecting and promoting breastfeeding. The restrictions are intended to allow for the provision of safe and adequate nutrition for infants by ensuring that information is disseminated by appropriately trained health care professionals, and is scientific and factual;
- it is unlikely that these restrictions will have any negative impact for consumers. This is because the benefits normally attributed to direct advertising (namely, ensuring best quality and the lowest cost and creating an informed public) do not appear to be applicable to advertising of infant formula;[32] and
- in any event, a decision on whether to use infant formula should not depend upon the effectiveness of commercial advertising; rather, it should be the result of informed decision making based on objective and consistent advice, and appropriate supervision.[33]

The MAIF Agreement does not restrict the activities of retailers of infant formula and the restrictions imposed by the MAIF Agreement on manufacturers and importers do not strike at the heart of competitive conduct as to price and quality of infant formula.

This distinction is made clear in the Interpretation Guidelines which acknowledges that in-store and catalogue promotions which refer only to price and price savings of infant formula and follow-on products would not be investigated as potential breaches of the MAIF Agreement. To clarify this position, the APMAIF developed *Guidelines for in-store promotions of infant formula by manufacturers in Australia through retailers.* A copy of these guidelines is provided at **Annexure 8**.

The INC has also developed a brochure for retailers that explains manufacturers and importers' obligations under the MAIF Agreement. A copy of this brochure, titled *Information for Retailers – Manufacturers and Importers' Obligations for the Marketing of Infant Formula in Australia,* is provided at **Annexure 9**. The brochure states that:

- retailers are not bound by the terms of the MAIF Agreement;

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[32] World Health Organisation, *Infant Formula and Related Trade Issues in the Context of the International Code of Marketing of Breast-Milk Substitutes* http://www.who.int/nutrition/infant_formula_trade_issues_eng.pdf.

[33] World Health Organisation, *Infant Formula and Related Trade Issues in the Context of the International Code of Marketing of Breast-Milk Substitutes* (http://www.who.int/nutrition/infant_formula_trade_issues_eng.pdf).

- the price promotion of infant formula (such as 'special prices' and discounts) is allowed; and
- 'it is therefore open to manufacturers and retailers to price promote infant formula products in a similar manner to other products'.

Further, the MAIF Agreement does not restrict product research and innovation, nor prevent appropriate communication of information about infant formula products, including the provision of scientific and factual information to appropriately qualified health care professionals.

The INC therefore submits that any minimal detriment associated with restricting the promotional activities of signatories to the MAIF agreement is substantially outweighed by the public benefits of the MAIF Agreement.

Allens

Solicitors for Infant Nutrition Council

20 July 2015

Annexure 1 – Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement

Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement

The MAIF Agreement

Preamble

This document sets out the obligations of manufacturers in and importers to, Australia of infant formulas and gives effect in Australia to the principles of the *World Health Organization's International Code of Marketing of Breast Milk Substitutes* (WHO Code)[1].

Clause 1: Aim

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 they are necessary[2], on the basis of adequate information and through appropriate marketing and distribution. (WHO Code Article 1)

Clause 2: Scope

This document applies to the marketing in Australia of infant formulas when such products are marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk. It also applies to their quality and availability, and to information concerning their use. (WHO Code Article 2)

Clause 3: Definitions

'Breast milk substitute' - any food marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.

'Container' - any form of packaging of infant formulas for sale as a normal retail unit, including wrappers.

'Health care system' - governmental, non-governmental or private institutions engaged, directly or indirectly, in health care for mothers, infants and pregnant women and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this document, the health care system does not include pharmacies or other retail outlets.

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

'Infant formula' - any food described or sold as an alternative for human milk for the feeding of infants up to the age of twelve months and formulated in accordance with Australian Food Standard R7 - Infant Formula.

'Label' - any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of infant formulas.

'Marketing' - includes the promotion, distribution, selling, advertising, public relations and information services related to infant formulas.

'Marketing personnel' - any persons whose functions include the marketing of infant formulas.

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[1] Where applicable, clauses in this document are cross-referenced to the relevant articles from the World Health Organization (1981) *International Code of Marketing of Breast-milk Substitutes*, Geneva (WHO Code).

[2] For the purposes of the Aim, 'necessary' includes mothers who make an informed choice to use breast milk substitutes.

'Samples' - single or small quantities of an infant formula provided without cost. (WHO Code Article 3)

Clause 4: Information and Education

4(a) Manufacturers and importers of infant formulas in Australia agree that informational and educational materials, whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women and parents of infants and young children, should always include clear information on all the following points:

(i) the benefits and superiority of breastfeeding;

(ii) maternal nutrition, and the preparation for and maintenance of breastfeeding;

(iii) the negative effect on breastfeeding of introducing partial bottle-feeding;

(iv) the difficulty of reversing the decision not to breastfeed; and

(v) where needed, the proper use of infant formula, whether manufactured industrially or home prepared. (WHO Code Article 4.2)

4(b) When such materials contain information about the use of infant formulas, they should include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods and, in particular, the health hazards of unnecessary or improper use of infant formulas. Such materials should not use any pictures or text which may idealise the use of infant formulas. (WHO Code Article 4.2)

4(c) Manufacturers and importers of infant formulas should not donate informational or educational equipment or materials unless it is at the request of, and with the written approval of, the appropriate government authority or within guidelines given by the Commonwealth, State or Territory Governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary infant formula, and should be distributed only through the health care system. (WHO Code Article 4.3)

Clause 5: The general public and mothers

5(a) Manufacturers and importers of infant formulas should not advertise or in any other way promote infant formulas to the general public. (WHO Code Article 5.1)

5(b) Manufacturers and importers of infant formulas should not provide samples of infant formulas to the general public, pregnant women, parents or members of their families. (WHO Code Article 5.2)

5(c) Manufacturers and importers of infant formulas should not distribute to pregnant women, or parents of infants and young children, any gifts of articles or utensils which may promote the use of breast milk substitutes or bottle-feeding. (WHO Code Article 5.4)

5(d) Marketing personnel, in their business capacity, should not seek direct or indirect contact with pregnant women or with parents of infants and young children. This does not prevent appropriately qualified personnel from responding to complaints or unsolicited requests for information. For these requests, parents should be referred to a health care professional whenever health advice is required. (WHO Code Article 5.5)

