



Australian Government

Department of Health and Ageing

Annual Report
of the Advisory Panel on the
Marketing in Australia of Infant Formula
2010–11

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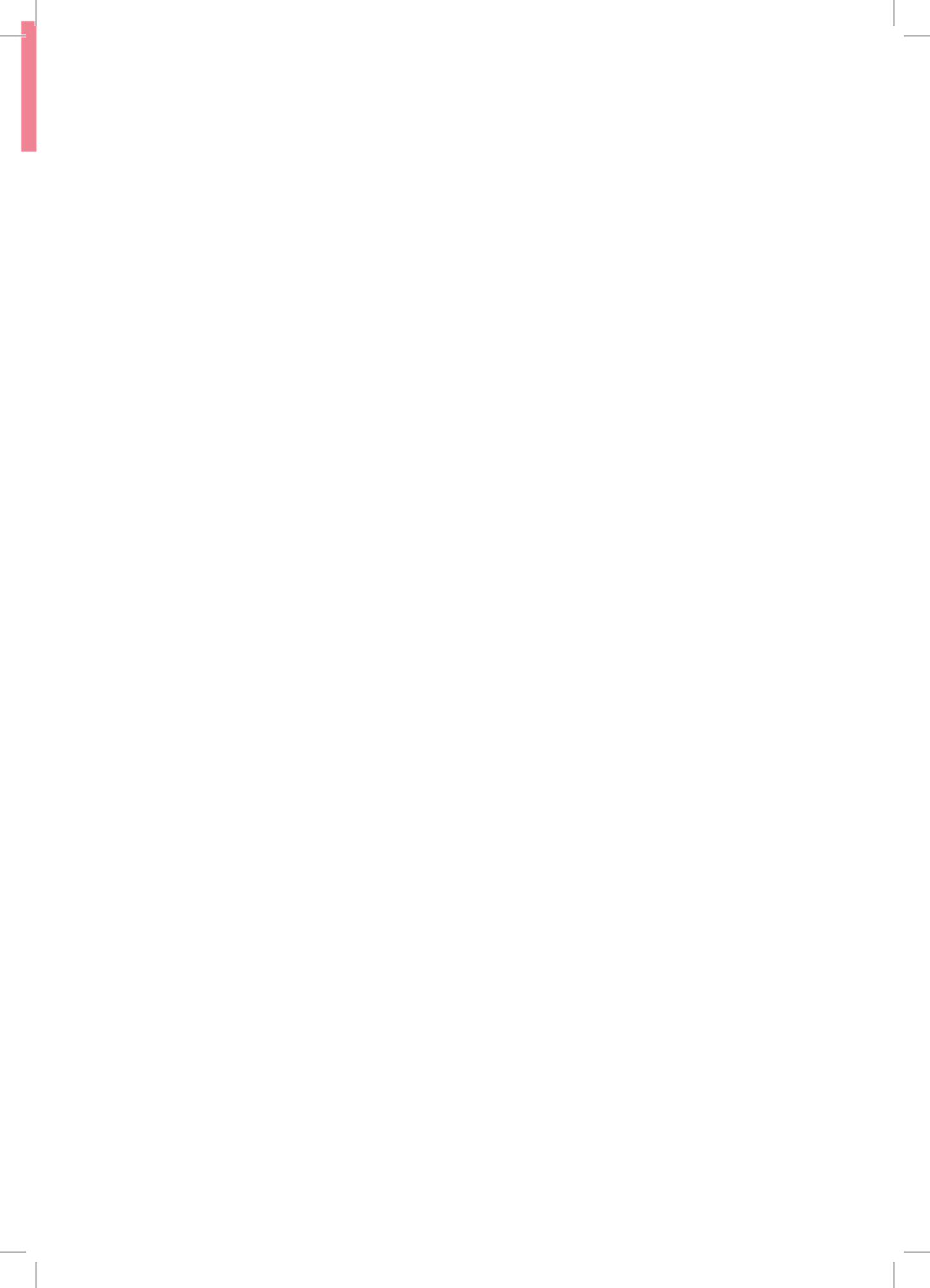
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Letter of Transmittal

The Hon Catherine King MP
Parliamentary Secretary for Health
Parliament House
CANBERRA ACT 2600

**2010–2011 ANNUAL REPORT OF THE
ADVISORY PANEL ON THE MARKETING IN AUSTRALIA OF INFANT FORMULA**

Dear Ms King

I am pleased to present to you the Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) for the year ending 30 June 2011.

