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Infant Nutrition Council Limited

Application for Revocation of an Authorisation for Proposed Conduct and Substitution of a Replacement

20 October 2020

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Contents

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

To the Australian Competition and Consumer Commission (email to: adjudication@accc.gov.au).

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.

Application

1 Applicant

(a) Applicant details

The Applicant is the Infant Nutrition Council Limited (***INC***), ACN: **23135154406**

The Applicant's address is: Infant Nutrition Council Limited, 13b/16 National Circuit, Barton ACT 2600.

The Applicant's telephone number: +61 2 6273 8164.

(b) Contact person details

Fiona Crosbie, Chairman, Allens

Address: 126 Phillip Street, Sydney NSW 2000

Telephone:

Email:

(c) Description of business activities

The INC is the association for the infant formula industry in Australia and New Zealand.

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.

(d) Email address for service of documents in Australia

2 Authorisation to be revoked (the existing authorisation)

(a) The registration number and date of the authorisation which is to be revoked

Authorisations A91506 and A91507 dated 15 July 2016.

(b) Other persons and/or classes of persons who are a party to the authorisation which is to be revoked

Current parties to the MAIF Agreement are party to the authorisation which is to be revoked. A list of those parties is set out in section 3(a) below.

(c) The basis for seeking revocation, for example because the conduct has changed or because the existing authorisation is due to expire

Revocation of authorisations A91506 and A91507 is sought because these authorisations will expire on 15 July 2021. The INC seeks to substitute in their place new authorisations of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (***MAIF Agreement***), on the same terms as the original authorisation.

The INC seeks authorisation of the MAIF Agreement for a period of ten 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 public benefits which flow from the MAIF Agreement outweigh any detriment which may result from the restrictions set out in the MAIF Agreement.

Please see attached submission for further detail.

3 Authorisation to be substituted (the new authorisation)

If applicable, provide details of any other persons and/or classes of persons who also propose to engage, or become engaged, in the proposed conduct and on whose behalf authorisation is sought. Where relevant provide:

(a) Name, address (registered office), telephone number, and ACN

The persons who also propose to engage, or becomes engaged, in the proposed conduct and on whose behalf the Applicant seeks authorisation are current and future manufacturers in, and importers into, Australia of infant formula that are or become parties to the MAIF Agreement.

Details in relation to the current signatories of the MAIF Agreement are included in the table below.

Name	Address of Registered Office)	Telephone Number	ACN
Abbott Austrasia Pty Ltd	299 Lane Cove Road, Macquarie Park NSW 2113	(02) 9384 9700	000 180 389
Australian Dairy Park Pty Ltd	120 Frankston Gardens Drive, Carrum Downs VIC 3201	(03) 8770 3809	162 478 373
Bayer Australia Ltd	875 Pacific Highway, Pymble NSW 2073	(02) 9391 6000	000 138 714
Bellamy's Organic	115 Cimitiere Street, Launceston TAS 7502	(03) 6332 9200	125 461 903
The Infant Food Co. Pty Limited	2-4/6 Tilley Ln, Frenchs Forest NSW 2086	(02) 9905 0050	164 765 360
The LittleOak Company Pty Ltd	Suite 1/120 Jonson Street, Byron Bay NSW 2481		627 359 782
Nature One Dairy Pty Ltd	12 Capital Place, Carrum Downs VIC 3201	(03) 9708 2988	602 371 684
Nestlé Australia Ltd	1 Homebush Bay Drive, Rhodes NSW 2138	(02) 8756 2000	000 011 316
Nuchev Ltd	194-196 Belmont Street,		163 225 090

Name	Address of Registered Office)	Telephone Number	ACN
	Belmont VIC 3216		
Nutricia Australia Pty Ltd	Talavera Corporate Centre Level 4, Building D 12-24 Talavera Road, Macquarie Park NSW 2113	(02) 8875 0300	076 246 752
Reckitt Benckiser (Australia) Pty Limited	Level 47, 680 George Street, Sydney NSW 2000	(02) 9857 2000	003 274 655
Sanulac Nutritional's Australia Pty Ltd	Level 1, 42-44 Chandos St, St. Leonards NSW 2065	(02) 8848 1400	160 607 509
Spring Sheep Milk Company	Level 17, Kingston St, Auckland CBC 1010 New Zealand	+64 27 305 0244	New Zealand company registration number: 2626251
Sprout Organic	Level 3, 9 Ouyan Steet, Bundall QLD 4217		639 172 517
Swisse Wellness Pty Ltd	111 Cambridge Street, Collingwood VIC 3066	(03) 9418 6767	004 926 005
The a2 Milk Company Ltd	Level 4, 182 Blues Point Road, McMahons Point NSW 2060	(02) 9697 7000	125 331 213
Wattle Health Australia Limited	17/71 Victoria Crescent, Abbotsford VIC 3067	(03) 8399 9419	150 759 363

(b) Contact person's name, telephone number, and email address

For each of the current signatories of the MAIF Agreement, the Applicant provides in the table below contact person details.

Party	Contact person	Telephone number	Email address
Abbott Australasia Pty Ltd	Dana Felder (Senior Regulatory Affairs Specialist)		
Australian Dairy Park Pty Ltd	Zhen Xia (Managing Director)		
Bayer Australia Ltd	Janie Heywood (Head of Consumer Health Regulatory Affairs)		

Party	Contact person	Telephone number	Email address
Bellamy's Organic	Shae Rickards (Paediatric Dietitian and Nutrition Manager)		
The Infant Food Co. Pty Limited	Sam Haifawi (Head of Quality & Innovation)		
The LittleOak Company Pty Ltd	Felicity Pascoe (Digital Marketing Manager)		
Nature One Dairy Pty Ltd	Nick Dimopoulos (CEO)		
Nestlé Australia Ltd	Xavier Payrard (Business Executive Officer)		
Nuchev Ltd	Matt Scarboro (General Manager Supply Chain); Justin Peace (Product Development Manager)	Matt Scarboro – Justin Peace –	
Nutricia Australia Pty Ltd	Scott Pettet (Head of Corporate Affairs)		
Reckitt Benckiser (Australia) Pty Limited	Lynda McFarlane (Regulatory Affairs Manager – Health ANZ)		
Sanulac Nutritional's Australia Pty Ltd	Philippe Mele (General Manager); Lira Yoon (Regulatory and Scientific Affairs Manager)	Philippe Mele – Lira Yoon –	

Party	Contact person	Telephone number	Email address
Spring Sheep Milk Co	Nick Hammond (Chief Operating Officer)		
Sprout Organic	Ben Chester (Director)		
Swisse Wellness Pty Ltd	Nick Mann (CEO)		
The a2 Milk Company Ltd	Dandan Chen (Head of Group Quality & Regulatory)		
Wattle Health Australia Limited	Dr Tony McKenna (CEO)		

(c) Description of business activities

Each of the persons who also propose to engage, or become engaged, in the proposed conduct and on whose behalf authorisation is sought (identified at paragraph 3(a) above) is a manufacturer in, and importer into Australia of infant formula.

4 The proposed conduct

(a) Provide details of the proposed conduct, including:

(i) a description of the proposed conduct and any documents that detail the terms of the proposed conduct

The INC seeks authorisation of the MAIF Agreement and associated guidelines.

Please see attached submission for further detail.

(ii) an outline of any changes to the conduct between the existing authorisation and the new authorisation

Please see attached submission for further detail.

(iii) the relevant provisions of the *Competition and Consumer Act 2010* (Cth) (the Act) which might apply to the proposed conduct

(A) cartel conduct (Division 1 of Part IV);

(B) contracts, arrangements or understandings that restrict dealings or affect competition (s. 45); and

(C) concerted practices (s. 45).

(iv) the rationale for the proposed conduct

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.

The purpose 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. The MAIF Agreement achieves this by providing adequate information and through appropriate marketing and distribution. The MAIF Agreement does this by governing the marketing of infant formula for infants up to 12 months.

Please see attached submission.

(v) the term of authorisation sought and reasons for seeking this period

The INC seeks a 10 year authorisation term.

Please see attached submission.

(b) Provide the name of persons, or classes of persons, who may be directly impacted by the proposed conduct (e.g. targets of a proposed collective bargaining arrangement; suppliers or acquirers of the relevant goods or services) and detail how or why they might be impacted.

Retailers and consumers of infant formula will be impacted by the proposed conduct because the MAIF Agreement imposes restrictions on the promotion and marketing of infant formula.

Health professionals will also be impacted by the proposed conduct because the MAIF Agreement imposes restrictions on the distribution of infant formula in healthcare settings.

5 Market information and concentration

(a) Describe the products and/or services, and the geographic areas, supplied by the applicants. Identify all products and services in which two or more parties to the proposed conduct overlap (compete with each other) or have a vertical relationship (e.g. supplier-customer).

