

ANNUAL REPORT MARKETING IN AUSTRALIA OF INFANT FORMULA INDEPENDENT TRIBUNAL 2017-2018

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Letter of Transmittal

Senator the Hon. Bridget McKenzie MP
Minister for Rural Health
Parliament House
Canberra ACT 2600

18 July 2018

Dear Senator McKenzie

I am pleased to present the Annual Report of the Marketing in Australia of Infant Formula Tribunal for our fourth year of operation, ending on 30 June 2018.

This has been the final year of operation of the Tribunal which was dis-established on 30 June 2018. The Department of Health will be resuming responsibility for arbitration of complaints made against the MAIF Agreement from 1 July 2018. Pending the establishment of a new complaints body, there will be no extant Tribunal from whom Australian consumers might seek redress.

The Tribunal has been pleased to serve the Australian community over the past few years – under a scheme, designed and overseen by The Ethics Centre and funded by Industry. The Tribunal has operated as an independent and disinterested decision-making.

We understand that you have agreed to provide the Infant Nutrition Council with a 'seat-at-the-table' – hearing complaints against its members. We note, in passing, that this was not a feature of the scheme developed by The Ethics Centre – which, as a general principle, believes that complaints are best heard by a disinterested Tribunal.

We wish you well as the Government resumes direct responsibility for its obligations under the relevant WHO Code.

Yours sincerely



James Kearney
MAIF Tribunal Chair

Chapter 1: Scope and functions

MAIF Tribunal

The MAIF Tribunal (The Tribunal) is a non-statutory dispute resolution body that handles complaints arising under the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (MAIF Agreement). The Tribunal replaces the former Advisory Panel on MAIF which previously handled complaints under the MAIF Agreement.

The Tribunal is conducted under the auspices of The Ethics Centre. The cost of operating the Tribunal in the period covered by this annual report was

- Secretariat - \$48,000; Tribunal - \$9,500

MAIF Agreement

The MAIF Agreement embodies a voluntary, self-regulatory code of conduct for those manufacturers and importers of infant formula who are parties to the MAIF Agreement. It aims to promote:

- + Safe and adequate nutrition for infants
- + Breastfeeding
- + Proper use of breast milk substitutes when necessary
- + Adequate information about infant nutrition
- + Appropriate marketing and distribution of breast milk substitutes.

The MAIF Agreement is Australia's primary means of implementing the *World Health Organization's International Code of Marketing Breast-milk Substitutes* (WHO Code). The MAIF Agreement implements those aspects of the WHO Code that are appropriate to Australia's legal and economic environment.

Australian manufacturers and importers who are parties to the MAIF Agreement undertake to observe its provisions with respect to marketing and promotion of formulas for infants up to 12 months of age. The MAIF Agreement applies to:

- + Infant formula, i.e., formula that is suitable for babies from birth (often described as Starter, Stage 1 or All Ages infant formulas)
- + Follow-on formulas, i.e., formula that is suitable for babies aged six to twelve months.

The MAIF Agreement does not apply to:

- + Toddler milk drinks (sometimes called Growing Up milks)
- + Complementary foods (such as baby cereal and packaged baby foods)
- + Feeding bottles and teats

The Tribunal has no formal powers to obtain information about a complaint. The Tribunal relies for information on voluntary cooperation from the parties to the MAIF Agreement and on other stakeholders.

Current signatories to the MAIF Agreement include (as at 30 June 2018):

- + The a2 Milk Company Ltd
- + Abbott Australasia Pty Ltd
- + Aspen Nutritionals Australia Pty Ltd
- + Australian Dairy Park Pty Ltd
- + Bayer Australia Ltd
- + Bubs Australia Ltd (The Infant Food Company)
- + Devondale Murray Goulburn Co-operative Co. Limited
- + H J Heinz Company Australia Ltd
- + Nature One Dairy Pty Ltd
- + Murray Goulburn Co-operative Co. Limited
- + Nestlé Australia Ltd
- + Nuchev Pty Ltd
- + Nutricia Australia Pty Ltd
- + Wattle Health

Authorisation of MAIF Agreement

The MAIF Agreement was authorised by the then Trade Practices Commission on 23 September 1992. Authorisation of the MAIF Agreement was necessary because it contains marketing restrictions limiting competition and was granted on the basis that public benefit outweighed any anti-competitive detriment. Authorised organisations can legally follow the provisions of the MAIF Agreement but could be in breach of the *Trade Practices Act 1974* if they agree to any further marketing restriction which is not covered in the MAIF Agreement, even if it is recommended in the WHO Code.