Clause 6: Health care system

6(a) Manufacturers and importers of infant formulas should not use any facility of the health care system for the purpose of promoting infant formulas. This does not, however, preclude the dissemination of information to health care professionals as provided in clause 7(a). (WHO Code Article 6.2)

6(b) Manufacturers and importers of infant formulas should be aware that facilities of health care systems should not be used for the display of products within the scope of this document, for placards or posters

concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in clause 4(c) above. (WHO Code Article 6.3)

6(c) The use by the health care system of pharmacies or retail outlets, 'professional service representatives', 'mothercraft nurses', or similar personnel, provided or paid for by manufacturers or importers of infant formulas is not permitted. (WHO Code Article 6.4)

6(d) Manufacturers and importers of infant formulas should be aware that feeding with infant formulas, whether manufactured or home prepared, should be demonstrated only by health care professionals. Such demonstrations should be made only to the parents or other persons who need to use it, and the information given should include a clear explanation of the hazards of improper use. (WHO Code Article 6.5)

6(e) Manufacturers and importers of infant formulas may make donations, or low-priced sales, of infant formulas to institutions or organisations, whether for use in the institutions or for distribution outside them. Such provisions should only be used or distributed for infants who have to be fed on breast milk substitutes. If these provisions are distributed for use outside the institutions, this should be done only by the institutions or organisations concerned. Manufacturers or importers should not use such donations or low-price sales as a sales inducement. (WHO Code Article 6.6)

6(f) Manufacturers and importers of infant formulas should note that, where donated infant formulas are distributed outside an institution, the institution or organisation should take steps to ensure that these provisions can be continued as long as the infants concerned need them. Donors, as well as the institutions or organisations concerned should bear in mind this responsibility. (WHO Code Article 6.7)

6(g) Equipment and materials, in addition to those referred to in clause 4(c), donated to a health care system may bear a company's name or logo, but should not refer to any proprietary infant formulas. (WHO Code Article 6.8)

Clause 7: Health Care Professionals

7(a) Manufacturers and importers of infant formulas providing information about the formulas to health care professionals should restrict the information to scientific and factual matters. Such information should not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. It should also include the information specified in clause 4(a) above. (WHO Code Article 7.2)

7(b) Manufacturers and importers of infant formulas should provide members of the medical profession and related health care professionals with information about the products, and this information should accurately reflect current knowledge and responsible opinion. Such material should be clearly identified with the name of the manufacturer or importer, the brand names of the infant formulas, and the date of publication.

7(c) Manufacturers and importers of infant formulas should not offer any financial or material inducement to health care professionals or members of their families to promote infant formulas, nor should such inducements be accepted by health care professionals or members of their families. (WHO Code Article 7.3)

7(d) Manufacturers and importers of infant formulas should not provide samples of infant formulas, or of equipment or 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. (WHO Code Article 7.4)

7(e) Manufacturers and importers of infant formulas should disclose to institutions, to which a recipient health care professional is affiliated, any contribution made to him/her, or on his/her behalf, for fellowships, study tours, research grants, attendance at professional conferences, or the like. (WHO Code Article 7.5)

Clause 8: Persons employed by manufacturers and importers

8(a) In systems of sales incentives for marketing personnel, the volume of sales of infant formulas should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it. (WHO Code Article 8.1)

8(b) Personnel employed in marketing infant formulas should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or parents of infants and young children. This does not prevent such personnel from being used for other functions by the health care system. (WHO Code Article 8.2)

Clause 9: Quality and Labelling

9(a) Manufacturers and importers of infant formulas must ensure that infant formulas sold in Australia conform to Australian Food Standard R7 — Infant Formula. (WHO Code Articles 9.2, 9.4, 10.1 and 10.2)

9(b) Manufacturers and importers of infant formulas must ensure that labels provide the information required to be provided by the Australian Food Standard A1 - Labelling and Advertising and Standard R7 - Infant Formula, and also provide the necessary information about the appropriate use of infant formula and should not discourage breastfeeding. (WHO Code Article 9.1)

Clause 10: Implementation and monitoring

10(a) Independently of any other measures taken to implement their obligations under this document, each manufacturer and importer of infant formulas should regard itself as responsible for monitoring its marketing practices according to the principles and aim of this document, and for taking steps to ensure that its conduct at every level conforms to those principles and aims. (WHO Code Article 11.3)

10(b) Manufacturers and importers of infant formulas agree to be represented on APMAIF and to participate fully in the work of the Advisory Panel.

10(c) Each manufacturer and importer of infant formulas should apprise its personnel of the existence of this document and of their responsibilities under it. (WHO Code Article 11.5)

Annexure 2 – List of current signatories to the MAIF Agreement

Abbott Australasia Pty Ltd

Aspen Nutritionals Australia Pty Ltd

Australian Dairy Park Pty Ltd (application pending)

Bayer Australia Ltd

H J Heinz Company Australia Ltd

Nestlé Australia Ltd

Nutricia Australia Pty Ltd

The a2 Milk Company Limited

The Infant Food Co Pty Ltd

Annexure 3 – Guidelines on the interpretation and application of the MAIF Agreement by the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF)

Guidelines on the interpretation and application of the MAIF Agreement by the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF)

These guidelines are developed by the APMAIF to assist with the interpretation and application of the MAIF Agreement. The guidelines do not form part of the Agreement and do not substitute for the actual wording of the terms of the Agreement. Where examples of specific activities are given, they are provided as guidance only and should not be considered exclusive or exhaustive. Each guideline is subordinate to, and should be considered in the context of, the clause(s) to which it relates.

The guidelines constitute a 'living document' which may be amended from time to time in order to remain relevant and up-to-date in a changing marketing environment.

In developing and reviewing these guidelines, the APMAIF focuses on the aim of the MAIF Agreement as outlined in Clause 1. The APMAIF is also aware of the need to ensure that the guidelines remain consistent with the requirements of the *Competition and Consumer ACT* (2010) (TPA) concerning anti-competitive conduct, having regard to the relevant TPA Authorisations relating to the MAIF Agreement itself.