The signatories of the MAIF Agreement are all manufacturers in, and/ or importers into, Australia of infant formula. All signatories overlap in either manufacturing or supply of infant formula in Australia.

(b) Describe the relevant industry or industries. Where relevant, describe the sales process, the supply chains of any products or services involved, and the manufacturing process.

The relevant market for the purposes of this authorisation is the Australian market for the supply of infant formula for the feeding of infants up to the age of 12 months.

Please see attached submission.

(c) In respect of the overlapping products and/or services identified, provide estimated market shares for each of the parties where readily available.

INC does not have access to this information.

(d) In assessing an application for authorisation, the ACCC takes into account competition faced by the parties to the proposed conduct. Describe the factors that would limit or prevent any ability for the parties involved to raise prices, reduce quality or choice, reduce innovation, or coordinate rather than compete vigorously. For example, describe:

(i) existing competitors;

(ii) likely entry by new competitors;

(iii) any countervailing power of customers and/or suppliers;

(iv) any other relevant factors.

Please see attached submission.

6 Public benefit

Describe the benefits to the public that are likely to result from the proposed conduct. Refer to the public benefit that resulted under the authorisation previously granted. Provide information, data, documents or other evidence relevant to the ACCC's assessment of the public benefits.

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

Please see attached submission.

7 Public detriment including any competition effects

Describe any detriments to the public likely to result from the proposed conduct, including those likely to result from any lessening of competition. Refer to the public detriment that may have resulted under the authorisation previously granted. Provide information, data, documents, or other evidence relevant to the ACCC's assessment of the detriments.

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 possible detriment to the public which may result from these restrictions.

Please see attached submission.

8 Contact details of relevant market participants

Identify and/or provide names and, where possible, contact details (phone number and email address) for likely interested parties such as actual or potential competitors, customers and suppliers, trade or industry associations and regulators.

The contact details for the INC and signatories to the MAIF Agreement are set out above.

Likely interested parties include:

- Department of Health
- The Royal Australasian College of Physicians
- Australian Breastfeeding Association
- Australian Nursing & Midwifery Federation
- Dietitians Association of Australia

The details for the relevant Department of Health representative are set out below:

- **Name and position:** Christel Leemhuis, Director Food and Nutrition Policy, Population Health and Sport Division, Preventive Health Policy Branch, Department of Health
- **Email:**
- **Phone:**

9 Additional information

Provide any other information or documents you consider relevant to the ACCC's assessment of the proposed application.

Please see attached submission.

Declaration by Applicant

The undersigned declare that, to the best of their knowledge and belief, the information given in response to questions in this form is true, correct and complete, that complete copies of documents required by this form have been supplied, that all estimates are identified as such and are their best estimates of the underlying facts, and that all the opinions expressed are sincere.

The undersigned undertake(s) to advise the ACCC immediately of any material change in circumstances relating to the application.

The undersigned are aware that giving false or misleading information is a serious offence and are aware of the provisions of sections 137.1 and 149.1 of the *Criminal Code* (Cth).

Signature of authorised person

Chief Executive Officer, Infant Nutrition Council

Office held

Jan Carey

Name of Authorised person

20 October 2020

Date

Note: If the Applicant is a corporation, state the position occupied in the corporation by the person signing. If signed by a solicitor on behalf of the Applicant, this fact must be stated.

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Infant Nutrition Council Limited

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

October 2020

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Glossary

Term	Definition
ACCC	Australian Competition and Consumer Commission
APMAIF	Advisory Panel on the Marketing in Australia of Infant Formula
Breastfeeding Strategy	*The Australian National Breastfeeding Strategy: 2019 and beyond* by the Australian Department of Health
CCA	*Competition and Consumer Act 2010* (Cth)
Committee	MAIF Complaints Committee
FSANZ	Food Standards Australia New Zealand
FSANZ Standard	Australia New Zealand Food Standards Code – Standard 2.9.1 – Infant formula products
INC	Infant Nutrition Council Limited
Infant Formula	Any food described or sold as a substitute for human breastmilk for the feeding of infants up to the age of 12 months and formulated in accordance with the FSANZ Standard
Interpretation Guidelines	The APMAIF developed Guidelines on the interpretation and application of the MAIF Agreement by the Advisory Panel on the Marketing in Australia of Infant Formula
MAIF Agreement	Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement
MAIF Tribunal	Independent non-statutory tribunal established in 2014 to determine complaints in relation to the MAIF Agreement
Nous Complaints Review	*Independent Review of the MAIF Complaints Handling Process – Review Report* by the Department of Health (15 August 2017)
Nous Effectiveness Review	*Review of the effectiveness and validity of operations of the MAIF Agreement – Research Paper* by the Department of Health and Ageing (13 June 2012)
Toddler Milk	Formulated supplementary food for young children over 12 months of age. Sometimes also referred to as 'growing up milk' or GUM. Toddler Milk is *not* a breastmilk substitute.
Toddler Milk Guidance	*Best-practice Guidance for INC Members for the Marketing of Toddler Milk Drinks to Consumers*
TPC	Trade Practices Commission
WHO Code	World Health Organization's *International Code of Marketing of Breast-milk Substitutes 1981*
2007 Determination	ACCC Determination in respect of minor variations of Authorisations A90539 and A90540 for the Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement
2016 Determination	ACCC Determination in respect of application for revocation of authorisations A90539 and A90540 and substitution with authorisations A91506 and A91507

1 Executive Summary

The Infant Nutrition Council Limited (***INC***) seeks re-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 importers 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 objectives of the INC include:

- promoting and protecting breastfeeding to ensure infant health and well-being and ensuring the proper use of breastmilk substitutes when they are necessary; and
- representing the Infant Formula industry in Australia and New Zealand.

Sixteen of the seventeen signatories to the MAIF Agreement are members of the INC.[1]

The MAIF Agreement was established in May 1992. It constitutes Australia's official response to the World Health Organization's *International Code of Marketing of Breast Milk Substitutes 1981* (***WHO Code***).[2] The MAIF Agreement is a voluntary self-regulatory code of conduct between the manufacturers and importers to Australia of Infant Formula. Among other things, it prohibits the advertising and promotion of Infant Formula for infants up to 12 months by manufacturers and importers directly to the public.

The Trade Practices Commission (***TPC***) and Australian Competition and Consumer Commission (***ACCC***) have previously concluded that the MAIF Agreement was likely to result in significant public benefits.

The INC submits that the MAIF Agreement and associated guidelines will continue to result in public benefits, and should be re-authorised for the following reasons:

- The MAIF Agreement promotes and protects breastfeeding while also ensuring that appropriate information is provided to those who are unable to (or make an informed choice not to) breastfeed.
- The MAIF Agreement is an effective voluntary industry code with associated benefits including enhanced transparency and low compliance costs.
- Since the MAIF Agreement was last authorised by the ACCC in 2016, a number of developments mean that the public benefits associated with the agreement are now greater. Those developments include:
  - the development of a stronger and more transparent mechanism for resolving complaints alleging breaches of the MAIF Agreement;
  - the resolution by the Committee of various complaints of alleged breaches of the MAIF Agreement including those regarding concerns raised about staging information on Infant Formula labels and the promotion of Infant Formula by retailers;

[1] **Nature One Dairy** is the only signatory of the MAIF Agreement that is currently supplying infant formula but is not a member of the INC.
[2] Available at: https://apps.who.int/iris/bitstream/handle/10665/40382/9241541601.pdf;jsessionid=29EF7B5A0BB5EA98537A8C0EB86EA386?sequence=1

- the development by the Committee of various guidelines on the application of the MAIF Agreement, including the 'Guidelines on staging information for the labelling of infant formula' to address concerns about this issue;
- the inclusion of additional signatories to the MAIF Agreement; and
- the publication by the INC in September 2020 of an updated brochure for retailers on the key features and application of the MAIF Agreement.

- Any possible detriment associated with restricting the promotional activities of signatories to the MAIF Agreement is substantially outweighed by the public benefits of the MAIF Agreement.
- In a future without the MAIF Agreement, at least until an alternative regulatory regime is put in place (both a time-consuming and costly process), Infant Formula marketing would be unrestricted to the detriment of Australian breastfeeding rates.

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** provides background information regarding the supply of Infant Formula and the relevant areas of competition.
- **Section 4** provides an overview of the MAIF Agreement and the role of the MAIF Complaints Committee in monitoring compliance with the MAIF Agreement.
- **Section 5** outlines developments since authorisation was last granted.
- **Section 6** outlines the public benefits arising from the MAIF Agreement.
- **Section 7** sets out the reasons that the public benefits arising from the MAIF Agreement outweigh any possible public detriments.
- **Section 8** sets out the likely future with and without the conduct for which authorisation is sought.