Yours sincerely



Venessa Tripp
Chair
APMAIF
October 2011



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Chapter 1: OVERVIEW

About the APMAIF and the MAIF Agreement

The APMAIF is a non-statutory advisory Panel established by the Australian Government in 1992 to monitor compliance with and advise the Government on the *Marketing in Australia of Infant Formulas: 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 aims to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information and through appropriate marketing and distribution. A copy of the MAIF Agreement is at Appendix A.

The MAIF Agreement is Australia's primary means of implementing the World Health Organization's *International Code of Marketing of 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. It applies to the marketing and promotion of formulas for infants up to 12 months of age, by those Australian manufacturers and importers of infant formula who are signatories to the MAIF Agreement.

In relation to the products, the MAIF Agreement applies to:

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

The APMAIF has no statutory or formal regulatory powers either to obtain information from industry participants or other parties or to enforce the MAIF Agreement. The APMAIF relies upon the cooperation of the industry participants in the MAIF Agreement and other stakeholders to provide information, and on the voluntary commitment of industry participants to implement any changes to marketing practices that are requested by the APMAIF.

There are no financial or legal sanctions associated with breaches of the MAIF Agreement. If the APMAIF determines that a breach of the MAIF Agreement has occurred, the Minister (or Parliamentary Secretary) is informed and details of the breach are published in the APMAIF's annual report. The annual report is normally tabled in Parliament and copies made available to stakeholders. The reports are also made available via the Department of Health and Ageing's APMAIF internet pages: www.health.gov.au/apmaif.

Terms of Reference

The APMAIF's terms of reference are to:

- receive and investigate complaints regarding the marketing in Australia of infant formulas;
- act as a liaison point for issues relating to the marketing in Australia of infant formulas;
- develop guidelines on the interpretation and application of the MAIF Agreement; and
- provide advice on the operation of the MAIF Agreement to the Australian Government Minister for Health and Ageing.

Panel Members

The APMAIF comprises five members including the Chair, a community and consumer representative, an industry representative, a member with legal expertise, and a public health and nutrition expert.

All the members of the APMAIF are part time. Remuneration arrangements are in accordance with Departmental policy and the relevant determinations of the Remuneration Tribunal. The Parliamentary Secretary for Health appoints the panel members.

APMAIF Chair

The APMAIF Chair leads the Panel in the adjudication of complaints and manages conflicting views concerning the implementation of the MAIF Agreement and the role of the APMAIF. The Chair takes the lead role in the duties of the Panel and maintains liaison with the Secretariat in progressing those duties.

In March 2008 Ms Venessa Tripp was appointed as the APMAIF Chair until February 2012.

Ms Tripp is currently the principal of her own executive coaching business, an associate with the Institute of Executive Coaching and has been providing one-on-one executive coaching services since 2001. She specialises in career management, leadership, communication, influencing, delegation, presentation, strategic planning, dealing with conflict, representation and dealing with stakeholders. She is also a member of the Australian Institute of Management and the University of Sydney Coaching and Mentoring Association. She has a Masters degree from the University of Sydney and an Honours degree from the University of Newcastle.

Member with Legal Expertise

The Legal Expert provides a legal perspective in Panel deliberations, including interpretations of the scope and particular clauses of the MAIF Agreement. He or she contributes to Panel deliberations and decisions by demonstrating the following:

- a good knowledge of the *Competition and Consumer Act 2010*;
- a good knowledge of the legal implications of voluntary self-regulation agreements; and
- knowledge of and an interest in infant nutrition.

Professor Bill Lane was appointed as the APMAIF member with legal expertise in January 2009, for a term of four years.

Professor Lane is the Clayton Utz Professor of Public Law at QUT Law School and is one of Australia's leading administrative law experts. He has taught law at La Trobe University, the University of Sydney and the University of Queensland. His published works lie within the fields of judicial review, Freedom of Information, and the application of public law remedies in the field of commercial government activity.

Professor Lane is a member of the Queensland Non State Schools Accreditation Board.

Community and Consumer Representative

The Community and Consumer Representative advocates on behalf of parents with infants or small children, and contributes to Panel deliberations and decisions by demonstrating the following:

- an understanding of the issues faced by parents in feeding their babies and young children;
- a balanced understanding of the reasons why some women may not be able to breastfeed successfully or for other reasons may choose to bottle feed their babies and small children;
- a balanced view of the issues related to breastfeeding and bottle feeding; and
- an understanding of the importance of the self regulatory model of infant formula marketing within Australia.

In January 2009 Ms Margaret Grove was appointed as the Community and Consumer Representative, for a term of four years.

Ms Grove has been a breastfeeding counsellor with the Australian Breastfeeding Association since 1983 and held many national positions in that time. She was a director from 2002–2008 and was the organisation's National President from 2006–2008. In addition to teaching mathematics at Bankstown TAFE, Ms Grove has authored a number of text books and educational resource books. Ms Grove is the mother of three children and has been very active in her local community for 25 years.