Clause 4(a): Manufacturers and importers of infant formulas in Australia agree that informational and educational materials, whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women and parents of infants and young children, should always include clear information on all the following points:

(i) the benefits and superiority of breastfeeding;
(ii) maternal nutrition, and the preparation for and maintenance of breastfeeding;
(iii) the negative effect on breastfeeding of introducing partial bottle-feeding;
(iii) the difficulty of reversing the decision not to breastfeed; and
(v) where needed, the proper use of infant formula, whether manufactured industrially or home prepared. (WHO Code Article 4.2).

Clause 4(b): When such materials contain information about the use of infant formulas, they should include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods and, in particular, the health hazards of unnecessary or improper use of infant formulas. Such materials should not use any pictures or text which may idealise the use of infant formulas. (WHO Code Article 4.2)

Inclusion of information

- The information required by clauses 4(a) and 4(b) should be included in material of any format (eg. video, written, audio, electronic, etc.) which refers to infant formula that is produced or sponsored by an infant formula manufacturer (December 1993).
- The information required by clauses 4(a) and 4(b) should be included in the main body of the material in the same type of presentation as the rest of the material, and at a level suitable for the target audience. A mother or other carer should be able to understand what it means (December 1993).

- The print size of the information required by clauses 4(a) and 4(b) should be the same size as the majority of the main text or at least 8 point (September 1993).
- The social and financial implications of infant formula use are inter-related. They may include the following points:
  - the weekly cost of formula and/or the impact on the family budget; and
  - notice that infant formula will need to be purchased until the baby is 12 months of age (March 1994).

Pictures on informational or educational material for health professionals

- Certain pictures may be acceptable on materials for health professionals (1994).
- Cartoons and pictures of animals and toys do not necessarily idealise the use of infant formulas and therefore may be acceptable. They should not depict an animal or toy being fed, whether by breast or by bottle, nor should they depict animal or toy 'mothers', because these may idealise the use of infant formula (1994).
- Real babies depicted in a normal context do not necessarily idealise the use of infant formulas and may legitimately draw a health professional's attention to information about an infant formula. However:
  - babies (with or without bottles) in fantasy situations (e.g. stars, heavens, clouds, sitting up in school) should not be depicted because they may suggest formula-fed babies are in some way 'ahead' of breastfed babies (March 1994);
  - babies with slogans over or adjacent to the pictures should not be used in such a way as to imply that the product is better than breast milk or idealise the use of infant formula (March 1994); and
  - A picture of an apparently newly born baby should not be used to draw attention to information about infant formula. Breast milk is the best milk for babies up to 12 months old, but it is particularly valuable in the first few weeks of life when the baby is most vulnerable. Baby models for such pictures should be no younger than three months (February 1995).
- A picture of a woman breastfeeding should not be used to draw attention to information about infant formula because it:
  - may create an impression that the product is equivalent to breastfeeding;
  - appropriates the image of breastfeeding for the purpose of promoting a product; and
  - may be considered a misleading way of gaining attention (March 1994).

Clause 4(c): Manufacturers and importers of infant formulas should not donate informational or educational equipment or materials unless it is at the request of, and with the written approval of, the appropriate government authority or within guidelines given by the Commonwealth, State or Territory Governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary infant formula, and should be distributed only through the health care system. (WHO Code Article 4.3)

- Instructions on how to prepare a specific infant formula may include the brand logo and should include the product name. Such materials should be limited to preparation instructions only and should not include other educational or promotional information (March 1994).

- Articles (such as pens and monogrammed paper) which bear a brand name and not just a logo should not be distributed at conferences. A slogan may be different to a logo (March 1994).
- Inexpensive materials likely to be used only in the process of professional duty (provided they are not readily given to mothers, for example small 'tear off' note pads) may be acceptable. Materials of a personal nature such as coffee mugs are not considered acceptable. Any such materials should bear only the company name and logo, and not a product brand name or a slogan (March 1994).
- The provision of basic refreshments at informational/educational events is acceptable provided it is in association with a presentation that coincides with a mealtime and that is not of a lavish nature (March 1994).

Clause 5(a): Manufacturers and importers of infant formulas should not advertise or in any other way promote infant formulas to the general public. (WHO Code Article 5.1)

Advertisements to the general public

- Information for parents about the availability of infant formula should be accessible subject to the following:
  - announcements regarding changes to availability of infant formulas (for example, when formulas became available in supermarkets) are acceptable, but only on a one-off basis. Advertisements should appear only once in any one publication over a maximum three month period (to allow for inclusion in quarterly publications);
  - references to outlets of availability should be restricted to generic locations such as 'toy stores' or 'supermarkets', but not to specific locations such as 'Coles' or 'Woolworths';
  - such advertisements should have no promotional content. There should be no slogans and the logo should not include a slogan. Advertisements should not promote or encourage use of formula;
  - changes in formulation should be referred to only on the container, not promoted in advertisements (March 1994); and
  - pack shot size should be restricted to 4 cm x 3 cm (February 1996).
- New infant formula products should not be advertised or 'announced' to the general public (1994).
- When an infant formula manufacturer advertises to the general public a product with the same name as an infant formula, the product name should be followed either by the range name (e.g. toiletries) or the specific product (e.g. baby powder). Generalised terms such as 'Brand X Baby Care Products' or 'Brand X, Best for Baby', should not be used where Brand X is the name of an infant formula (June 1996).
- Slogans which could imply that feeding a baby the product would be better than breastfeeding should not be used – for example 'Every baby deserves the best' or 'A little extra something' (March 1994). However, slogans which clearly and distinctly compare infant formula products may be acceptable.

Clause 5(b): Manufacturers and importers of infant formulas should not provide samples of infant formulas to the general public, pregnant women, parents or members of their families. (WHO Code Article 5.2)

- Free samples should not be provided by manufacturers through pharmacies except at the request of a qualified health professional for the purposes of professional evaluation. However, small packs could be made available in retail outlets for purchase at commercial competitive rates. (February 1993).

Clause 7(a): Manufacturers and importers of infant formulas providing information about the formulas to health care professionals should restrict the information to scientific and factual matters. Such information should not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. It should also include the information specified in clause 4(a) above. (WHO Code Article 7.2)

Interpretation of the term 'scientific'

- Scientific information should reflect the current scientific knowledge in total, not simply selective parts that can be used in a misleading way (February 1993).