On 4 July 2007 Nestlé Australia Ltd lodged an application with the Australian Competition and Consumer Commission (ACCC) for a minor variation to the authorisation of the MAIF Agreement. The application was necessary because several infant formula manufacturers and importers had exited or entered the market since the 1992 authorisations. This created uncertainty for the APMAIF and the infant formula manufacturers about the authorisation status of parties to the MAIF Agreement. The application was made to provide for the addition of parties to the MAIF Agreement and introduce a new time limit on the authorisations to allow for more regular review.

The ACCC granted an interim authorisation on 11 July 2007. On 30 August 2007 the ACCC made a determination varying the 1992 authorisations so that:

Authorisation applies to current and future manufacturers in, and importers into, Australia of infant formula that are or become parties to the Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement.

This determination came into effect on 21 September 2007, replacing the interim authorisation. Authorisations A90539 and A90540 were due to expire on 31 December 2015 but remained in force temporarily while the ACCC considered their long-term renewal. The Tribunal provided information about its activities to the ACCC to assist them in making a determination about the MAIF Agreement.

On 15 July 2016, the ACCC made final determinations A91506 and A91507 authorising the continuation for a further five years of the MAIF Agreement and the Guidelines made under the Agreement. Full details of the reasons for the determination are available from the [ACCC's website](#).

Reference to Guidelines

It is clear from the determination of the ACCC that the Guidelines, developed by the APMAIF, made under the MAIF Agreement form an integral part of the self-regulatory regime that the Agreement has established. The Guidelines are given careful consideration by the Tribunal when assessing complaints that allege breaches of the Agreement. The Tribunal therefore encourages complainants and respondents to refer to the Guidelines when making submissions to the Tribunal.

Chapter 2: Tribunal members

Tribunal Chair: James Kearney, Barrister-at-Law

Mr James Kearney has been a barrister in private practice for over 30 years. Prior to practicing law, Mr Kearney was a biochemist having graduated with a Bachelor of Science from the University of New England in 1976 and worked for a time for the Medical Research Council of New Zealand.

In 1985 Mr Kearney graduated with a Bachelor of Laws with First Class Honours from University of Technology, Sydney and was called to the bar the following year where he developed a diverse practice including medical related fields such as personal injury and medical negligence. He also works as a mediator and currently has national accreditation as a mediator. He is appointed to the panel of mediators recommended by the NSW Bar Association to the NSW District and Supreme Courts. He has worked for various arms of government as a mediator including the NSW Department of Primary Industry, Dust Diseases Tribunal and the NSW Workers Compensation Commission. He is also an arbitrator with the Local and District Courts and is an expert contributions assessor with the Dust Diseases Tribunal. He is currently also a Senior Legal Member with NSW Civil and Administrative Tribunal (NCAT) and sits in its Guardianship and Appeal Panel Divisions.

Mr Kearney brings a wealth of legal experience to the role together with a unique background in science.

Tribunal Member: Dr Jacqueline Dalby-Payne MBBS BSc MMed(Clin Epi) PhD FRACP

Dr Dalby-Payne is a General Paediatrician with a special interest in feeding and behavioural feeding problems. She graduated with her MBBS from the University of New South Wales in 1992. She initially trained at Royal North Shore Hospital in Internal Medicine and commenced Paediatric training at The Children's Hospital at Westmead in 1996. She completed a Masters Degree in Clinical Epidemiology at the University of Sydney in 2000 and graduated with her PhD from the University of Sydney in 2002. Dr Dalby-Payne is currently a Senior Staff Specialist and Head of the Department of General Medicine at The Children's Hospital at Westmead. She has a conjoint appointment as a Senior Lecturer with the University of Sydney. She is a founding member of the Multi-Disciplinary Feeding Team at The Children's Hospital at Westmead.