Public Health and Nutrition Expert

In January 2009 Associate Professor Heather Yeatman was appointed for four years as the Public Health and Nutrition Expert, with particular expertise in regulation around therapeutic goods and the food/medicines interface.

Currently an Associate Professor with the School of Health Sciences at the University of Wollongong, Associate Professor Yeatman has taught public health nutrition at the post-graduate level since 1989 and chairs the Australian Public Health Nutrition Academic Collaboration. She has extensive experience working for and with government on health promotion and nutrition policy issues and has held several positions on statutory government bodies relating to food standards, food safety, complementary medicines, agricultural chemicals and veterinary medicines and animal welfare. She is also a member of several professional societies & associations related to public health and nutrition.

Industry Representative

The Industry Representative is nominated by the Infant Nutrition Council (INC) and is appointed by the Parliamentary Secretary for Health. He or she liaises between the Panel and INC member companies and plays an important role in maintaining industry awareness of the responsibilities of signatories to the MAIF Agreement. He or she contributes to Panel deliberations and decisions by representing the views of INC member companies and working to maintain a cooperative relationship between the Panel and signatories to the MAIF Agreement.

Ms Jan Carey is the CEO of the Infant Nutrition Council, and was appointed as the industry representative on the APMAIF in 2007. Ms Carey has an extensive background in infant health, having previously been responsible for developing and maintaining the national not for profit organisation, SIDS and Kids' research and educational programs which have successfully reduced infant mortality in Australia. She was Chair of SIDS and Kids Scientific Advisory Committee, a member of the Global Strategy Task Force for education and SIDS and Kids' representative on SIDS International.

Ms Carey is committed to best outcomes for infants and in addition to her role with the INC, is a co-founder of the research organisation the Australian and New Zealand Stillbirth Alliance.

Departmental Observer

A senior officer of the Australian Government Department of Health and Ageing attends all APMAIF meetings as an observer. The Departmental Observer provides advice to the Panel on matters of Government policy and advises the Minister for Health and Ageing on matters of governance for the APMAIF. He or she does not participate in APMAIF decision making.



Companies Authorised under the MAIF Agreement

Participating manufacturers and importers of infant formula during 2010–11 were:

- Abbott Australasia Pty Ltd
- Bayer Australia Ltd
- H J Heinz Company Australia Ltd
- Nestlé Australia Ltd
- Nutricia Australia Pty Ltd
- Pfizer Australia Pty Ltd

The Infant Nutrition Council

The Infant Nutrition Council Ltd (INC) was formed in 2009 through the amalgamation of the Infant Formula Manufacturers' Association of Australia (IFMAA) and the New Zealand Infant Formula Marketers' Association (NZIFMA). The INC represents the significant majority of companies marketing and manufacturing infant formula in Australia and New Zealand. All signatories to the MAIF Agreement are members of the INC, with the exception of Abbott Australasia Pty Ltd. The members work together and with key stakeholders to support the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative.

Further information can be found on the INC's website at www.infantnutritioncouncil.com.

Chapter 2: COMPLAINTS

How Complaints are Processed

The APMAIF relies upon the assistance of interested parties, such as breastfeeding advocate groups, health professionals and members of the public, in monitoring compliance with the MAIF agreement. Suspected breaches of the Agreement are brought to the attention of the APMAIF by the submission of formal complaints through the APMAIF Secretariat. The APMAIF does not independently audit compliance with the MAIF agreement.

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

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

The Secretariat advises complainants in writing if their complaints are outside the scope of the MAIF Agreement.

Where a complaint is considered to be within the scope of the MAIF Agreement, or where it is unclear whether the complaint is out of scope, or where more information is required before this assessment can be made, the Secretariat advises the manufacturer or importer of the product concerned that a complaint has been received alleging a breach of the MAIF Agreement. The manufacturer or importer is invited to respond with any evidence or other information it wishes to submit for consideration.

Complaints that have been assessed as falling within the scope of the MAIF Agreement are then considered by the APMAIF at the next possible meeting. Complaints requiring consideration by the APMAIF are summarised by the Secretariat prior to being forwarded to the APMAIF. 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 about the material, relevant clauses of the MAIF Agreement, results of any inquiries made by the Secretariat (e.g. responses from formula companies or health professionals) and any previous consideration of a similar complaint or relevant guidelines on the interpretation of the MAIF Agreement which have been made by the APMAIF.

The APMAIF considers the complaint and may decide that it does not reveal 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 of the APMAIF's preliminary views and is invited to respond with any further relevant information.