Use of the terms 'resembles', 'is close to' and 'is similar to'

- It is not considered scientific or factual to claim that a product resembles, or is similar to, or is close to breast milk unless the ingredient that the company claims is similar to that in breast milk is specified, and evidence is provided which satisfies the Panel that this specific claim is valid.
- Where these terms are used without a specific claim, the manufacturer may be considered to be implying equivalence with breast milk.
- In informational material for health professionals, a manufacturer sometimes wishes to point out that mothers who cannot breastfeed should be advised that they should use an infant formula that resembles breast milk more closely than cow's milk. The term 'resembles breast milk' should be used only in this context of the comparison with cow's milk (December 1993).
- The following should be included in information used in promotional pieces to compare breast milk with infant formula or ingredients of infant formula:
    1. the units of measurement;
    2. the specific type of breast milk sample which is being compared;
    3. the average or mean values and the standard deviation; and
    4. the references for the source of data (January 1999).

Access to health professionals

- It is up to health care professionals to decide whether they wish to see representatives of formula manufacturers. There is nothing in the MAIF agreement, nor in the WHO Code, which prevents the access of representatives to health care professionals, and indeed such

access may play an important part in providing information about infant formula to health care professionals (June 1994 – February 1995).

- Information materials for health professionals should not contain pictures, music or other devices that are likely to be attractive to young children, and therefore might lead to health professionals putting them on display or giving them to children and parents to look at or play with. Examples might include use of music, posters or mobiles (December 1995).
- It is reasonable for manufacturers to provide information for retailers of their products in trade journals only. The information should comply with the restrictions of clause 7(a) and clause 4(a) of the MAIF Agreement. They should not be promotional in any way, and the information should be restricted to the scientific and factual. In addition, such information should be able to be understood by retailers who are not health professionals (June 1996).

Clause 7(c): Manufacturers and importers of infant formulas should not offer any financial or material inducement to health care professionals or members of their families to promote infant formulas, nor should such inducements be accepted by health care professionals or members of their families. (WHO Code Article 7.3)

Inducements

- Items such as pens and papers (with the company name or logo only) designed for personal use may be handed out at a conference. However, if the gifts were designed to be taken home, this may be classed as an inducement. These materials should not be left in a hospital ward or other health care facility (September 1993).
- Anything intended or likely to be taken home may be considered an inducement.
- Competitions, included in information material for health professionals, which are clearly for the purpose of emphasising information that is restricted to the scientific and factual, may be acceptable. Such competitions, however, should not be an inducement to promote infant formulas. Therefore the prize should not exceed a value of $100. Manufacturers should also be mindful of clause 4(c) (February 1996).
- The provision of basic refreshments at informational/educational events is acceptable provided it is in association with a presentation that coincides with a mealtime and is not of a lavish nature (March 1994).

Advertising

- A diary may be considered an inducement; however, where the diary provides information regarding infant formula in a subtle and appropriate manner, the information conforms with the requirements of the MAIF agreement and its interpretations, and the diary offers a source of scientific information not readily available to health professionals, then the diary may be viewed as primarily informational with the intention that the diary be for professional use rather than home use. Without the appropriate informational component, the diary may be considered similar to an item intended to induce the professional health care worker (September 2003).

Clause 7(d): Manufacturers and importers of infant formulas should not provide samples of infant formulas, or of equipment or 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. (WHO Code Article 7.4)

- Infant formula given to child care or day care centres for distribution in single or small quantities to parents when a mother has forgotten to bring her own formula or when the baby's formula has unexpectedly been exhausted, will be considered, according to the definition in the MAIF Agreement, as a 'sample'. Child care centres are not a setting in which professional evaluation of infant formula occurs, there is therefore no valid reason for manufacturers to give samples of infant formula to child care centres (May 1995).

The position of APMAIF on conferences, seminars or publications, under the auspices of another organisation, by manufacturers of infant formula

Sponsorship of conferences, seminars or publications by manufacturers of infant formula does not necessarily breach the Agreement. However:

- Any sponsorship of meetings, seminars or conferences should be declared. There should be no conditions which relate to the marketing of the sponsor's product or to restrictions on promotion of breastfeeding.
- The sponsor should not exert any influence on the choice of speakers or the content of presentations.
- In line with clause 4(c) of the Agreement, any conference materials may bear the donating company's logo, but should not refer to a proprietary infant formula, and should be distributed only through the health care system.

Annexure 4 – Marketing of Infant Formulas via Electronic Media

Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

MARKETING OF INFANT FORMULAS VIA ELECTRONIC MEDIA

Overall Principles

1. The purpose of these guidelines is to support the interpretation of the MAIF Agreement and the INC Code of Practice in NZ.

2. These guidelines are to be read with the aim of the MAIF Agreement and the INC Code of Practice in mind and as an overarching principle: that is, to contribute to the 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, on the basis of adequate information and through appropriate marketing and distribution.

Consumer-based websites

3. Prior to a consumer accessing information about infant formula on a manufacturer website, manufacturers should display to the consumer the information required by clauses 4(a) and 4(b) (**Important Notice information**). This display should include a click-through acknowledgement by the consumer that the consumer has read and understood the information. The display should be provided at least once per day for each consumer who accesses the site on multiple occasions.

4. A tab or link labelled 'Breastfeeding is Best', 'Benefits of Breast Milk' or similar, which links to the Important Notice information, should be included on each page of a website which provides information about an infant formula product. The tab/link should be included on the navigation toolbar of each web page or another equally prominent location.

5. The inclusion of product information about infant formula, including pack shots, on a website is acceptable, provided guidelines 3 and 4 are followed and:

   - the product information is the same as the information on the label of the product (for example: ingredient listing, nutritional profile and nutrition information);
   - any additional information provided is factual in nature and intended to provide sufficient information to help consumers to make an informed choice as to the specific nature of the infant formula, any intended special purpose, and the differences between formulas; and
   - product logos are not displayed independently of pack shots.

[*Note: the objective here is a safe harbours approach – provide parameters around what is ok, and then it will be for individual companies to take a view outside of that.*]

Frequently Asked Questions

6. FAQ pages on websites are an important means of providing information regarding formulas to consumers, and assisting consumers to differentiate between different types of formula.