Tribunal Member: Gillian Calvert AO

Gillian Calvert AO has been an advocate for children for over 30 years. As inaugural NSW Children's Commissioner she established it as one of Australia's leading children's policy and research centers, one built on being child centered and child inclusive. Prior to that she was Director of the Office of Children and Young People in The Cabinet Office, responsible for coordinating government action for children and importantly re-focusing attention on the importance of the early years. She was instrumental in breaking the silence around child sexual assault where her leadership at the NSW Child Protection Council established NSW's collaborative and comprehensive approach to tackling child abuse and neglect. She started her career as a family therapist with troubled children and their families and the importance of listening to children and families experience has underpinned her lifelong commitment to children and their well-being. She holds a BA, BSW and MBA. Currently she sits on the Board of Life Without Barriers, chairs their Practice Governance sub-committee and is a member of the Risk sub-committee. She also sits on the Australian Centre for Child Protection Advisory Committee and chairs the Women's Committee for The Big Issue.

Tribunal Secretariat: Leigh Woodgate

Executive Assistant to Executive Director, Dr Simon Longstaff AO and Executive General Manager, Ed St John of The Ethics Centre.

Chapter 3: How complaints are processed

The MAIF Tribunal relies upon interested parties, such as breastfeeding advocacy groups, health professionals and members of the public, to monitor compliance with the MAIF Agreement. Alleged breaches of the MAIF Agreement are brought to the attention of the MAIF Tribunal by the submission of formal complaints. The Tribunal does not initiate audit compliance with the MAIF agreement.

Information about how to lodge a complaint is available from the [Australian Government Department of Health website](#).

Upon receipt, complaints are assessed by the Australian Government Department of Health and are classified as being within or outside the scope of the MAIF Agreement. Complaints considered outside the scope of the MAIF Agreement may include, but are not limited to, the following:

- + An infant formula manufacturer or importer that is not a current member to the MAIF Agreement or was not a member at the time the complaint was made
- + Retailer activity where there is no involvement by the manufacturer/importer (e.g. price promotions in retail stores and/or catalogues)
- + Infant merchandise (e.g. infant feeding bottles, teats and dummies)
- + Foods, including milk products formulated for children over 12 months of age (sometimes referred to as “toddler milks”)

The Australian Government Department of Health advises complainants in writing if their complaints are considered to be outside the scope of the MAIF Agreement. All other complaints are forwarded to the Tribunal Secretariat. The Tribunal Secretariat records all complaints received in its complaints register and maintains confidentiality about the identities of complainants.

The Tribunal Secretariat advises the manufacturer or importer of the product concerned that a complaint has been received alleging a breach of the MAIF Agreement:

- + Where a complaint is considered to be within the scope of the MAIF Agreement
- + If more information is required before an assessment can be made

The manufacturer or importer is invited to respond with any evidence or other information it wishes to submit for consideration.

Complaints that are assessed to be within the scope of the MAIF Agreement are then considered by the Tribunal. Complaints requiring consideration by the Tribunal are summarised by the secretariat prior to being forwarded to the Tribunal. Summaries are prepared using a standard format to present the key information relevant to making a decision. This includes:

- + How and where the complainant obtained the complaint material
- + The complainant's concerns regarding the material
- + Relevant clause(s) of the MAIF Agreement
- + Results of any enquiries made by the Tribunal Secretariat (e.g. responses from formula companies or health professionals)
- + Any previous consideration of a similar complaint or relevant guidelines on the interpretation of the MAIF Agreement

The Tribunal considers the complaint and may decide that it does not represent a breach of the MAIF Agreement or that further consideration is required before a determination can be made. Where further consideration is required, the manufacturer or importer is notified and is

invited to respond with any further relevant information. The Tribunal is able to seek information from other sources, including expert scientific or clinical advice.

The Tribunal considers all relevant information provided and makes a decision that the conduct alleged in the complaint is either 'in breach' or 'not in breach' of the MAIF Agreement.

When a decision is made, both the complainant and the subject company are advised of the final outcome of the complaint, including reasons for the decision. Decisions that are 'in breach' are reported via the Tribunal's Annual Report, which is provided to the Assistant Minister for Health and then published on the Department of Health's website.