2 Authorisation of the MAIF Agreement

The TPC authorised the MAIF Agreement on 23 September 1992.

The authorisation was varied by the ACCC on 30 August 2007 (the ***2007 Determination***). 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.

On 15 July 2016 the MAIF Agreement and associated guidelines were re-authorised for a further five years (the ***2016 Determination***). The re-authorisation expires on 8 August 2021.

2.1 Terms of authorisation

The INC seeks revocation of authorisations A91506 and A91507 in respect of the MAIF Agreement (these authorisations will expire on 8 August 2021) and substitution with a replacement authorisation of the MAIF Agreement.

The INC is seeking authorisation of the MAIF Agreement for a period of ten 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 will become parties to the MAIF Agreement. The INC sets out the reasons for the proposed term and application below.

(a) Ten year term

The INC submits that the period of authorisation sought is appropriate. The original authorisations granted by the TPC were not time limited. In 2007, the ACCC amended the authorisations to introduce a circa eight year time limit.

In 2015, the INC sought re-authorisation of the MAIF Agreement for a further ten year term. In the light of uncertainties as to whether the Federal Government would revise its policies regarding the marketing of Infant Formula and Toddler Milk in the near term, the ACCC granted authorisation for a period of five years.[3]

The INC considers that a ten year term for re-authorisation is appropriate for the following reasons:

- Very few changes were made to the MAIF Agreement in the eight years following the 2007 Determination, and there have been no changes to the MAIF Agreement since the 2016 Determination.
- The Federal Government has not, at this stage, indicated any intention to request changes to the MAIF Agreement or to otherwise change its policies in respect of the marketing and promotion of Infant Formula.
- If any relevant policy change were to be proposed by the Federal Government, the INC submits it would take a considerable amount of time for any such changes to be agreed and implemented.
- As noted by the ACCC in the 2016 Determination, any significant change in the policy environment during the period of authorisation is likely to provide a basis for the ACCC to review the authorisation if it wishes to do so.[4]
- The costs incurred by the INC and other interested parties in undertaking a re-authorisation process every five years are considerable. In circumstances where there is no evidence at present that the Federal Government's policies will change in the near-term, it is appropriate that a longer term be granted.

(b) Application to both current and future members

Previously, the ACCC has considered it important to maintain the level of certainty afforded by the original authorisations by ensuring that new parties who sign the MAIF Agreement are covered by the authorisations.

In its 2007 Determination, 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.[5] Similarly, in its 2016 Determination, the ACCC extended the authorisation to future parties to the MAIF Agreement.[6]

[3] ACCC: Determination in respect of application for revocation and authorisations A90539 and A90540 and substitution with authorisations A91506 and A91507 (***2016 Determination***), [148].
[4] 2016 Determination, [145].
[5] 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 ***(2007 Determination***), [6.6].
[6] 2016 Determination, [158].

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 thereby avoiding the erosion of public benefits 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, varied by the ACCC on 30 August 2007 and re-authorised by the ACCC on 15 July 2016, be substituted under subsection 91C(1) of the *Competition and Consumer Act 2010* (Cth) (***CCA***).

Specifically, the INC's applications for a substitute authorisation in respect of the MAIF Agreement are:

- 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, if a provision of the proposed contract, arrangement or understanding would be, or might be, a cartel provision within the meaning of ss 45AF and 45AJ; or
  - to give effect to a provision of a contract, arrangement or understanding if the provision is, or may be, a cartel provision within the meaning of 45AG and 45AK;
- 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 has (or may have) the purpose, effect or likely effect of substantially lessening competition within the meaning of section 45(1)(a) of the CCA; and
  - to give effect to a provision of a contract, arrangement or understanding where the provision has (or may have) the purpose, effect or likely effect, of substantially lessening competition within the meaning of section 45(1)(b) of the CCA; and
- an application under subsection 88(1) of the CCA for an authorisation under that subsection to engage with one or more persons in a concerted practice that has (or may have) the purpose, effect or likely effect of substantially lessening competition.

3 Infant Formula Products

3.1 Overview

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

- **Infant Formula**, which is any food described or sold as a substitute for human breastmilk for the feeding of infants up to the age of 12 months. Only products that meet the mandatory compositional and labelling requirements of the *Australia New Zealand Food Standards Code – Standard 2.9.1 – Infant formula products* (***FSANZ Standard***), are permitted to be represented as Infant Formula in Australia.[7]; and

[7] *Australia New Zealand Food Standards Code- Standard 2.9.1 – Infant formula products*.

- **Toddler Milk**, which is not a breastmilk substitute, and is formulated supplementary food for young children over 12 months of age. Toddler Milk is also referred to sometimes as 'growing up milk' or GUM.

Infant Formula and Toddler Milk are often sold in different 'stages'. Infant Formula is typically available in two compositions:

- **Stage 1**: starter infant formula – for infants aged zero to six months; and
- **Stage 2**: follow-on formula – for infants aged six to twelve months.

Toddler Milk is formulated for children aged from one and usually up to three 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.

Further comments regarding market definition and the relevant areas of competition for the purposes of assessing the INC's application are set out in section 3.2 below.

There are a number of companies that manufacture, export, import and/or market Infant Formula in Australia. The major companies include a2 Milk, Sanulac Nutritionals, Bayer, Bellamy's Organic, Nestlé, Nutricia Australia and The Infant Food Co.

There have also been a number of new signatories of the MAIF Agreement since the 2016 Determination, including: Bellamy's Organic, Nuchev, Wattle Health, Reckitt Benckiser, The Little Oak Company, Spring Sheep Milk Company, Sprout Organic and Swisse. In addition, some pharmacies and supermarkets supply their own private label Infant Formula.

The major retail outlets for selling Infant Formula are supermarkets and pharmacies. According to IBISWorld:[8]

> … 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 market for milk powder manufacturers. The significant bargaining power of large retail chains is pushing down the price manufacturers receive. Despite this, revenue from sales to supermarkets has risen as a share of revenue over the past five years, as supermarkets have increasingly bypassed wholesalers, and sourced industry products directly from manufacturers.

The signatories to the MAIF Agreement include all of Australia's major manufacturers and importers of Infant Formula.[9] The INC understands that the signatories to the MAIF Agreement account for the vast majority of sales of Infant Formula in Australia.

3.2 Relevant areas of competition

The INC submits that, consistent with the ACCC's approach in its review of the acquisition by Nestlé of Pfizer Nutrition, the relevant market for the purpose of this authorisation is the Australian market for the supply of Infant Formula.[10]

The INC notes, however, that in the 2016 Determination, the ACCC found that it is not necessary to precisely define the relevant markets to examine the likely public benefits and detriments.[11]

[8] IBISWorld Industry Report C1133b, *Milk Powder Manufacturing in Australia* (February 2019), p20.
[9] Department of Health, *Independent Review of the MAIF Complaints Handling Process – Review Report* (15 August 2017), p8.
[10] ACCC: Public Competition Assessment – Nestle – proposed acquisition of Pfizer Nutrition, 3 May 2013, p5.
[11] 2016 Determination, [70].

4 The MAIF Agreement

4.1 Overview of the MAIF Agreement

The MAIF Agreement was developed by the Australian Government, the Infant Formula industry, public health advocates and other stakeholders. The MAIF Agreement is a voluntary self-regulatory code of conduct between manufacturers and importers to Australia of Infant Formula.

The MAIF Agreement applies to those Australian manufacturers and importers of Infant Formula who are signatories to the MAIF Agreement. The aim of the MAIF Agreement is to: (ii) promote and protect breastfeeding to ensure infant health and well-being; and (ii) ensure the proper use of breastmilk substitutes when they are necessary. The MAIF Agreement does this by requiring members to provide adequate information through appropriate marketing and distribution (as per Article 1 of the WHO Code).

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, which is any food described or sold as an alternative for human breastmilk for the feeding of infants up to the age of 12 months;
- 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;
- prohibits the distribution of samples of Infant Formula to health care professionals except when necessary for the purpose of professional evaluation or research at the institutional level;
- prohibits the use of any facility of the health care system for the purpose of promoting Infant Formula. However, the MAIF Agreement allows for the donation or low-priced sale of Infant Formula to institutions or organisations for the use of infants who have to be fed on breastmilk substitutes;
- restricts to scientific and factual matters the information provided to health care professionals by manufacturers and importers regarding Infant Formula;
- prohibits health care professionals and persons employed by manufacturers and importers from accepting or offering incentives to promote or sell Infant Formula; and
- requires internal monitoring and compliance practices by signatories to ensure conduct conforms to the principles and aims of the MAIF Agreement.

4.2 Implementation of the WHO Code through the MAIF Agreement

The WHO Code is a set of guidelines which recommends the imposition of various restrictions on the marketing and distribution of breastmilk substitutes.