7. Any FAQ pages relating to infant formula should commence with a statement as to why breastfeeding is best. This can be in the form of a statement at the top of the page, or an initial question and answer.

8. FAQs relating to infant formula should be guided by the same principles as guideline 5 above. For example, the following type of question and answer is acceptable:

    - *'What is [ingredient/component]?'* [Ingredient/component] is a [description]. [Ingredient/component] can [describe function eg help maintain bowel motions / reduce the incidence of [condition].

9. If an FAQ relates to a named health condition, then in addition to any other information provided the answer should direct consumers to speak to a healthcare professional should they require further information.

Other electronic communications and social media

10. In accordance with these guidelines, manufacturers and importers should adopt reasonable measures, to monitor social media forums such as Twitter, Facebook and YouTube, which are within their control.

11. Manufacturers should not initiate discussion or actively provide information about infant formula via social media such as Twitter, Facebook, YouTube or electronic forums. However it is recognised that manufacturers and importers cannot control postings by consumers or third parties on such forums, which are not under their control and are therefore entitled to respond to issues or questions raised provided:

    - the question is directed to the manufacturer or the issue requires a corrective or clarifying statement;
    - the response is in the same forum;
    - the response is in line with guideline 5 above and, unless the context otherwise requires, limited to the matters raised by the consumer or third party post;
    - if a question relates to a health condition, the consumer is directed to speak to a healthcare professional; and
    - includes a statement to the effect that breastfeeding is best for babies, which links to the Important Notice Information on the manufacturer's website.

12. Electronic mailings to consumers (such as e-newsletters) should only include information about infant formula, which is otherwise permitted under the MAIF Agreement (for

example, an announcement about change of availability). Where appropriate, the relevant communication should include the Important Notice information.

13. Manufacturers are entitled to initiate communication to consumers via social media on urgent health and safety matters provided the communication is limited to the health and safety matter.

Annexure 5 – Guidance on Interactions with Healthcare Professionals

Infant Nutrition Council
Industry supporting both Breastfeeding & Infant Formula
AUSTRALIA & NEW ZEALAND

Guidance on Interactions with Healthcare Professionals

The Infant Nutrition Council supports appropriate interactions between infant formula manufacturers and healthcare professionals, with the primary aim of providing scientific and factual information about infant and follow-on formulas. Interactions with healthcare professionals may include visits with company representatives, educational events, consultancy arrangements, and sponsorship of healthcare professionals.

For the purposes of this guidance document, the term *healthcare professional* includes, but is not restricted to, medical practitioners, pharmacists, nurses, midwives, dietitians and nutritionists. Pharmacy technicians or assistants are not considered healthcare professionals. However, it is recognised that they play an important role as part of the community pharmacy healthcare team, and as such may be provided with educational material and training on infant formula with the agreement or at the request of the relevant pharmacist.

1. Visits with Company Representatives

These visits should ideally occur at the workplace of the healthcare professional, but may take place at an appropriate alternative venue. Any hospitality provided during such visits must be modest, secondary to the intent of the interaction, and should be considered appropriate by a reasonable person based on the professional standing of the healthcare professionals in attendance.

2. Educational Events

The primary purpose of an educational meeting must be the enhancement of medical or scientific knowledge or product information, products. At company-organised meetings which relate to infant formula, the benefits of breastfeeding should always be clearly communicated. For company-organised educational meetings, venues should be chosen in reasonable proximity to the majority of delegates, and must not be considered by a reasonable person to be lavish or offer excessive hospitality. Companies may also sponsor third party meetings, but must ensure that these meetings contain a suitable level of medical or scientific education. The independence of external speakers educational content must be maintained at both company and third-party sponsored events.

3. Sponsorship of Healthcare Professionals

Companies may sponsor individual healthcare professionals to attend educational meetings within Australia or New Zealand, or at international venues. The choice of healthcare professional must be based on the individual's interest in the area of science being discussed and if required, their ability to communicate any relevant information gathered from these meetings.

Approved by the Board – 31 January 2012

It is recommended that when agreeing to provide sponsorship of a healthcare professional to attend an educational meeting, companies should have a formal letter of agreement with the individual that will receive the sponsorship.

In Australia, it is a requirement of the MAIF Agreement that companies disclose any such sponsorship (as well as fellowships or study tours) to the institution with which the recipient healthcare professional is affiliated, and this is also encouraged in New Zealand.

4. Consultancy Arrangements

Companies have a number of legitimate reasons for engaging healthcare professionals in consultancy arrangements, including as speakers at educational meetings, to provide scientific advice, prepare scientific reports, and for clinical or basic research. It is recommended that all such arrangements are formally documented in consultancy agreements, and any payments should be consistent with fair and usual market rates for the service provided.

In Australia, it is a requirement of the MAIF Agreement that companies disclose research grants to the institution with which the recipient healthcare professional is affiliated, and this is also encouraged in New Zealand.

5. Sponsorship of Healthcare Professional Practice Activities

Companies may sponsor bona fide activities aimed at improving patient health outcomes, provided that there is no direct financial benefit for the participating healthcare practices or professionals. Funding for practice staff involved in routine activities, or 'mothercraft nurses' or staff engaged in similar activities is not permitted.

6. Entertainment

The Infant Nutrition Council has agreed that no stand-alone entertainment should be provided to healthcare professionals. Examples of conduct which would not be considered acceptable include invitations to any sporting or artistic events, regardless of the cost or circumstance. This prohibition does not extend to entertainment provided to delegates at scientific conferences.

7. Travel

The cost of travel for delegates to educational meetings may be subsidised or paid for in full. For meetings held within Australia or New Zealand, it is recommended that travel ideally be by economy class only (unless there is a documented medical condition or on reasonable grounds which requires business class travel). However the professional standing of the healthcare professional may also be taken into consideration. For international travel either economy or business class is acceptable.

8. Venue / Accommodation

The cost of accommodation for delegates to educational meetings may also be subsidised or paid for in full.

The venue for educational meetings should be appropriate to the meeting, based on the type and length of meeting and facilities required and taking into account the standing of the delegates.

Approved by the Board – 31 January 2012

9. Hospitality

Hospitality in the form of food and beverages may be offered to healthcare professionals, but the cost must always be reasonable, and appropriate for the situation. The Infant Nutrition Council has agreed that hospitality should not be provided at venues which would be considered by a reasonable person to be lavish or excessive.