Chapter 4: Complaints outcomes July 2017 – June 2018

In this reporting period the MAIF Tribunal decided eight complaints. Three complaints were dismissed. Three complaints were upheld. The two remaining complaints were dismissed in part and upheld in part. Set out below is a summary of the complaints decided.

Tribunal reference Complaint 2017 18 01 decided on 28 July 2017

A complaint against Aspen Nutritionals Australia Pty Ltd alleged that the label on a container of S26 Gold Newborn infant formula for infants from newborn to six months displayed the product logo and brand name of a follow on formula for infants 6 to 12 months called S26 Gold Progress. The respondent argued that the display of Progress on the container of Newborn, does not breach the MAIF agreement because it provides information to the consumer that there is a follow-on formula or a replacement to Newborn that is formulated specifically to meet the changing nutritional needs of babies when solid foods are being introduced. The Tribunal did not accept this submission finding that the display promoted or endorsed or advertised a progression to the general public in breach of Clause 5(a) of the MAIF agreement. This view is consistent with the earlier APMAIF decision reported in the 2012 – 13 annual report regarding the use of similar sequential numbering in a brochure. The Tribunal also notes this decision is consistent with the prior decision it made reported in the Tribunal's annual report of 2014 – 2015 (Complaint No 2015-15-01).

Tribunal reference Complaint 2017 18 02 decided on 23 November 2017

A complaint against Nuchev Pty Ltd alleged that an altered image on a Facebook page promoting toddler milks idealised the use of infant formula in breach of Cl. 4(b) of the MAIF agreement because it included an image of an infant. The Tribunal was provided with screenshots of the image which is an altered photograph. Above the image are the words (in large type) "If you want your children to be intelligent read them fairy tales – Albert Einstein". The image of the infant had been altered to add a shock of white hair and a moustache typical of images of Albert Einstein. The company logo also appeared next to the image. This was held to be a breach of the MAIF agreement because the image was clearly that of an infant less than 12 months of age. Further, the information accompanying the image of the infant also breached Cl. 4(a) of the MAIF agreement because it did not contain the information required by that clause. The Tribunal noted that the respondent permanently withdrew the post and has taken steps to ensure that future advertising subjects are more clearly identifiable as of toddler age so no further steps were necessary to remedy the breach. Nevertheless, the Tribunal observed from this and earlier decisions that it should be clear that the use of infant images in marketing and promotional material must be handled with great care if not to be found in breach of the MAIF agreement

Tribunal reference Complaint 2017 18 03 decided on 23 November 2017

A complaint against Aspen Nutritionals Australia Pty Ltd alleged that the use of the words "generations of babies have been nurtured by SMA" on a label of infant formula was a breach of Clause 4(b) of the MAIF agreement. The complainant urged the adoption of a dictionary definition to interpret the MAIF agreement while the respondent suggested the rules of contractual interpretation should apply. The Tribunal decided to adopt a common sense approach. The decision requires essentially a subjective judgment about whether the words used "idealise" the use of infant formula. The Tribunal found the use of those words did not "idealise" the use of infant formula, nor was there a breach of Clause 9(b) because the use of

those words did not breach the relevant food standards code as it did not “humanize” or “maternalise” the use of infant formula.

Tribunal reference Complaint 2017 18 04 decided on 23 November 2017

A complaint was received concerning Aspen Nutritionals Australia alleging a breach of Clause 6(b) of the MAIF agreement because an invitation to an education meeting was addressed to an individual clinician at their hospital address rather than a home address. The Tribunal determined this did not breach the MAIF agreement as there is nothing in the MAIF agreement that provides this is a breach. The fact that the invitation was placed on a hospital notice board by an unknown person was also found not to be a breach of the MAIF agreement because the Tribunal accepted it was not intended for display. Further, the Tribunal found that the invitation placed on the hospital notice board did not constitute materials donated to a health system in breach of clause 6(g).