The MAIF Agreement seeks to implement the elements of the WHO Code that relate to manufacturers and importers of Infant Formula.

In addition to supporting the MAIF Agreement, the Australian Government has sought to implement aspects of the WHO Code in the following ways:

- The FSANZ Standard gives effect to elements of the WHO Code by providing mandatory labelling standards for Infant Formula.
- The National Health and Medical Research Council *Infant Feeding Guidelines: Information for Health Workers*, contain guidance for health workers on interpreting the WHO Code in Australia.[12]

Further, the marketing of Infant Formula remains subject to the Australian Consumer Law prohibitions on (i) misleading and deceptive conduct; and (ii) false and misleading representations.

4.3 Scope of the MAIF Agreement

The WHO Code is broader in scope than the MAIF Agreement.[13] 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, short of the full WHO Code, could be implemented in the sectors of the industry which import and manufacture infant formula*'.[14]

The MAIF Agreement applies only to:

- Infant Formula, which is any food described or sold as a substitute for human breastmilk for the feeding of infants up to the age of 12 months and formulated in accordance with the FSANZ Standard; and
- manufacturers and importers of Infant Formula that are signatories to the MAIF Agreement.

The MAIF Agreement does not apply to:

- Toddler Milk (which is not a breastmilk substitute, and, rather is formulated supplementary foods for young children over 12 months of age), complementary foods, feeding bottles and teats. The INC's submissions in relation to the marketing and promotion of Toddler Milk are set out in section 6.4(a) below; and
- Retailers, such as supermarkets and pharmacies. However, to the extent that manufacturers and importers indirectly market Infant Formula to the public through retail channels (for example by providing funding and / or content directly for retailer advertisements), this conduct will be captured by the MAIF Agreement.

4.4 Amendments to the MAIF Agreement

There have been no amendments to the MAIF Agreement since the 2016 Determination.

[13] 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.
[14] TPC Determination, [2.3]-[2.7].

4.5 Guidance documents for interpretation of the MAIF Agreement

The INC seeks authorisation of the following guidelines associated with the MAIF Agreement:

- guidance documents developed and endorsed by the Committee and APMAIF, which are published on the Australian Department of Health Website (***Committee Guidelines***); and
- INC publications, including guidelines, policy and brochure documents (***INC Publications***).

(a) Committee guidelines

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***) are provided at **Annexure 3**.[15] The Interpretation Guidelines were developed to assist with the interpretation and application of the MAIF Agreement. However, the Interpretation Guidelines do not form part of the MAIF Agreement.

When reviewing complaints, the MAIF Complaints Committee (***Committee***), which is discussed further below, refers to the Interpretation Guidelines. However, the Committee is not bound to apply the Interpretation Guidelines when it makes a decision.

In addition, the Committee has finalised the following guidance documents:

- *MAIF Complaints Committee's interpretation of the MAIF Agreement related to electronic media marketing.* These guidelines were finalised at the Committee's February 2020 meeting, to support the interpretation of the MAIF Agreement. A copy of these guidelines is provided at **Annexure 4**.[16]
- *MAIF Complaint Committee's interpretation of Clause 7(a) of the MAIF Agreement relating to scientific and factual information provided to health care professionals*. Also finalised in February 2020, a copy of this guidance is provided at **Annexure 5**.[17]

The Interpretation Guidelines and the guidance documents listed above are referred to in this submission as the ***Committee Guidelines*.** The Committee is in the process of reviewing all the various guidance available on the MAIF Agreement, including the Committee Guidelines.

The Committee is also currently developing the following three separate guidance documents:

- Guidelines on the interpretation of 'Clause 4: Information and Education'. Clause 4 includes the educational and informational requirements for promotional materials and prohibits the donation of informational or educational equipment or materials.

[15] Also available on the Australian Department of Health website at https://www1.health.gov.au/internet/main/publishing.nsf/Content/guide-maif-agreement.

[16] Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/B8D64A18E546D9FBCA257BF0001ACE26/$File/MAIF%20Guidance%20Document%20-%20Electronic%20media.pdf

[17] Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/B8D64A18E546D9FBCA257BF0001ACE26/$File/D20-1406749%20%20Scientific%20and%20Factual.pdf

- Guidelines on the interpretation of 'Clause 5(a): The general public and mothers'. Clause 5(a) prohibits manufacturers and importers of Infant Formula from advertising or in any other way promoting Infant Formula to the general public.
- Guidelines on staging information for the labelling of Infant Formula to address concerns about this issue.

We will provide these further guidance documents listed above to the ACCC once they are finalised.

(b) INC publications

In addition to Committee guidelines, the INC also actively promotes the Infant Formula industry's understanding of the MAIF Agreement. The INC has developed various documents to aid the interpretation of the MAIF Agreement over time and seeks to proactively support and protect breastfeeding. The INC's publications include:

- *Best-practice Guidance for INC Members for the Marketing of Toddler Milk Drinks to Consumers* (***Toddler Milk Guidance***). The INC developed this document to provide guidance on the distinguishing features of Toddler Milk marketing (even though Toddler Milk is outside the scope of the MAIF Agreement). The guidance was approved by the INC board on 27 February 2018. A copy of this guidance is attached at **Annexure 6**.
- *Information for Retailers brochure*. The INC recently updated its retailer brochure, which is designed to explain to retailers of Infant Formula the key features and best practice application of the MAIF Agreement. A copy of this brochure is provided at **Annexure 7**.
- *Policy – Breastfeeding*. The INC Board approved this policy on 29 July 2010.[18] Under the policy, the INC aims to promote the value of breastfeeding and improve breastfeeding rates by proactively supporting the protection and promotion of breastfeeding. A copy of this policy is attached at **Annexure 8**.
- *Guidance on Interactions with Healthcare Professionals*. The guidance was approved by the INC Board on 31 January 2012 and was presented to the APMAIF on 16 February 2012, who noted it appeared to have a 'common sense' approach. A copy of the guidance is provided at **Annexure 9**.[19]
- *Policy - 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 aims to ensure the proper use of Infant Formula samples under the terms of the MAIF Agreement and provides restrictions on the provision of samples. A copy of the policy is provided at **Annexure 10**.

[18] The policy was amended on 17 August 2011.

[19] Available at: https://www.infantnutritioncouncil.com/wp-content/uploads/2014/07/Guidance-on-interactions-with-HCPs-3101121.pdf

- *Template Infant Formula Samples Request Form (Australia)*. The INC worked with the Australian Government and (now disbanded) APMAIF to develop a template for a Samples Request Form that must be used before any Infant Formula 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. A copy of this template is provided at **Annexure 11**.

5 Developments Since Authorisation Last Granted

Since reauthorisation of the MAIF Agreement was last granted, there have been a number of developments in Australia, in respect of the MAIF Agreement, including:

- An independent review of the MAIF complaints handling process, resulting in the creation of the Committee.
- The Australian Department of Health released a national breastfeeding strategy which includes a recommendation that the Federal Government commission a review into the MAIF Agreement and Committee.
- Food Standards Australia New Zealand is conducting a review of the FSANZ Standard to ensure it is clear and reflects the latest scientific evidence, and to consider harmonising the Australia New Zealand Food Standards Code with international regulations.

These developments are explained in further detail below.

5.1 New complaints handling process

In 2018, a new complaints handling process overseen by the Australian Department of Health was established following an independent review into complaints handling under the MAIF Agreement.

(a) Review of MAIF complaints handling process

In 2017, the Department of Health commissioned an independent review (undertaken by the Nous Group) into the complaints handling process under the MAIF Agreement (the ***Nous Complaints Review***).[20] The objective of the review was to inform Australia's current and future commitment to the WHO Code and to ensure best practice in the complaints handling process.

In the years leading up to the Nous Complaints Review, the complaints handling process for the MAIF Agreement had undergone the following changes:

- Prior to 2014, the APMAIF was tasked with monitoring compliance with, and advising the Government on, the MAIF Agreement. The APMAIF was disbanded and ceased to operate from 8 November 2013.[21]
- In 2014 the INC negotiated an arrangement with the Ethics Centre to establish an independent non-statutory tribunal to determine complaints (the ***MAIF Tribunal***). To ensure the MAIF Tribunal's independence, its Terms of Reference were at the sole discretion of the Ethics Centre, the head of which was responsible for the appointment of the three MAIF Tribunal members.

[20] Department of Health, *Independent Review of the MAIF Complaints Handling Process – Review Report* (15 August 2017) (***Nous Complaints Review),*** p2.
[21] Nous Complaints Review, p3.

The Nous Complaints Review concluded that aspects of the MAIF Tribunal's complaints handling process could be improved.