At its next meeting, the APMAIF considers any additional information provided and makes a decision that the conduct that is the subject of the complaint is either 'in breach' or 'not in breach' of the MAIF Agreement, based on the evidence at hand.

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. In addition, any 'in breach' decisions are reported to the Parliamentary Secretary for Health and are recorded in the APMAIF Annual Report.

The APMAIF Secretariat records all complaints received in its Complaints Register, which is used to compile statistics for presentation to the APMAIF at its quarterly meetings.

The complainants' identities are not disclosed to the Panel or other parties at any time.

Complaint Statistics 2010–11

	Brought Forward	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Total
Out of scope	0	2	3	2	0	1	1	0	0	2	0	0	0	11
Retail—store		1	2	2		1								6
Retail—pharmacy			1				1			1				3
Health Professional														0
Toddler milk		1												1
Non-signatory														0
Other										1				1
In scope	3	0	0	1	0	0	0	0	1	0	0	0	0	10
In breach	1													1
Not in breach	1			1					1					3
Industry-wide action	1													1
Carried forward														0
Total complaints	0	2	3	3	0	1	1	0	1	2	0	0	0	13
Complainants	0	2	3	3	0	1	1	0	1	2	0	0	0	12

In 2010–11 the APMAIF received 13 new complaints, representing a significant decrease on the previous reporting period in which 36 complaints were received. Of the new complaints received, 11 (approximately 85%) were assessed as falling outside the scope of the MAIF Agreement.

The majority of 'out-of-scope' complaints in 2010–11 were within the category of retail activity. There was a marked decrease in complaints about both toddler milk and conference sponsorship in this period compared to the previous period. A number of complaints were received regarding retail price promotions in popular women's magazines, and it was noted that price promotion by retailers in media other than weekly store catalogues, such as the internet, may be a new and emerging trend.



In 2010–11 the APMAIF made one ‘in breach’ decision on a complaint carried over from the previous reporting period, where two instances of the same activity had been considered separately by the Panel. Details of the activity and the pending decision were set out in the 2009–10 Annual Report.

Of the remaining ‘in-scope’ complaints considered by the Panel, three were determined to be ‘not in breach’ and one was resolved through industry-wide action.

Industry-wide Action on Electronic Media Marketing

In November 2009, the APMAIF received a complaint about the content of a manufacturers’ website. The Panel gave careful consideration to a range of relevant issues and, in the absence of a precedent for consideration of complaints about electronic media marketing, sought legal advice on how the agreement would apply in this new medium. The APMAIF also sought formal input from MAIF Agreement signatories.

In November 2010, the APMAIF completed its deliberations on this complaint. Given the absence of an interpretation and the complexity of the area the APMAIF decided to provide an industry wide rather than company specific response. It concluded that, in so far as material on manufacturers’ websites is available to the general public, the requirements of the MAIF Agreement regarding information intended to reach parents and pregnant women would apply. The intent is to ensure that material made available on manufacturers’ websites is exclusively informational in nature and includes required material relating to breastfeeding. The full interpretation in this area will be reported in the 2011–12 Annual Report.

The web based material that was the subject of the original complaint has been removed or amended at the APMAIF’s request.

The APMAIF considers this industry wide approach to be a robust way to proceed in the rare case where the issues are complex, no precedent or interpretation exists and the circumstances were not anticipated when the MAIF Agreement was created.

Chapter 3: APMAIF ACTIVITIES

In 2010–11 the APMAIF commenced work on a number of important areas of the application of the MAIF Agreement and its interpretations.

As discussed in the previous chapter, issues have arisen relating to internet based material. The APMAIF has worked with industry to ensure that a standard approach to internet based material is achieved. The APMAIF has undertaken a revision of the Complaints Handling Process to increase the fairness and transparency of its procedures. Along with this, the Panel has established a review of the Interpretation Guidelines to ensure there is a clear understanding of the intent and meaning of the clauses of the MAIF Agreement.

Panel Meetings

Meeting	Date	Complaints considered	Other items discussed
74th	12 August 2010	3 carried over 2 new	Infant Nutrition Council's amended Samples Policy Review of Interpretation Guidelines Notification of product re-formulation
75th	18 November 2010	1 carried over 1 new	Review of Interpretation Guidelines Wording of Step 3 of the Complaints Handling Process Australian National Breastfeeding Strategy 2010–2015—Stakeholder update
76th	17 February 2011 (half day)	–	Electronic media marketing—industry wide action
77th	19 May 2011 (half day)	1 new	Review of Interpretation Guidelines Electronic media marketing—industry wide action