Tribunal reference Complaint 2017 18 05 decided on 1 March 2018

A complaint was received against the a2 Milk Company alleging the label on a container of infant formula designed for babies from birth to six months (A2 Platinum Premium Infant Formula) displayed a description of it a follow-on formula for infants aged 6 to 12 months, as part of a numbered progression from infant formula to toddler milks. This was held to breach of Cl. 5(a) of the MAIF agreement because in the opinion of the Tribunal, the label promotes or endorses or advertises a progression which is inconsistent with clause 5(a) of the MAIF agreement. An earlier decision (Complaint 1 25.02.2014 and Review 12.02.2016) should not be distinguished on the ground that it involved an image while this complaint refers to text. The MAIF agreement makes no such distinction, it only refers to “advertise” or “promote”. The Tribunal was invited to review a proposed new label for the product and expressed a view that the new label would also breach Cl. 5(a) of the MAIF agreement because it still promoted a progression to a follow-on formula and the use of “teddy bear” image as part of the display possibly idealized the use of infant formula.

Another part of this complaint was held to not breach the MAIF agreement at the Tribunal’s preliminary stage on 23 November 2017. This part of the complaint was that the label on the tins of A2 Platinum Premium Infant Formula contain the words “Formulated for tiny tummies” and “Supported by science”. The complaint alleged this “idealises” infant formulas in breach of clause 4(b). The Tribunal accepted that that the words “Formulated for tiny tummies” only describes that the product is formulated to be digested by infants and does not idealise infant formula in breach of clause 4(b). As to the words “Supported by science” the complainant alleges those words are non-specific and misleading as there is no evidence which supports any benefit of a2 milk in infants. The Tribunal accepted that the product was developed and formulated in a manner supported by science and found that the phrase “Supported by science” does not idealise infant formula in breach of clause 4(b). To allege it is misleading is an incorrect characterization of the phrase, in the context in which it appears.

Tribunal reference Complaint 2017 18 06 decided on 1 March 2018

A complaint received against Nutricia Australia Pty Ltd alleged a breach of Clause 5(a) of the MAIF agreement in that the rear label on a container of infant formula displayed a description of a follow-on formula as part of a progression in a range of products. The Tribunal found the label advertises or promotes a product range and thus is promoting infant formulas to the general public in breach of Clause 5(a). The Tribunal did not accept the Respondent’s submissions that the display was appropriate health and safety information but went beyond that to promote the

product as part of a progression of products. The Tribunal held that the test whether there has been a breach of clause 5(a) is objective so evidence that information on the label is unlikely to influence a consumer is not relevant. The Tribunal did not accept an argument that an earlier decision was not relevant to the complaint because the prior decisions involved pictorial representations of infant formula while the current complaint involved factual information contained in words. The Tribunal found that the MAIF agreement does not make any distinction between images or text, it only refers to “promote” or “advertise”, which can occur with images or text.

Two other parts of this complaint were held not to breach the MAIF agreement at the Tribunal’s preliminary stage on 23 November 2017. The first part was a complaint that the label on the tins of Aptamil AllerPro Gold + Infant Formula contain the words “As experts in Early Life Nutrition, at Nutricia we know breast milk is best. Our specialty formulas are developed to support your baby’s progress in combination with over 50 years of continuous scientific research into breast milk and maternal and early life nutrition”. The complaint alleged this implies equivalence to breast milk in breach of clause 7(a). The Tribunal accepted the Respondents argument that clause 7(a) applies only to health professionals and secondly, that the superiority of breast milk is plainly stated. The Tribunal accepted these submissions and decided that the words alleged do not imply equivalence to breast milk and do not breach Clause 7(a).

The second part of the complaint not upheld at the preliminary stage was that the words used on the can of Aptamil AllerPro Gold + Infant Formula include “Aptamil Gold + helps lay the foundations for your baby’s future progress” were alleged to breach clause 5(a) of the MAIF agreement because it implies the product would be better than breastfeeding. The Tribunal decided that this is not a breach of clause 5(a) because it is factually accurate, appears below the words “Breast Milk is best”, it makes no express or implied comparison with breast milk and does not advertise or promote infant formula in a manner that breaches clause 5(a).