(b) Establishment of the MAIF Complaints Committee

Following the Nous Complaints Review, the Australian Department of Health assumed responsibility for handling complaints received in relation to the MAIF Agreement through the Committee. The Committee's terms of reference are to:[22]

- Receive complaints and determine whether they are in-scope or out-of-scope of the MAIF Agreement.
- For in-scope complaints, investigate complaints against signatories of the MAIF Agreement and determine if a breach of the MAIF Agreement has occurred.
- Develop, manage and amend guidelines on the interpretation and application of the MAIF Agreement as needed.
- Provide advice on the operation of the MAIF Agreement to the relevant Australian Government Minister as needed.

A copy of the Committee's Terms of Reference is provided at **Annexure 12**.

The Committee has three members: an independent representative, a public health representative and an industry representative. The current members are:

- **Independent representative**: Professor Debra Thoms, Acting Head, School of Nursing, Faculty of Health, Queensland University of Technology (Chair);
- **Public health representative**: Professor Peter Davies, Honorary Professor of Childhood Nutrition in the Children's Health Research Centre within the University of Queensland; and
- **Industry representative**: Ms Jan Carey - Chief Executive Officer, Infant Nutrition Council.

(c) The complaints process

Upon receiving a complaint, the Committee considers whether the complaint is in scope or out of scope of the MAIF Agreement. If in-scope, the Committee investigates the complaint and is responsible for making a determination on whether the conduct the subject of the complaint constitutes a breach of the MAIF Agreement. In cases where a breach of the MAIF Agreement has been found, the Committee will advise the signatory of its decision in writing.

Under the Committee Terms of Reference, the Committee Secretariat must upload the outcome of complaints onto the Department of Health website after determination. It must also prepare an annual report after the end of each financial year, to be posted on the Department of Health website.

5.2 National breastfeeding strategy

Since the 2016 Determination, the Department of Health has developed a revised strategy incorporating recent research on effective strategies to support breastfeeding.

[22] MAIF Complaints Committee Terms of Reference, available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/71DA9AB1418526CDCA2583A6007D76E6/$File/Terms%20of%20Reference-revised%2021%20November%202019.pdf

The Australian National Breastfeeding Strategy: 2019 and beyond (the ***Breastfeeding Strategy***) seeks to provide an enabling environment for breastfeeding.[23] All Health Ministers endorsed the Breastfeeding Strategy on 8 March 2019.

The Breastfeeding Strategy outlined a number of recommended actions for the Federal Government including:[24]

- Raising awareness of the MAIF Agreement in the community by:
  - providing information on the complaints process and encouraging the community to report inappropriate advertising and promotion of breastmilk substitutes; and
  - actively seeking out and promoting membership of the MAIF Agreement to manufacturers and importers of breastmilk substitutes.
- Commissioning an independent review to determine:
  - the effectiveness of the MAIF Agreement in restricting inappropriate marketing of breastmilk substitutes;
  - the feasibility of including all manufacturers of Infant Formula and all retailers (including supermarkets and pharmacies) in the scope of the MAIF Agreement; and
  - the transparency of the complaints process and outcomes of the Committee meetings.

As far as the INC is aware, the Federal Government has not yet developed an implementation plan for the Breastfeeding Strategy, including in relation to the proposed review of the MAIF Agreement.

5.3 Food standards review

Food Standards Australia New Zealand (***FSANZ***) is currently reviewing Standard 2.9.1 and other standards in the Australia New Zealand Food Standards Code that regulate Infant Formula.[25]

The aim of the review is to ensure that regulation of Infant Formula is clear and reflects the latest scientific evidence. FSANZ is also considering the harmonisation of the Australia New Zealand Food Standards Code with international regulations.

6 Significant Benefits to the Public

The INC submits that the MAIF Agreement provides a number of significant benefits to the public, including public health benefits and low regulatory costs.

6.1 Continued public health benefits will result from re-authorisation

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.

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[23] Available here: http://www.coaghealthcouncil.gov.au/Portals/0/Australian%20National%20Breastfeeding%20Strategy%20-%20FINAL%20.pdf

[24] COAG Health Council, *Australian National Breast Feeding Strategy 2019 and beyond*, p 34.

[25] Further information is available at: https://www.foodstandards.gov.au/code/infant/Pages/default.aspx

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.

The MAIF Agreement provides restrictions on the marketing of Infant Formula. In doing so, the MAIF Agreement contributes to the protection and promotion of breastfeeding. 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 breastmilk substitutes when 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 and its use;
- outlining the boundaries for appropriate relationships between manufacturers and importers of Infant Formula and health care professionals to limit the potential for conflicts of interest; and
- requiring manufacturers and importers of Infant Formula to have internal compliance procedures which promote compliance by all company employees.

6.2 The MAIF Agreement is an effective voluntary code

The MAIF Agreement is an effective voluntary industry code with associated benefits including enhanced transparency and low compliance costs.

These benefits have been acknowledged by the ACCC and the New Zealand Commerce Commission.

As the ACCC Guidelines for developing effective voluntary industry codes of conduct state, '*there are significant benefits in developing and complying with voluntary industry codes*'.[26] The ACCC Guidelines note that those benefits include:

- Greater transparency of, and stakeholder confidence in, the industry;
- 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; and
- Complaint handling procedures under such codes are generally more cost effective, time efficient and user friendly in resolving complaints than government bodies.

In relation to the MAIF Agreement, in the 2016 Determination, the ACCC concluded:[27]

- The ACCC accepts that the operating costs of a voluntary self-regulatory code are likely to be lower than the costs associated with regulatory alternatives.

[26] ACCC *Guidelines for developing effective voluntary industry codes of conduct* July 2011, p3.
[27] 2016 Determination, [94].

- Consequently, the ACCC considers that the MAIF Agreement is likely to result in a public benefit by avoiding these regulatory costs, at least in the short to medium term.

The INC submits the MAIF Agreement is more cost-effective than other regulatory solutions, resulting in significant public benefits of being an effective voluntary code with low associated costs.

The cost-effectiveness of the broadly similar Infant Nutrition Council Code of Practice, was considered by the New Zealand Commerce Commission, with avoided net regulatory costs in New Zealand quantified at approximately $NZ3.2 million over two years.[28]

In addition, independent research has evidenced the benefits associated with a voluntary code.

- 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.[29] 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 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 (*the ***Nous Effectiveness Review****),* dated 13 June 2012, concluded that the *'voluntary, self-regulatory nature of the MAIF Agreement is the most cost effective regulatory mechanism*'.[30] The paper also concluded that the MAIF Agreement should continue provided that it continues to promote the achievement of the aim of the MAIF Agreement and industry coverage levels remain high.

6.3 TPC and ACCC determined the MAIF Agreement is likely to result in public benefits

(a) TPC Determination

The TPC determined that the public benefits likely to result from the MAIF Agreement were likely to outweigh any anti-competitive detriment or other public detriment.[31] The TPC accepted that the following public benefits were likely to arise from the MAIF Agreement:[32]

[28] New Zealand Commerce Commission, Determination: Infant Nutritional Council Limited [2015] NZCC 11, p18.
[29] 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.
[30] Department of Health and Ageing, *Review of the effectiveness and validity of operations of the MAIF Agreement – Research Paper* 13 June 2012 ***(Nous Effectiveness Review*****),** p 28.
[31] TPC Determination, [6.6].
[32] TPC Determination, [6.2].

- 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.

(b) 2016 Determination

In its 2016 Determination, the ACCC considered that the MAIF Agreement had resulted, and was likely to continue to result in significant public benefits by (i) protecting and promoting breastfeeding leading to improved health outcomes; and (ii) avoiding regulatory costs from alternative solutions.[33]

The ACCC concluded that the public benefits likely to result from the MAIF Agreement were likely to outweigh any public detriment, including from any lessening of competition caused by the restrictions on marketing.[34] The ACCC reached that conclusion notwithstanding two concerns.

First, the ACCC had some concerns that practices around the marketing of Toddler Milk may be undermining the benefits of the MAIF Agreement to some extent by effectively inadvertently promoting Infant Formula. The ACCC considered, however, that the publication of the MAIF Tribunal (as it then existed) decisions on this issue would be likely to result in changes in industry practice.[35]

As noted in section 6.4(a) below, this concern has been addressed by the development and dissemination by the INC of guidance to its members on the marketing of Toddler Milk, and the resolution by the MAIF Complaints Committee of various complaints relating to the inadvertent promotion of Infant Formula in Toddler Milk marketing.

Second, the ACCC considered the benefits of the MAIF Agreement would only be achieved to the extent that it was effective in its operation. The ACCC noted that transparency of the MAIF Tribunal decisions and the development of guidelines by the MAIF Tribunal would be key elements in encouraging compliance with MAIF Tribunal decisions.[36] As explained in section 6.4(b) below, this concern has been addressed by actions taken by the Committee.