Meetings with MAIF Agreement Signatories

Meeting	Date	Items discussed
Signatories meeting	18 November 2010	Review of Interpretation Guidelines Step 3 of the Complaints Handling Process Investigation of clauses in addition to those specified by the complainant

Review of Interpretation Guidelines

At its 74th meeting on 12 August 2010, the APMAIF conducted a preliminary review of past interpretations of the MAIF Agreement and agreed in principle that:

- in accordance with the APMAIF's third term of reference, the interpretations should be referred to as "guidelines on the interpretation of the MAIF Agreement" and should be expressed in guideline-style terminology;
- there is a need to inform stakeholders about the nature and purpose of the Interpretation Guidelines; and
- industry should be actively engaged on issues that arise during the process of reviewing the Interpretation Guidelines.

On 18 November 2010, the APMAIF met with representatives of all signatories to the MAIF Agreement, to agree on a way forward regarding the review. Participants agreed that the process should be led by the Panel but that industry participation was essential to the success of the review.

The APMAIF has commenced the process of updating and clarifying the Interpretation Guidelines, and is seeking industry feedback to ensure a common understanding of the intent and meaning of the clauses of the MAIF Agreement and associated Interpretation Guidelines. The revised guidelines will be reported in the 2011–12 Annual Report.

Appropriate distribution of free samples

APMAIF initiated a discussion with MAIF Agreement signatories about the operation of Clause 7(d) of the MAIF concerning the provision of samples of infant formula to health care professionals. APMAIF wanted to understand the approach taken by industry and pharmacies in this area and ensure compliance with the agreement. Samples are provided to a pharmacy in response to a specific request from a pharmacist and, once receipt has been acknowledged, representatives of the manufacturers do not involve themselves in the processes followed by individual health professionals in pharmacies. It was agreed that it is nevertheless possible to encourage compliance with MAIF by making the governance process around the provision of samples to pharmacies more robust.

As a result of these discussions the Infant Nutrition Council updated its policy regarding the provision of free samples of infant formula to health professionals, and developed a new template for the “Infant Formula Sample Request Form” which all health professionals must use to request samples for professional evaluation. The new template includes a statement on the benefits of breastfeeding and quotes the aim of the MAIF Agreement in a prominent position. It also requires the requesting health professional to state his or her qualification as evidence that the samples are not being provided to any lay person, and to take individual responsibility for the appropriate use of the samples.

The INC’s revised Samples Policy can be viewed on the Infant Nutrition Council website at www.infantnutritioncouncil.com.

Chapter 4: ISSUES ARISING FROM APMAIF BUSINESS

The Complaints Handling Process

In 2008, the APMAIF revised its Complaints Handling Process (CHP) in an effort to support transparent discussions of its procedures. As part of this revision, an extra step was added to the CHP so that companies who are the subject of a complaint under APMAIF consideration are routinely given the opportunity to respond to any preliminary concerns of the Panel before a decision is reached. This consultation step now applies to the handling of all complaints when a 'not in breach' decision cannot be reached at the first sitting.

The wording of this additional step to the process was drafted on the basis of legal advice and, in its summary form, is expressed as follows:

Company informed that there is insufficient information to determine that there has been no breach [of the MAIF Agreement] and invited to respond.

The APMAIF became aware of a lack of clarity around the meaning of the so-called "double negative" contained within this wording.

In response this, the APMAIF offered the following clarification:

The phrase "insufficient information to determine that there has been no breach" was included in the Complaints Handling Process on the basis of procedural fairness, and is intended to protect the subject company from either the reality or the perception of a premature determination. The phrase does not imply that there is insufficient information to make any determination, but rather advises a subject company that although no determination has yet been made, the balance of currently available evidence has failed to convince the Panel that no breach has occurred and therefore the potential for an 'in breach' decision

remains. The company is then invited to provide any further evidence that it may wish the Panel to consider in conjunction with the existing evidence when the Panel makes its final determination.

The need to further clarify this terminology will be monitored during 2011–12.

Operation of the MAIF Agreement

Re-formulation of infant formula products

A manufacturer sought the APMAIF's advice on how to raise awareness of a planned change to the formulation of one of its products, noting that in rare instances some infants may have a reaction to a formulation change. The Panel noted the 1994 interpretation guideline which states that "*changes in formulation should be referred to only on the container, not promoted in advertisements*" and upheld this guideline. It was suggested that a notice regarding the change and the potential for adverse reactions should be included on both the inside and the outside of the can. It was also considered appropriate for the manufacturer to advise the relevant food safety authorities of the planned change and potential consequences.

Interpretation Guidelines

In accordance with its Terms of Reference, the APMAIF occasionally develops guidelines on the interpretation and application of the MAIF Agreement.