Tribunal reference Complaint 2017 18 07 decided on 10 May 2018

A complaint was received that Murray Goulburn Co-operative Co. Ltd breached Clause 5(a) because the label on a container of infant formula displayed a description of a follow-on formula as part of a progression in a range of products. The product was Devondale Natra Start Infant Formula which is formulated for infants up to 6 months of age. The allegations was that the label advertises or promote a “follow on” formula for infants aged 6 to 12 months called Devondale Natra Start Follow on Formula and therefore an “infant formula” within the scope of the MAIF agreement. The Tribunal found the label advertises or promotes a product range and thus is promoting infant formulas to the general public in breach of Clause 5(a) of the MAIF agreement. The Tribunal further held that the information on the label of infant formula is available to the “general public” within clause 5(a) because it is placed on the retailer’s shelves without restriction. The respondent argued that the information on the label was consistent with the MAIF agreement because it informed consumers about the age-appropriate product for the child and the information about the follow-on formula is vital to a consumer given the nutritional requirements of infants at various stages of development. The Tribunal did not accept this argument because the information regarding a follow-on formula was provided against the background of a numbered progression that, in the Tribunal’s decision, promotes the use of the follow-on formula. Finally, the respondent suggested that a significant number of competitors present their products in an identical manner and this is evidence of compliance. The Tribunal did not accept this argument. Just because everybody else does it, does not make it right.

Tribunal reference Complaint 2017 18 08 decided on 10 May 2018

A complaint alleged that Nature One Dairy breached clauses 4(a), 4(b) and 5(a) of the MAIF agreement through an advertisement for Optigold Infant Formula (Optigold) in the form of an

infomercial by “The House of Wellness TV” – Episode 18 broadcast on 4 March 2018. A number of still photographs sourced from the infomercial were included with the complaint. In finding no breach of the MAIF agreement, the Tribunal accepted that it is unlikely that Nature One Dairy was the manufacturer of the product shown in the infomercial given that it ceased manufacturing that product about 16 months beforehand. In any event, the Tribunal also accepted Nature One Dairy’s assertion that the infomercial was created without its knowledge or consent and it should not be held liable for any breach that may have occurred.

Appendix A: Marketing in Australia of Infant Formulas: Manufacturers and Importers 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) 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).

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, 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.

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 for breast milk. It also applies to their quality and availability, and to information concerning their use. (WHO Code Article 2)

Clause 3: Definitions

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

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

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

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

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

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

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

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

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

Clause 4: Information and Education

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

- + the benefits and superiority of breastfeeding;
- + 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 infant formula, whether manufactured industrially or home prepared. (WHO Code Article 4.2)

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

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

Clause 5: The general public and mothers

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

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

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

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

Clause 6: Health care system

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

6(b) Manufacturers and importers of infant formulas should be aware that facilities of health care systems should not be used for the display of products within the scope of this document, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in clause 4(c) above. (WHO Code Article 6.3)

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

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

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

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

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

Clause 7: Health Care Professionals

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

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

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

7(d) Manufacturers and importers of infant formulas should not provide samples of infant formulas, or of equipment or utensils for their preparation or use, to health care professionals except when necessary for the purpose of professional evaluation or research at the institutional level. (WHO Code Article 7.4)

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

Clause 8: Persons employed by manufacturers and importers

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

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

Clause 9: Quality and Labelling

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

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

Clause 10: Implementation and monitoring

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

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

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

Appendix B: Guidelines concerning interactions with health care professionals for the purpose of interpreting the MAIF Agreement

This document provides guidance for the MAIF Tribunal to assist in interpreting the MAIF Agreement where a complaint received concerns interactions between infant formula manufacturers & importers and healthcare professionals.

Interpretative approach

It is recognised that modern marketing environments are complex. In that respect, matters appropriate for the Panel to consider in reviewing the interactions between infant formula manufacturers & importers and healthcare professionals include:

- + the scope and purpose of the MAIF Agreement;
- + the purpose or intention of the activity and interaction;
- + the environment or context in which the activity and interaction occurred; and
- + the outcome of the activity and interaction.

Although interpretations may differ, depending on the circumstances of the interaction, this approach should ultimately result in an interpretation that accords with the scope and purpose of the MAIF Agreement.

General

All interactions between infant formula manufacturers & importers and healthcare professionals should:

- + be transparent and capable of public and professional scrutiny;
- + be based on an awareness by the representatives of infant formula manufacturers & importers of the obligations of the MAIF Agreement; and
- + have the primary objective of providing medical and/or scientific knowledge and/or providing factual information about the product.