6.4 Factors which enhance the benefits of the MAIF Agreement

As outlined above, a number of developments have occurred since the 2016 Determination which address the concerns raised by the ACCC and enhance the benefits of the MAIF Agreement.

(a) Toddler milk marketing has been addressed

In the 2016 Determination, the ACCC considered the issue of whether the marketing of Toddler Milk effectively cross-promotes Infant Formula because of the lack of clear distinction between the two products in packaging and marketing materials.[37]

[33] 2016 Determination, [123].
[34] 2016 Determination, [137].
[35] 2016 Determination, [124].
[36] 2016 Determination, [125].
[37] 2016 Determination, [96]-[109].

There have been a number of developments since the 2016 Determination which have improved industry practice in respect of the marketing of Toddler Milk.

- **First**, as outlined at 4.5(b) above, the INC has developed and disseminated to its members the Toddler Milk Guidance to provide guidance on the appropriate marketing of Toddler Milk. The guidance provides practical suggestions to ensure there is no inadvertent promotion of Infant Formula through the marketing of Toddler Milk. For example, the guidance recommends that INC members:
    - Use distinguishing features in promotional materials for Toddler Milk (for example using images of children clearly identifiable as toddlers aged 1 to 3 years and depicting children with teeth, that can walk, have suitable clothing, and are engaged in activities consistent with that group).
    - Avoid any direct comparison of Toddler Milk to breastmilk.
    - Clearly specify the intended age group or consumption age.
    - Avoid featuring images of Infant Formula on Toddler Milk, as this could be considered inadvertent promotion of Infant Formula.
- **Second**, as outlined at 4.5(a) above, the Committee is currently developing 'Guidelines on staging information for the labelling of infant formula' to address concerns about this issue.
- **Third**, the Committee is able to consider complaints in relation to the marketing of Toddler Milk by manufacturers and importers, to the extent that marketing may have the effect of promoting Infant Formula. Over the past few years, the Committee (and formerly the MAIF Tribunal) has issued a number of determinations on this issue. The Committee's decisions illustrate the rigour with which the Committee discharges its functions.[38]

As outlined by the ACCC in the 2016 Determination, whether marketing restrictions in the MAIF Agreement should be extended to Toddler Milk is a policy decision for the Federal Government.[39] The Federal Government has not given any indication that it considers the MAIF Agreement should be extended in this manner. The Federal Government has not yet published an implementation plan in response to the Breastfeeding Strategy, nor has it commissioned a review of the MAIF Agreement following the recommendation of the strategy. A review of the MAIF Agreement may conclude, as did the Nous Effectiveness Review, that an extension of the agreement to include to Toddler Milk is not necessary.[40]

[38] See, Annual Report Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF) Complaints Committee 2018-2019 available at https://www1.health.gov.au/internet/main/publishing.nsf/Content/EC11D71D50B3C404CA2584B9001D746B/$File/Annual%20Report-MAIF%20Complaints%20Committee-2018-19%20for%20publication.pdf

[39] 2016 Determination, [108].

[40] Nous Effectiveness Review, p29, Recommendation 3.

Given that there is no firm evidence that the marketing of Toddler Milk has an effect on breastfeeding rates, the inclusion of Toddler Milk in the MAIF Agreement may result in:

- deterring companies who are not presently signatories of the MAIF Agreement from signing; and
- existing signatories withdrawing from the MAIF Agreement.

(b) Enhanced transparency of and compliance with complaints process

In its 2016 Determination, the ACCC also noted the benefits of the MAIF Agreement will only be achieved to the extent it is effective in its operation, and considered (i) the transparency of the then MAIF Tribunal decisions; and (ii) the development of guidelines by the MAIF Tribunal, to be key elements to ensure compliance with Tribunal decisions.[41]

As explained above at section 5.1(a), in 2017 the Department of Health commissioned an independent review of the MAIF Tribunal, following which a new complaints handling system was put in place, led by the Committee. Previously, MAIF Tribunal decisions were reported to the Department of Health and published once per year in the MAIF Tribunal's annual report.

In contrast, under the Committee Terms of Reference, the outcome of complaints must be uploaded onto the Department of Health website after determination. The INC submits that publication of the outcome of complaints on the Department of Health website in a timely manner has increased the transparency of Committee decisions.

The MAIF Agreement and Committee Terms of Reference do not specify sanctions in the event that the Committee determines a breach of the MAIF Agreement has occurred. Rather, the adverse publicity from the publication of the Committee's determination provides an effective mechanism to regulate the conduct of MAIF signatories.

Since its creation the Committee has also developed (and is continuing to develop) a number of guidelines as outlined in section 4.5(a) above.

The development of such guidelines is a key element to ensure compliance with Committee decisions, and to achieve the effective operation of the MAIF Agreement. Overall, the INC submits that the improvements to the complaints process brought about by the establishment of the Committee has resulted in an enhancement to the public benefits of the MAIF Agreement.

(c) Scope of the MAIF Agreement has been extended and clarified

Since the 2016 Determination, the MAIF Agreement has been extended to apply to new signatories, while guidance and determinations have been issued which clarify the extent to which the MAIF Agreement applies to the conduct of retailers.

Increased signatories

The MAIF Agreement applies to manufacturers and importers who are signatories. Despite the voluntary nature of the MAIF Agreement, market coverage remains high. Since the 2016 Determination, the number of signatories of the MAIF Agreement has increased from ten to seventeen, accounting for the majority of the Infant Formula market in Australia.

There are only a small number of manufacturers and importers who are not signatories including: Royal Australia New Zealand, Munchkins and Blackmores.

[41] 2016 Determination, [125]

In the light of the above, the INC submits that any possible detriment associated with the scope of the MAIF Agreement does not undermine the significant public benefits associated with the agreement.

Retailers

While the MAIF Agreement does not apply to retailers of Infant Formula, it does apply to manufacturers and importers who indirectly market Infant Formula to the public through retail channels.

Steps have been taken since the 2016 Determination to clarify the position in respect of retailers. This includes the publication of an updated Information for Retailers brochure in September 2020.

The INC notes that the Nous Effectiveness Review concluded that expanding the MAIF Agreement to cover retailers presents a number of issues, including requiring a major change to the MAIF Agreement and significant costs.[42] It would also pose practical issues for example, whether both major and smaller retailers should be covered by the agreement. The review did not identify sufficient evidence to warrant a change of this nature.[43]

7 Benefits Outweigh Any Public Detriments

The MAIF Agreement does not result in any anti-competitive or other public detriment. The MAIF Agreement restricts the promotional activities of signatories. For the following reasons, this is not 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.
- 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.[44]
- It is unlikely that the 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.[45]
- In any event, benefits relating to product price, quality and information are still achievable under the MAIF Agreement.
- Price competition is not adversely affected by the MAIF Agreement as retailers of Infant Formula are able to engage in inter and intra-brand price competition. Retailers are outside the scope of the MAIF Agreement and the price promotion of Infant Formula (through for example 'special prices' and discounts) is permissible under the MAIF Agreement.[46]

[42] Nous Effectiveness Review, p40.
[43] Nous Effectiveness Review, p40.
[44] 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).
[45] 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.
[46] 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

- Research and innovation is not restricted under the MAIF Agreement. In any event, Australia is a relatively small consumer of Infant Formula in the world. As such, the MAIF Agreement is unlikely to have any detrimental effect on product research and innovation.
- The MAIF Agreement does not prevent appropriate communication of information about Infant Formula products, including the provision of scientific and factual information to appropriately qualified health care professionals.

Further, in the absence of the MAIF Agreement, manufacturers would still be constrained in their ability to market Infant Formula, particularly under foods standards legislation, and any restrictions which may in future exist under a regulatory regime put in place to implement the WHO Code.

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

8 Future With and Without the Conduct

The ACCC has previously accepted that in a future without the MAIF Agreement:

- Infant Formula marketing would '*not be subject to any restriction and members of the Council would be free to market as they see fit (subject to the requirements of foods standard legislation and Australian Consumer Law), at least in the short to medium term*';[47]
- an alternative regulatory response would likely take a number of years to develop and implement;[48]
- it is not possible to know '*what form any response by Government would take, and whether restrictions imposed under such a regulatory regime may be more or less restrictive than under the current MAIF Agreement*';[49] and
- there would be costs associated with developing and implementing an alternative regulatory regime.[50]

The INC submits that each of these considerations remains applicable to the present application. If re-authorisation is not granted, it is likely there would be unrestricted marketing of Infant Formula which would have a detrimental impact on Australian breastfeeding rates.

Allens

Solicitors for Infant Nutrition Council

the Marketing of Infant Formula in Australia. Available here: https://www.infantnutritioncouncil.com/wp-content/uploads/2016/09/FINAL-INC-Retail-brochure-6pp-DL-Australia-FA.pdf

[47] 2016 Determination, [75].
[48] 2016 Determination, [76].
[49] 2016 Determination, [76].
[50] 2016 Determination, [76].