In considering complaints concerning alleged breaches of the MAIF Agreement, the APMAIF has, from time to time and in the interests of consistency, referred to past guidelines on the interpretation and application of the clauses of the agreement. Past interpretation guidelines are made available on the APMAIF website as a reference source for stakeholders.

The APMAIF is currently reviewing the interpretation guidelines.



The use of past interpretations of the MAIF Agreement

Formal guidelines on the interpretation of the MAIF Agreement often provide a useful benchmark to signatories in determining the acceptability or otherwise of certain marketing activities. However, the guidelines do not form part of the Agreement and do not substitute for the APMAIF's ongoing task of analysing and assessing complaints on their individual merits on a case-by-case basis. Past interpretation guidelines should not be viewed as stand-alone requirements, but must always be viewed in the context of the relevant clause(s) of the MAIF Agreement.

In addition, the interpretation guidelines should not be considered to be exclusive or exhaustive—for example, where the APMAIF has determined a specific activity to be unacceptable, it should not be assumed that other activities are acceptable simply because they were not canvassed in the interpretation guideline.

Chapter 5: FINANCES

Funding Arrangements

The Department of Health and Ageing administers funding for the operating costs of the APMAIF.

In 2010–11 the Chair and Panel members, except for the industry representative, were remunerated in accordance with Departmental policy and the applicable Remuneration Tribunal determinations. All remuneration and expenses for the industry representative were met by the INC.

In 1998 a cost-sharing agreement was reached between the infant formula companies and the Treasury, who provided the APMAIF Secretariat services at that time. Under this agreement, the industry funded 70% of the APMAIF Secretariat expenses, which included the salary of one Secretariat staff officer, printing, room hire and catering. The Treasury funded the remaining 30% of Secretariat expenses, along with 100% of remuneration and travel costs for members.

This cost-sharing arrangement was informally continued when the APMAIF Secretariat was transferred to the Department of Health and Ageing in 2001. Financial contributions and expenditure for the running costs of the APMAIF were administered through the Department's *Services for Other Government and Non-Government Bodies* Special Account.

In 2007 the cost-sharing arrangement with industry was discontinued pending a review of APMAIF funding mechanisms, and no further contribution has been requested from the industry since that time.

In 2010–11, the majority of administrative and committee costs were covered by residual equity held against the Special Account, while the Department continued to provide staffing for the Secretariat.



Financial Report 2010–11

FUNDING SOURCE		EXPENDITURE	
Special Account Equity	36,753	APMAIF Committee	33,723
Department	117,000	APMAIF Secretariat	120,030
TOTAL FUNDING	153,753	TOTAL EXPENDITURE	153,753

Appendices



Appendix A:

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 necessary², 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 for breast milk. It also applies to their quality and availability, and to information concerning their use. (WHO Code Article 2)

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.



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:
- (i) *the benefits and superiority of breastfeeding;*
 - (ii) *maternal nutrition, and the preparation for and maintenance of breastfeeding;*
 - (iii) *the negative effect on breastfeeding of introducing partial bottle-feeding;*
 - (iv) *the difficulty of reversing the decision not to breastfeed; and*
 - (v) *where needed, the proper use of infant formula, whether manufactured industrially or home prepared. (WHO Code Article 4.2)*
- 4(b) When such materials contain information about the use of infant formulas, they should include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods and, in particular, the health hazards of unnecessary or improper use of infant formulas. Such materials should not use any pictures or text which may idealise the use of infant formulas. (WHO Code Article 4.2)
- 4(c) Manufacturers and importers of infant formulas should not donate informational or educational equipment or materials unless it is at the request of, and with the written approval of, the appropriate government authority or within guidelines given by the Commonwealth, State or Territory Governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary infant formula, and should be distributed only through the health care system. (WHO Code Article 4.3)



Clause 5: The general public and mothers

- 5(a) Manufacturers and importers of infant formulas should not advertise or in any other way promote infant formulas to the general public. (WHO Code Article 5.1)
- 5(b) Manufacturers and importers of infant formulas should not provide samples of infant formulas to the general public, pregnant women, parents or members of their families. (WHO Code Article 5.2)
- 5(c) Manufacturers and importers of infant formulas should not distribute to pregnant women, or parents of infants and young children, any gifts of articles or utensils which may promote the use of breast milk substitutes or bottle-feeding. (WHO Code Article 5.4)
- 5(d) Marketing personnel, in their business capacity, should not seek direct or indirect contact with pregnant women or with parents of infants and young children. This does not prevent appropriately qualified personnel from responding to complaints or unsolicited requests for information. For these requests, parents should be referred to a health care professional whenever health advice is required. (WHO Code Article 5.5)