For both domestic and international educational events, accommodation costs may include an allowance for meals while travelling, and transfers. These allowances should reflect the professional standing of healthcare professionals, but should not be excessive.

10. Gifts

Gifts are not to be provided to healthcare professionals. In addition to the complying items above, exceptions to this requirement are the provision of educational items such as article reprints, or authoritative texts, and company branded stationery items for use at educational events. Competitions based on the acquisition of medical knowledge may also be conducted, where individual prizes must be directly relevant to the practice of the healthcare professional group(s) and not exceed what a reasonable person would consider excessive. No gifts should be provided to the families or friends of healthcare professionals.

Annexure 6 – Distribution of Infant Formula Samples to Health Care Professionals

Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

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);

Approved by Infant Nutrition Council Board 19th May 2010. Minor amendment approved 15 May 2012

- 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 external 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 external 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.*)

Approved by Infant Nutrition Council Board 19th May 2010. Minor amendment approved 15 May 2012

- 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.

Annexure 7 – MAIF Complaints Tribunal Terms of Reference

Marketing in Australia of Infant Formulas (MAIF): Manufacturers and Importers Agreement

Complaints Tribunal

Terms of Reference

Background[1]:

1. The MAIF Agreement is a voluntary self-regulatory code of conduct between the manufacturers and importers of infant formula in Australia. It is Australia's response to the World Health Organization's *International Code of Marketing of Breast-milk Substitutes 1981* (WHO Code). The MAIF Agreement applies to those Australian manufacturers and importers of infant formula who are signatories to the MAIF Agreement. The MAIF Agreement aims 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, on the basis of adequate information through appropriate marketing and distribution.

   Current signatories to the MAIF Agreement include:
   - Abbott Australasia Pty Ltd
   - Aspen Nutritionals Australia Pty Ltd
   - Bayer Australia Ltd
   - H J Heinz Company Australia Ltd
   - Nestlé Australia Ltd
   - Nutricia Australia Pty Ltd
   - The a2 Milk Company Ltd

2. Prior to 8 November 2013, industry compliance with the MAIF Agreement was monitored by the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF). Part of APMAIF's role was to hear and determine complaints made under the terms of the MAIF Agreement. As of 8 November 2013, the APMAIF ceased to operate.

3. As a result of APMAIF becoming inoperative, the Infant Nutrition Council (INC)[2] approached St James Ethics Centre with a request that the Centre establish and convene an independent and credible process by which complaints might continue to be heard and determined under the terms of the MAIF Agreement.

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[1] Source: Australian Government Department of Health: http://www.health.gov.au/apmaif

[2] The Infant Nutrition Council (INC) represents the major manufacturers and marketers of infant formula in Australia and New Zealand as well as local manufacturers who are producing product for export
The members of the Infant Nutrition Council work with key stakeholders to support the public health goals of promoting breastfeeding and good nutrition for infants.
The Council aims to:
- 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;
- represent the infant formula industry in Australia and New Zealand

Source: http://www.infantnutritioncouncil.com/about-us/

4. St James Ethics Centre has agreed to this request under the following conditions:

   a) The process will be established and managed according to *Terms of Reference* determined solely by St James Ethics Centre.
   b) Funding of the process will be by industry (signatories to the MAIF Agreement) in an unrestricted form (retainer) that:
      i. ensures operational independence to St James Ethics Centre in the operation of the Tribunal, and
      ii. is of an amount sufficient to fund the effective operation of such a body.
   c) St James Ethics Centre will establish the service so that the deliberations of the Tribunal are free from influence by any other organisation, including St James Ethics Centre.

MAIF Complaints Tribunal

Terms of Reference

Purpose:

1) The MAIF Complaints Tribunal (the Tribunal) has been established to:

   a) receive and investigate complaints regarding the marketing in Australia of infant formulas; and
   b) develop guidelines on the interpretation and application of the MAIF Agreement.

Proceedings:

2) All proceedings of the Complaints Tribunal must be conducted in accordance with the principles of natural justice.

3) The Members of the Tribunal shall be the sole determinants of any complaint.

4) The Tribunal may not take into consideration any interests other than those to be served under the MAIF Agreement (see clause 23).

Composition:

5) The Tribunal shall be composed of three members being:

   a) A disinterested person with legal qualifications and demonstrable experience in hearing and determining complaints that have involved both private and public interests.
   b) A disinterested Public Health and Nutrition Expert with scientific and technical expertise in public health, nutrition, regulation around therapeutic goods and the food/drug interface.
   c) A disinterested community representative.

Appointment:

6) Members of the Tribunal shall be appointed by the Executive Director of St James Ethics Centre.

7) The power of appointment may not be delegated to another person.

8) In making an appointment the Executive Director of St James Ethics Centre must be satisfied that the appointee is:

   a) Competent to perform the assigned role,
   b) Disinterested (i.e. free from any conflict of interest or duty that might affect the independence of judgement to be exercised in the discharge of their duties).

Conflicts of Interest

9) Members of the Tribunal shall be under a standing obligation to declare any conflict of interest or duty that might affect the independence of judgement that they are required to exercise in the discharge of their duties.

Term of appointment

10) Each Member may be appointed for a period of three years.

11) Subject to clause 11, Members are eligible for appointment for one further term of three years.

12) If serving a second term, then one third of those appointed to the Tribunal at its establishment will be required to retire by way of annual rotation according to a process agreed by the Tribunal.

Termination of Appointment

13) Appointment to the Tribunal may be terminated by:

   a) the resignation of the Member;
   b) the expiry of their term of appointment;
   c) for proven misconduct, including a failure to disclose a conflict of interest.

Casual Vacancies

14) The Executive Director of St James Ethics Centre must as soon as is practicable appoint suitably qualified persons to fill any casual vacancy that might arise on the Tribunal.

15) In filling a casual vacancy the Executive Director of St James Ethics Centre must apply the same criteria for selection as if making a regular appointment of a Member.

Chair of the Tribunal

16) The person with legal qualifications shall serve as Chair of the Tribunal.

Remuneration

17) Members of the Tribunal shall be paid a daily rate, as specified in Appendix 1.