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

(a) '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.

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

(c) '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.

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

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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.

(e) '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 all relevant clauses of the Australia New Zealand Food Standards Code, including Infant Formula Products Standard 2.9.1.

(f) '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.

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

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

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

Clause 4: Information and Education

(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)

(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)

(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

(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)

(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)

(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)

(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

(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)

(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)

(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)

(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)

(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)

(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)

(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

(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)

(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.

(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)

(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)

(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

(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)

(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

(a) Manufacturers and importers of infant formulas must ensure that infant formulas sold in Australia conform to all relevant clauses of the Australia New Zealand Food Standards Code, including Infant Formula Products Standard 2.9.1. (WHO Code Articles 9.2, 9.4, 10.1 and 10.2)

(b) Manufacturers and importers of infant formulas must ensure that labels provide the information required to be provided by the Australia New Zealand Food Standards Code Part 1.2 and Infant Formula Products Standard 2.9.1., 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

(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)

(b) 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

Australian Dairy Park Pty Ltd

Bayer Australia Ltd

Bellamy's Organic

The Infant Food Co. Pty Limited

The LittleOak Company Pty Ltd

Nature One Dairy Pty Ltd

Nestlé Australia Ltd

Nuchev Ltd

Nutricia Australia Pty Ltd

Reckitt Benckiser (Australia) Pty Limited

Sanulac Nutritional's Australia Pty Ltd

Spring Sheep Milk Company

Sprout Organic

Swisse Wellness Pty Ltd

The a2 Milk Company Ltd

Wattle Health Australia Limited

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 – MAIF Complaints Committee's interpretation of the MAIF Agreement related to electronic media marketing

MAIF Complaints Committee's interpretation of the MAIF Agreement related to electronic media marketing activity

Overall Principles

1. The purpose of these guidelines is to support the interpretation of the MAIF Agreement. This guidance does not replace the responsibility of the MAIF Complaints Committee to apply the MAIF Agreement objectively, using common sense in light of the context of the website, on a case by case basis.
2. These guidelines are to be read with the aim of the MAIF Agreement 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 a description and pack shots, on a website is acceptable, provided the above guidelines 3 and 4 of this document 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; and
    - product logos are not displayed independently of pack shots.

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.
   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.

Other electronic communications and social media

7. In accordance with these guidelines, manufacturers and importers should adopt reasonable measures, to monitor and manage social media forums and other electronic platforms which are within their control to ensure they comply with the MAIF Agreement. Manufacturers and importers must not conduct any paid influencer activity for their infant formula products.
8. Manufacturers and importers should not initiate discussion or actively provide information about infant formula via social media forums and other 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.
9. 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.
10. Manufacturers are entitled to initiate communication to consumers via social media forums and other electronic platforms on urgent health and safety matters provided the communication is limited to the health and safety matter.

Annexure 5 – MAIF Complaint Committee's interpretation of Clause 7(a) of the MAIF Agreement relating to scientific and factual information provided to health care professionals

MAIF Complaint Committee's interpretation of Clause 7(a) of the MAIF Agreement relating to scientific and factual information provided to 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.*

Scientific information about infant formulas that is provided to health care professionals by manufacturers and importers should reflect the totality of the evidence. Manufacturers and importers should continue to take note of the APMAIF Interpretation (February 1993) *"Scientific information should reflect the current scientific knowledge in total, not simply selective parts that can be used in a misleading way".*

Scientific claims should be supported by a reference to the scientific literature and the cited publication/s should be relevant and have been published in a peer reviewed journal. If this is not possible, the manufacturer should be able to provide the MAIF Complaints Committee, if requested, with supporting evidence and the rationale for supporting the scientific claims with that evidence.

The language used in scientific claims should reflect the quality and strength of the supporting reference(s)/ evidence and have regard to the NHMRC Evidence Hierarchy[1], while noting limitations on randomisation in nutrition studies involving methods of infant feeding.

Such information should not imply or create a belief that the infant formula product is equivalent or superior to breastfeeding.

[1] National Health and Medical Research Council (NHMRC). NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. Commonwealth of Australia, 2009

NHMRC Evidence Hierarchy: designations of 'levels of evidence' according to type of research question

Level	Intervention [1]	Diagnostic accuracy [2]	Prognosis	Aetiology [3]	Screening Intervention
I [4]	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard,[5] among consecutive persons with a defined clinical presentation[6]	A prospective cohort study[7]	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard,[5] among non-consecutive persons with a defined clinical presentation[6]	All or none[8]	All or none[8]	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial[9] ▪ Cohort study ▪ Case-control study ▪ Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study
III-3	A comparative study without concurrent controls: ▪ Historical control study ▪ Two or more single arm study[10] ▪ Interrupted time series without a parallel control group	Diagnostic case-control study[6]	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: ▪ Historical control study ▪ Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)[11]	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

*Explanatory notes are provided in the Merlin et al 2009 article; including glossary for the different study designs

Annexure 6 – Best-practice Guidance for INC Members for the Marketing of Toddler Milk Drinks to Consumers

Best-practice Guidance for INC Members for the Marketing of Toddler Milk Drinks to Consumers

Scope and background

Toddler milk drinks (regulated by FSC 2.9.3 as formulated supplementary foods for young children) are scientifically researched and formulated to supplement the nutritional needs of young children 1-3 years of age.

The nutritional composition of these products is not suitable to replace breast-milk for infants and is unsafe as a sole source of nutrition. For this reason, toddler milk drinks are not breast-milk substitutes, but are supplementary foods especially suited to young children.

In Australia and New Zealand, toddler milk drinks are intended as an alternative to cow, sheep, goat or other commercial (i.e. non-human) milks in young children over 1 year of age to be consumed when energy and nutrient intakes may not be adequate.

Purpose of this document

The Infant Nutrition Council and its members support the public health goals that protect and promote breastfeeding through adherence to the MAIF Agreement in Australia and the INC Code of Practice in New Zealand. Marketing of toddler milk drinks is outside the scope of the MAIF Agreement and the INC Code of Practice.

The purpose of this document is to provide non-binding guidance to INC members on the distinguishing features of toddler milk drinks' marketing. INC members should be aware that this best practice guidance does not preclude other relevant laws or regulations pertaining to the marketing of toddler milk drinks in Australia or New Zealand.

Best Practice Guidance

1 In order to make clear that any advertisements for toddler milk drinks are for products which are intended for consumption by young children over 1 year of age, INC suggests that members consider including the following distinguishing features in any advertising or promotional materials for toddler milk drinks:

   (a) use images of young children that are clearly identifiable as aged over 1 year and up to 3 years (toddlers) – for example, by depicting children with teeth, that can walk, have hair, suitable clothing, and are engaged in activities with behaviour that is consistent with that age group;

   (b) where images involve the toddler consuming the toddler milk drink, use images that show toddlers drinking from a cup appropriate to that age group, and not using a baby feeding bottle or other accessories which might be more suitable to infants under 12 months of age;

2 Avoid any direct comparison of toddler milk drinks to breast milk;

3 Clearly specify the intended age group, for example by stating the word "toddler" and/or the appropriate consumption age (e.g. "from 1 year of age");

4 Avoid featuring images of Infant Formula or Follow on Formula products (e.g. pictures of tins of stage 1 or stage 2 products) on toddler milk drinks, as this could be considered inadvertent promotion of Infant Formula or Follow on Formula.

Approved by the INC Board 27 February 2018

Annexure 7 – Information for Retailers brochure

MAIF Agreement and Retailers[1]

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

Due to the sensitive nature of Infant Formula products from 0 to 12 months, and strict regulations, special consideration needs to be taken when these products run into short expiry or get damaged. INC recommends that the following procedures are implemented by a responsible retailer:

- Strong stock management processes to ensure expired stocks are not on shelves.
- For cases of damaged or expired stocks, destruction of these products should be monitored by a certified process to ensure that they cannot be accessed by the public.
- Donations from signatories to the MAIF Agreement should, by all means, be avoided as these are strictly governed under the MAIF Agreement.

1 - Defined as businesses engaged in the trade or on-selling of infant formula in physical retail outlets or via e-commerce.

Price promotions

Price promotion of infant formula (such as 'special prices' and discounts) is allowed. The MAIF Agreement is currently authorised under the Competition and Consumer Act 2010. However, the MAIF Agreement and the authorisation do not restrict price promotions of infant formula.