Clause 6: Health care system

- 6(a) Manufacturers and importers of infant formulas should not use any facility of the health care system for the purpose of promoting infant formulas. This does not, however, preclude the dissemination of information to health care professionals as provided in clause 7(a). (WHO Code Article 6.2)
- 6(b) Manufacturers and importers of infant formulas should be aware that facilities of health care systems should not be used for the display of products within the scope of this document, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in clause 4(c) above. (WHO Code Article 6.3)
- 6(c) The use by the health care system of pharmacies or retail outlets, 'professional service representatives', 'mothercraft nurses', or similar personnel, provided or paid for by manufacturers or importers of infant formulas is not permitted. (WHO Code Article 6.4)

- 6(d) Manufacturers and importers of infant formulas should be aware that feeding with infant formulas, whether manufactured or home prepared, should be demonstrated only by health care professionals. Such demonstrations should be made only to the parents or other persons who need to use it, and the information given should include a clear explanation of the hazards of improper use. (WHO Code Article 6.5)
- 6(e) Manufacturers and importers of infant formulas may make donations, or low-priced sales, of infant formulas to institutions or organisations, whether for use in the institutions or for distribution outside them. Such provisions should only be used or distributed for infants who have to be fed on breast milk substitutes. If these provisions are distributed for use outside the institutions, this should be done only by the institutions or organisations concerned. Manufacturers or importers should not use such donations or low-price sales as a sales inducement. (WHO Code Article 6.6)
- 6(f) Manufacturers and importers of infant formulas should note that, where donated infant formulas are distributed outside an institution, the institution or organisation should take steps to ensure that these provisions can be continued as long as the infants concerned need them. Donors, as well as the institutions or organisations concerned should bear in mind this responsibility. (WHO Code Article 6.7)
- 6(g) Equipment and materials, in addition to those referred to in clause 4(c), donated to a health care system may bear a company's name or logo, but should not refer to any proprietary infant formulas. (WHO Code Article 6.8)

Clause 7: Health Care Professionals

- 7(a) Manufacturers and importers of infant formulas providing information about the formulas to health care professionals should restrict the information to scientific and factual matters. Such information should not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. It should also include the information specified in clause 4(a) above. (WHO Code Article 7.2)
- 7(b) Manufacturers and importers of infant formulas should provide members of the medical profession and related health care professionals with information about the products, and this information should accurately reflect current knowledge and responsible opinion. Such material should be clearly identified with the name of the manufacturer or importer, the brand names of the infant formulas, and the date of publication.



- 7(c) Manufacturers and importers of infant formulas should not offer any financial or material inducement to health care professionals or members of their families to promote infant formulas, nor should such inducements be accepted by health care professionals or members of their families. (WHO Code Article 7.3)
- 7(d) Manufacturers and importers of infant formulas should not provide samples of infant formulas, or of equipment or utensils for their preparation or use, to health care professionals except when necessary for the purpose of professional evaluation or research at the institutional level. (WHO Code Article 7.4)
- 7(e) Manufacturers and importers of infant formulas should disclose to institutions, to which a recipient health care professional is affiliated, any contribution made to him/her, or on his/her behalf, for fellowships, study tours, research grants, attendance at professional conferences, or the like. (WHO Code Article 7.5)

Clause 8: Persons employed by manufacturers and importers

- 8(a) In systems of sales incentives for marketing personnel, the volume of sales of infant formulas should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it. (WHO Code Article 8.1)
- 8(b) Personnel employed in marketing infant formulas should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or parents of infants and young children. This does not prevent such personnel from being used for other functions by the health care system. (WHO Code Article 8.2)

Clause 9: Quality and Labelling

- 9(a) Manufacturers and importers of infant formulas must ensure that infant formulas sold in Australia conform to Australian Food Standard R7—Infant Formula. (WHO Code Articles 9.2, 9.4, 10.1 and 10.2)
- 9(b) Manufacturers and importers of infant formulas must ensure that labels provide the information required to be provided by the Australian Food Standard A1—Labelling and Advertising and Standard R7—Infant Formula, and also provide the necessary information about the appropriate use of infant formula and should not discourage breastfeeding. (WHO Code Article 9.1)

Clause 10: Implementation and monitoring

- 10(a) Independently of any other measures taken to implement their obligations under this document, each manufacturer and importer of infant formulas should regard itself as responsible for monitoring its marketing practices according to the principles and aim of this document, and for taking steps to ensure that its conduct at every level conforms to those principles and aims. (WHO Code Article 11.3)
- 10(b) Manufacturers and importers of infant formulas agree to be represented on 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 for Lodging Complaints About Alleged Breaches of the MAIF Agreement

The following Guidelines are for lodging complaints about alleged breaches of the MAIF Agreement and are intended to assist both complainants and subject companies to ensure that a fair and full review is conducted. Complaints should be lodged in writing.