Specific matters

In addition to the above, the following points are intended to provide guidance concerning specific activities and interactions.

1(a) It should be obvious and apparent that the primary purpose of interactions between importers & manufacturers and health professionals should be the enhancement of medical and/or scientific knowledge and/or the provision of product information including the correct use of infant formula in accordance with Clauses 4 and 7 of the MAIF Agreement.

1(b) The extent to which such interactions accord with the primary purpose may be determined by taking account of a number of factors including the *time* allocation of the interaction and the *content* of the interaction.

Time Allocation: It should be obvious and apparent that the scheduled time allocation for the interaction between importers and manufacturers and health professionals is the major proportion of the total time allocated. This proportional analysis may be applied to all events involving an entertainment or hospitality component and/or travel and accommodation.

Content of the interaction: It is recognised that educational events are important for the dissemination of scientific knowledge and experience to healthcare professionals. Such events should have a clear objective of providing current, accurate and balanced medical and scientific education in an ethical and professional manner. It should be obvious and apparent that the content itself is the major reason that health professionals attend any particular event rather than entertainment or hospitality.

Similarly, scientific sponsorship of educational events by infant formula manufacturers and importers should have as the primary objective the enhancement of medical and/or scientific knowledge.

Example: A short educational presentation, of 30 mins would normally be expected to be accompanied by only light or no refreshments. It may be reasonable for a longer presentation to be accompanied by a meal. A proportional time analysis would place the provision of hospitality as the majority of the total time allocated.

2: The optimum 'best practice' approach for manufacturers & importers when interacting with health care professionals is that no gifts, benefits, competitions, incentives, give-aways or items of any value, whether tangible or in kind, should be given or offered to health care professionals – whether at conferences, seminars, educational/information sessions, trade shows or comparable events.

However, it is recognised that certain matters, such as the common practice of providing free pens and paper to attendees at a seminar or conference are not, in themselves, inconsistent with what should be the primary purpose of the interaction. Situations may be determined on a case-by-case basis based on an assessment which includes consideration of one or all of the following elements:

- + the purpose or intention of providing the items or 'in kind' benefit (i.e. what are the gifts or benefits being provided for, does it have a function?);
- + the value of the item or 'in kind' benefit; and
- + any targeting of the item or 'in kind' benefit.

Example: It is recognised that providing free pens and paper to attendees of conferences and seminars is intended for the purpose of enabling participants to take notes or exchange details. However, if the pens were relatively valuable – for example made of precious metals rather than plastic – then the practice may well be viewed as exceeding that required for the intended purpose.

As well as this, if, in a similar situation, such free gifts were only given to certain groups of health care professionals and not others, then this could be viewed as conferring a benefit or gift to that particular group.

It is also recognised that in some circumstances it is culturally respectful and appropriate to adopt practices such as mutual gift exchange or the provision of a certain standard of hospitality.

However, these should not be regarded as 'blanket exceptions.' It remains important for the panel to consider each situation as it arises.

Example: Tradeshow are an increasingly common way of showcasing products and innovations, and small gifts and free give-a-ways are commonly distributed. To determine whether the provision of items in this context would constitute a breach of the MAIF Agreement, the intention, value and targeting of the items would need to be considered.

3: Any assistance provided to health professionals to attend an event sponsored by or involving importers & manufacturers - such as a conference or seminar, must be *appropriate and practical*.

Any assistance for travel and/or accommodation expenses offered by importers & manufacturers should be confined to the purpose of providing practical assistance to attend, rather than being a reason in itself to attend.

Any travel expenses offered or provided should be justifiable by reference to the educational content and the origin of the delegates and should meet the proportionality test outlined in 1 (above).

Sponsorship provided to a healthcare professional to attend an educational event should only be provided where the event is directly related to the healthcare professional's area of expertise.

Example: Accommodation and travel offered or provided to delegates' family members would not generally be regarded as appropriate and confined to the purpose of providing practical assistance to the health care professional to attend the event. This information should be made clear in all invitations to healthcare professionals for educational events.