18) The daily rate of remuneration is to be reviewed on an annual basis.

19) Members of the Tribunal are to be reimbursed for out-of-pocket expenses reasonably incurred in the conduct of their duties.

Basis for a determination

20) In normal circumstances, all complaints are to be determined by the Tribunal solely on the evidence presented to it by the Secretariat and thus 'on the papers'. In exceptional circumstances, the Chair may seek expert oral testimony in order to aid the Tribunal in reaching a well-informed and fair determination.

21) The Tribunal shall publish, by means that it deems appropriate, reasons for its determinations.

Process

22) A person wishing to make a complaint arising under the MAIF Agreement will do so, in the first instance, by lodging their complaint with the Commonwealth Department of Health (the Department). Complaints may be submitted online at - maif@health.gov.au or may be posted to MAIF Agreement Officer, Department of Health, MDP 802, GPO Box 9848, Canberra ACT 2601.

23) Upon receipt, complaints will be assessed by the Department and are classified as being within or outside the scope of the MAIF Agreement. Those considered outside the scope of the MAIF Agreement may include, but are not limited to, the following:

    a) an infant formula manufacturer or importer that is not a current signatory to the MAIF Agreement or was not a signatory at the time the complaint was made;
    b) retailer activity where there is no involvement by the manufacturer/importer (e.g. price promotions in retail catalogues);
    c) infant merchandise (e.g. infant feeding bottles, teats, dummies, etc); and/or
    d) foods, including milk products formulated for children over 12 months of age (sometimes referred to as "toddler milks").

24) The Department may, at its absolute discretion, seek further information (if required) in order to make a determination in relation to scope.

25) The Department is to write to complainants acknowledging receipt of a complaint and will advise complainants in writing if their complaints are outside the scope of the MAIF Agreement.

26) Complaints that have been assessed as falling within the scope of the MAIF Agreement ('in scope' complaints), along with any supporting documents will be forwarded to St James Ethics Centre (the Secretariat) for submission to the Tribunal at its next available meeting.

27) Upon receipt of a complaint that is deemed to be within scope, the Secretariat (St James Ethics Centre) will advise the manufacturer or importer of the product concerned that a complaint has been received alleging a breach of the MAIF Agreement. The manufacturer or importer (respondent) will be invited to respond with any evidence or other information it wishes to submit for consideration by the Tribunal in making its determination.

28) Complaints requiring consideration by the Tribunal will be summarised by the Secretariat prior to being forwarded to the Tribunal.

29) Summaries will be prepared using a standard format to present the key information relevant to making a decision. Where available, this information is to include:

    a) how and where the complainant obtained the complaint material,
    b) the complainant's concerns regarding the material,
    c) an identification of relevant clause(s) of the MAIF Agreement that are alleged to have been breached or that are otherwise deemed to be relevant,
    d) the results of any enquiries made by the Department (e.g. responses from formula companies or health professionals) and
    e) any previous consideration of a similar complaint or relevant guidelines on the interpretation of the MAIF Agreement which has been made by the APMAIF (the predecessor to the Tribunal).

30) The Tribunal is to consider the complaint and may decide initially that it does not represent a breach of the MAIF Agreement or that further consideration is required before a determination can be made.

31) Where further consideration is required, the manufacturer or importer is to be notified by the Secretariat and provided with relevant material and invited to respond with any further relevant information.

32) At its next available meeting, the Tribunal is to consider all relevant information provided and make a decision that the complaint is either 'in breach' or 'not in breach' of the MAIF Agreement.

33) In cases where a breach of the MAIF Agreement has been found, the Tribunal may make recommendations as to how the breach might best be remedied.

34) In all but exceptional circumstances, the deliberations of the Tribunal are to be concluded within a period of three months after an 'in scope' complaint has been received by the Secretariat.

35) When a decision is made, both the complainant and the subject company are to be advised of the final outcome of the complaint, including the Tribunal's reasons for the decision and any recommendations that the Tribunal may have made in relation to the matter.

36) Decisions that there has been a breach of the MAIF Agreement, along with any recommendations by the Tribunal, are to be reported to the Department and are to be recorded in the Tribunal's Annual Report.

37) The Department will record all complaints received in its complaints register and forward relevant information concerning these (including statistics noting the total number of complaints received) to the Secretariat for incorporation in the Tribunal's Annual Report.

38) Except with the consent of the complainants, the complainants' identities are not to be disclosed to parties other than the Members of the Tribunal.

Appeals

39) There shall be no appeal from a decision of the Tribunal.

Residual Rights

40) Nothing in these Terms of Reference should be taken to limit the legal rights of any party in relation to matters heard by the Tribunal.

Observer

41) A representative of the Commonwealth Minister for Health may attend a meeting of the Tribunal as an Observer.

42) The Observer must undertake to be bound by the conditions of confidentiality that apply under these *Terms of Reference* and more generally, in relation to the conduct of the Tribunal. As such, the Observer may provide to the Minister a general report of the Tribunal's activities but may not report specific details of its deliberations – unless specifically authorised to do so by the Chair of the Tribunal.

43) An observer may not speak, nor otherwise contribute to, the deliberations of the Tribunal.

APPENDIX 1

REMUNERATION OF COMPLAINTS TRIBUNAL MEMBERS

Remuneration rates have been set with reference to the scale of fees payable to persons performing similar roles within the administrative remit of the Commonwealth of Australia.

Chair	$922 per day
Member	$794 per day

Annexure 8 – Guidelines for in-store promotions of infant formula by manufacturers in Australia through retailer

APPENDIX 4: Guidelines for in-store promotions of infant formula by manufacturers in Australia through retailers.

Price tickets on the 'shelf-talkers' that simply advertise the price of the product, or the fact that it has a 'special' price are acceptable. The ticket may also state the saving to be made - eg. 'Special. Save $1'. Shelf tickets should have no content other than the price and the name of the product.

- The Panel considers that descriptors such as 'soy formula' or 'lactose free' should not be allowed on these price promotion announcements or 'shelf-talkers'. This is because manufacturers may claim that a list such as 'cholesterol-free, cow's milk protein-free, lactose-free' should be allowed, as these are all 'descriptors'. Also, that infant formula other than standard formulas based on cow's milk should only be used if there is a medical indication. If these descriptors are used in promotion some parents may mistakenly believe that 'lactose-free' or 'cow's milk protein-free' formulas are superior to cow's milk formula. There should be no slogans or promotional messages.