Further information

Find the MAIF Agreement on the INC website:
infantnutritioncouncil.com/marketing-codes

Industry supporting both
Breastfeeding & Infant Formula

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

INFANT NUTRITION COUNCIL
AUSTRALIA & NEW ZEALAND

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

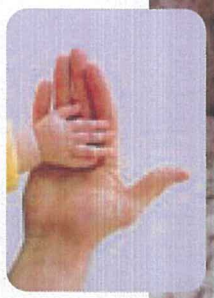
Information for Retailers

Contact us

Phone +61 2 6273 8164
Email info@infantnutritioncouncil.com

INFANT NUTRITION COUNCIL
AUSTRALIA & NEW ZEALAND

www.infantnutritioncouncil.com



Breastfeeding is the normal way to feed a baby and is important for baby's health and well-being. The World Health Organization and the National Health and Medical Research Council in Australia recommend exclusive breastfeeding 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 breastfeeding is the normal way to feed an infant and that breastmilk provides the best possible nutrition, however, when an infant does not receive breastmilk, the only suitable and safe alternative is a scientifically developed infant formula product.

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 Australia's 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, public health advocates and other stakeholders and was implemented in 1992.

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 breastmilk 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.

Monitoring Code Compliance

The Australian government through the Department of Health monitors compliance with the MAIF Agreement. Individuals, members of industry, community and consumer groups can lodge a complaint with the Department of Health alleging a breach of the MAIF Agreement. Complaints are provided to the MAIF Complaints Committee which determines whether they are in-scope. The MAIF Complaints Committee will then decide about in-scope complaints as to whether or not the matter complained of constitutes a breach. More information about the MAIF Agreement and complaints process is available at www.health.gov.au/maif

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 1or All Ages infant formulas)
- **Follow-on formula i.e. formula that is suitable for babies from six to twelve 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**

Annexure 8 – Policy – Breastfeeding

Policy - Breastfeeding

Principles

The Infant Nutrition Council recognises;

- that breastfeeding is the normal way to feed a baby.
- that breastfeeding provides valuable short and long-term health benefits for babies and mothers.
- the rights of women to breastfeed without discrimination and the rights of infants to receive optimum nutrition from breastmilk.
- that it is unlawful to treat a woman less favourably on the basis that she is breastfeeding under anti-discrimination laws (such as the Australia Federal Sex Discrimination Act 1984 and the NZ Human Rights Commission Act 1977 and Employment Relations Act 2000).
- that breastfeeding provides long term benefits for employers and communities.

Aim

The Infant Nutrition Council is committed to promoting the value of breastfeeding and improving breastfeeding rates by proactively supporting the protection and promotion of breastfeeding.

Policy

- The Infant Nutrition Council supports the aim of the World Health Organisation International Code of Marketing of Breast Milk Substitutes (WHO 1981) through its members' voluntary restriction of the marketing of infant formula through the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement 1992 (MAIF Agreement) and in New Zealand the Infant Nutrition Council Code of Practice for the Marketing of Infant Formula.
- The Infant Nutrition Council and its members are committed to including strategies and activities in their annual strategic planning that support, promote and protect breastfeeding.
- The Infant Nutrition Council and its members encourage their employees to breastfeed and are committed to providing ongoing support to their employees to continue to breastfeed after returning to work.
- The Infant Nutrition Council will work in collaboration with other breastfeeding advocates such as the Australian Breastfeeding Association, the New Zealand Breastfeeding Authority and other NGOs.

Support to breastfeed will include:

- Support of legislation around paid maternity leave and enhancements to paid maternity leave.
- The provision of paid maternity leave and further unpaid leave to a total of 12 months.
- The offer of flexible working arrangements to more easily enable women to return to work and breastfeed simultaneously.
- Workplace support to ensure that breastfeeding employees feel comfortable to breastfeed or express breastmilk in the workplace and do not suffer discrimination or harassment as a result of doing so.

Promotion of breastfeeding will include:

- Information about breastmilk and breastfeeding on the Infant Nutrition Council website.
- Information on breastfeeding and expressing of breastmilk, including local resources, to all pregnant and breastfeeding employees.
- The positive promotion of breastfeeding in appropriate company workplace areas and in-house communications with staff.
- Awareness of the company's breastfeeding policy to all staff and included in new employee induction.

INC's members will work towards additional support to breastfeed through:

- The provision of lactation breaks to enable mothers to breastfeed their infant or express their breastmilk.
- The provision of a suitable facility in which mothers can breastfeed their infant or express and store their breastmilk. The facility will be clean, comfortable and private. It will include hand washing and milk storage facilities and an electrical outlet for mothers who use an electric breast pump.

References

- World Health Organization Global Strategy for Infant and Young Child Feeding. (WHO 2003)
- National Health and Medical Research Council: Dietary guidelines for children and adolescents in Australia: A guide to healthy eating (NHMRC 2003)
- Food and Nutrition Guidelines for Healthy Infants and Toddlers (Aged 0-2) - A background paper (Ministry of Health 2008)
- World Health Organisation International Code of Marketing of Breastmilk Substitutes (WHO 1981)

Approved by the Board
29th July 2010
Amended 17th August 2011

Annexure 9 – Guidance on Interactions with Healthcare Professionals

INFANT NUTRITION COUNCIL
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.

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 10 – Policy – Distribution of Infant Formula Samples to Health Care Professionals

Policy – Distribution of Infant Formula Samples to Health Care Professionals

Aim

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

Scope

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

Definitions

'Samples'

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

'Professional Evaluation' and 'Research'

The words *'professional evaluation'* apply to:

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

- An individual patient assessment includes a follow-up meeting between the health professional and the mother of the infant. (Note: This guideline was developed following discussions at the 46th meeting of the APMAIF Panel on 5 December 2002)

The word *'research'* applies to:

- Clinical research carried out at the institutional level.

'*Health Care System'*

- Governmental, non-governmental or private institutions engaged, directly or indirectly, in health care for mothers, infants and pregnant women. It also includes health workers in private practice. For the purposes of this policy document, the health care system does not include voluntary workers, nurseries, social welfare agencies or childcare centres.

'*Health Care Professional'*

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

Policy

- Manufacturers and Importers may provide infant formula samples to 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.*)
- 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 11 – Template Infant Formula Samples Request Form (Australia)

«Company logo»

Template Infant Formula Samples Request Form (Australia)

(contains minimum information required, format is not mandatory)

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

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

"The aim is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of Breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution." (WHO Code Article 1)

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

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

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

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

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

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

- Analysis of products (ingredients, taste, nutritional profile);
- Trial preparation and mixing of infant formula products (includes preparation and mixing instructions to mothers);
- Investigative or development projects, using sound methodology and involving a number of infants;

- A thorough assessment of the suitability of a product for an individual infant, including acceptance by the infant, when mothers have made the informed choice to use infant formula.

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

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

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

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

Annexure 12 – MAIF Complaints Committee Terms of Reference

Terms of Reference

The Marketing in Australia of Infant Formulas; Manufacturers and Importers (MAIF) Agreement Complaints Committee terms of reference are to:

- Receive complaints and determine whether they are in-scope or out-of-scope of the MAIF Agreement;
- For in-scope complaints, investigate complaints against Members (signatories of the MAIF Agreement) and determine if a breach of the MAIF Agreement has occurred:
    - If a complaint is considered a breach, a letter will be sent to the signatory advising of this decision.
    - Decisions of the MAIF Complaints Committee will be by majority.
- Develop, manage and amend guidelines on the interpretation and application of the MAIF Agreement as needed; and
- Provide advice on the operation of the MAIF Agreement to the relevant Australian Government Minister as needed.

Secretariat functions

The Secretariat to the MAIF Complaints Committee will:

- Receive complaints made against the MAIF Agreement.
- Make an initial assessment of whether scope can be determined, and then provide its assessment of the complaint to the MAIF Complaints Committee for ratification.
- If unable to determine if a complaint is in or out of scope of the MAIF Agreement, submit the complaint to the MAIF Complaints Committee to determine if it is within scope of the MAIF Agreement and subsequently to assess whether a breach has occurred.
- Act as a liaison point for issues relating to the MAIF Agreement;
- Organise the MAIF Complaints Committee meetings including travel and venue arrangements and sitting fee payments.
- Prepare agenda papers and minutes for meetings.
- Prepare letters on behalf of the MAIF Complaints Committee to Members and complainants.

    - If a complaint is considered to be in-scope, a letter will be sent to the complainant informing them the complaint will be considered by the MAIF Complaints Committee. Once considered by the MAIF Complaint Committee, a letter will be sent to the complainant notifying them of the outcome.
    - If a complaint is considered out-of-scope, a letter will be provided to the complainant informing them of this outcome.
- Maintain and update the MAIF web page on the Department of Health website.
- Upload the outcome of complaints onto the Department of Health website after determination.
- Prepare an annual report post end of financial year and publish on the Department of Health website.
- Update guidelines for interpretation of the MAIF Agreement as necessary.
- Maintain registry of Members of the MAIF Agreement and invite new infant formula companies to become Members of the MAIF Agreement.