- Posters, in-store radio announcements, catalogues and magazine advertisements should only advertise the price, the name of the product and a pack shot which in size, colour etc, must be relative to the other product depictions.

- Large stacks of cans (gondola ends or shelf stacks) are not necessary to make consumers aware of the price of the product, but the Panel recognises that they are apparently necessary to provide 'stock weight' (sufficient stock) for the increased demand created by 'special offers'. Stock in gondola end stacks and shelf stacks should be kept in their boxes and efforts should be made to ensure that the stack is not overly promotional.

- Window displays, window stacks and pavement displays are not acceptable.

- Care should be taken not to display infant formula products or the name of the product under generic slogans for a range of products, such as 'Everything that is best for baby'.

- There should be no price or product promotion on radio, television or any other electronic media.

Annexure 9 – Information for Retailers – Manufacturers and Importers' Obligations for the Marketing of Infant Formula in Australia

KEY FEATURES OF THE MAIF AGREEMENT

The following are some of the key obligations of manufacturers and importers of infant formula under the MAIF Agreement:

1. Manufacturers and importers of infant formula should not advertise or in any other way promote infant formula or follow-on formula to the general public.
2. Manufacturers and importers of infant formula should not provide samples of infant or follow-on formula to the general public (including pregnant women).
3. Manufacturers and importers of infant formula should not distribute to pregnant women, or parents of infants and young children, any gifts of articles or utensils which may promote the use of breast milk substitutes or bottle-feeding.
4. Informational and educational material produced by manufacturers and importers of infant formula (such as pamphlets or booklets) dealing with the feeding of infants should always include clear information on the benefits and superiority of breastfeeding (e.g. "Breastmilk is the perfect food for baby"); maternal nutrition, and the preparation for and maintenance of breastfeeding; the negative effect on breastfeeding of introducing partial bottle-feeding; the difficulty of reversing the decision not to breastfeed; and where needed, the proper use of proprietary infant formula. Where such materials contain information about the use of infant formulas, additional information is required.
5. Manufacturers and importers of infant formula must not idealise the use of infant formula through pictures and text on infant and follow-on formula or information and educational materials.
6. Manufacturers and importers of infant formula should not give financial or material incentives to health professionals to promote infant formula.
7. Manufacturers and importers of infant formula can provide information about the formulas to health care professionals, but should restrict the information to scientific and factual matters, and such information should not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding.

MAIF AGREEMENT SIGNATORIES

The manufacturers and importers of infant formula who are signatories to the MAIF Agreement in Australia (along with their leading brands) are:

- Abbott Australasia Pty Ltd
- Bayer Australia Ltd (Novalac)
- H. J. Heinz Company Australia Ltd (Nurture)
- Nestlé Australia Ltd (NAN)
- Nutricia Australia Pty Ltd (Karicare)
- Pfizer Australia Pty Ltd (S-26)

FURTHER INFORMATION

You can find a full copy of the MAIF Agreement on the Department of Health and Ageing website at **www.health.gov.au/apmaif**

CONTACT US

For further information or questions:

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Infant Nutrition Council

The Infant Nutrition Council is committed to working in partnership with government, regulatory authorities, health care professionals and breastfeeding advocates, to improve the health and wellbeing of infants in Australia.

Manufacturers and Importers' Obligations for the Marketing of Infant Formula in Australia

Information for Retailers

Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

Breastfeeding is the normal way to feed a baby and is important for baby's health and well-being.

The World Health Organisation and the National Health and Medical Research Council in Australia recommend exclusive breast feeding until six months of age, and then to complement with the appropriate introduction of solid foods up to two years of age.

There is no question that breast milk provides the best possible nutrition for infants however, when a baby is not being breastfed the only suitable and safe alternative is a scientifically developed infant formula.

THE MARKETING IN AUSTRALIA OF INFANT FORMULA: MANUFACTURERS AND IMPORTERS AGREEMENT (MAIF AGREEMENT)

The MAIF Agreement is a voluntary self-regulatory code of conduct between manufacturers and importers of infant formula in Australia.

It is based on the World Health Organisation International Code of Marketing of Breast Milk Substitutes (WHO 1981) and is Australia's official application of the WHO Code within the context of our legal and economic environment. Both the MAIF Agreement and the WHO Code have the same aim 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 MAIF Agreement was developed by the Australian government, the infant formula industry, breastfeeding advocates and other stakeholders and implemented in 1992.

MONITORING CODE COMPLIANCE

Compliance with the MAIF Agreement is monitored by the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF), a non-statutory body established by the Australian government.

Individuals, members of industry, community and consumer groups are able to lodge a complaint with the APMAIF Secretariat alleging a breach of the MAIF Agreement.

More information about APMAIF and the complaints process is available at **www.health.gov.au/apmaif**

APPLICATION OF THE MAIF AGREEMENT

The MAIF Agreement applies to the marketing and promotion of formulas for infants up to 12 months of age, by the Australian manufacturers and importers of infant formula who are signatories.

In relation to products, the MAIF Agreement applies to:

- **Infant formula i.e. formula that is suitable for babies from birth** (e.g. Starter, Stage 1 or All Ages infant formulas)
- **Follow-on formula i.e. formula that is suitable for babies from six to 12 months.**

The MAIF Agreement does not apply to:

- **Toddler milk drinks suitable from 12 months** (sometimes called Growing Up milks)
- **Complementary foods** (i.e. baby cereal and packaged baby foods)
- **Feeding bottles and teats**

MAIF AGREEMENT AND RETAILERS

Retailers are not signatories to the MAIF Agreement and are not bound by its terms. However, manufacturers and importers must not pursue or endorse promotional activities through retail channels unless those activities are allowed under the MAIF Agreement.

PRICE PROMOTIONS

Price promotion of infant formula (such as 'special prices' and discounts) is allowed. Certain aspects of the MAIF Agreement are authorised under the Trade Practices Act, but this authorisation does not extend to price restrictions. It is therefore open to manufacturers and retailers to price promote infant formula products in a similar manner to other products.