What you should do before lodging a complaint with the APMAIF

Whenever possible, complainants should contact the subject company prior to lodging a complaint with the APMAIF, as a satisfactory explanation or solution may be immediately available.

Who can lodge a complaint?

Individuals and members of industry, community and consumer groups are able to lodge a complaint with the APMAIF about alleged breaches of the MAIF Agreement. However, inter-company complaints should not be used as a competitive tool. Before a complaint is lodged, companies should seek to have the issue resolved directly with the subject company, or through the Infant Nutrition Council's competitive complaints process.

What you should include in the complaint

Where possible, complaints should be submitted on a Complaint Form which can be downloaded from the APMAIF website. Complaints should include the following:

1. A summary page containing:
 - details of the product/activity and the companies involved;
 - if relevant, the title of promotional piece and date of publication;
 - date when alleged breach was identified;
 - where and how the material was obtained;
 - a brief description of the complaint, itemising specific claims and issues;
 - section/s of the MAIF Agreement alleged to be breached (if known); and
 - details of any attempts to resolve the matter with the companies involved.
2. If relevant, any supporting data cross-referenced to specific claims for medical, scientific and marketing based complaints.
3. A photocopy or original of the relevant promotional material.
4. Your contact details.

If these criteria are not met, the APMAIF may return the complaint to the complainant for further information.

Sending the complaint to the subject company for further information or comment

The Secretariat will forward the complaint to the relevant manufacturer or importer for further information or comment.

In seeking a response from the subject company, the Secretariat will forward only the relevant extract/s of the complainant's letter and if available, a photocopy of the complaint material/s. The complainant's identity will not be revealed to the subject company.



Response to the APMAIF by the subject company

When the subject company has received a request for further information about a complaint, the subject company should state whether or not the information supporting the complaint is correct and provide the following:

- details of any attempts to resolve the matter with the complainant;
- a brief summary of the response to each alleged breach;
- substantiation of the specific claims at issue with full supporting data;
- any other information requested by the Secretariat; and
- the signature of the Chief Executive or delegate of the company.

The subject company's response should be received by the Secretariat within 21 days (3 weeks). If this is not possible, the subject company should notify the Secretariat and provide an indication of when the response will be sent.

Where to send complaints

APMAIF Secretariat
Australian Government Department of Health and Ageing
MDP 802
GPO Box 9848
CANBERRA ACT 2601

Email: apmaif@health.gov.au

Secretariat telephone: (02) 6289 7358

Complaint forms and other APMAIF information can be obtained at:
www.health.gov.au/apmaif

Appendix C:

APMAIF Complaints Handling Process

The APMAIF, in keeping with its terms of reference, receives and investigates complaints regarding the marketing in Australia of infant formula.

All complaints received are registered by the APMAIF Secretariat. The complaints register and complaint statistics are provided at each APMAIF meeting for the panel's review.

COMPLAINTS CLASSIFICATION

Complaints are classified as within or outside the scope of the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (MAIF Agreement) by the APMAIF Secretariat.

The Secretariat may refer a complaint to an appropriate agency if a complaint is considered within its jurisdiction, for example to:

- Food Standards Australia New Zealand (FSANZ)
- State/Territory Food Regulatory Authorities
- Australian Competition and Consumer Commission (ACCC)
- Department of Health and Ageing—Therapeutic Goods Administration (TGA)

COMPLAINTS THAT ARE CONSIDERED OUTSIDE THE SCOPE OF THE MAIF AGREEMENT

Complaints considered **outside the scope** of the MAIF Agreement may include the following (but not limited to):

- an Infant Formula Manufacturer or Importer (Company) that is not a current signatory to the MAIF Agreement or was not a signatory at the time the complaint was made;
- some retailer activity (e.g. price promotions in retail catalogues);
- infant merchandise (e.g. infant feeding bottles, teats, dummies, etc); and/or
- infant foods, including milk products formulated for children over 12 months of age.

A complaint may require further investigation before it can be determined as outside the scope of the MAIF Agreement.

The Secretariat advises the complainant in writing that their complaint is outside the scope of the MAIF Agreement and the reason/s for this classification.

COMPLAINTS THAT ARE CONSIDERED WITHIN THE SCOPE OF THE MAIF AGREEMENT

Complaints considered **within the scope** or where it is not certain that they are **within the scope** of the MAIF Agreement are handled as follows:

1. Investigation of the complaint by the APMAIF Secretariat

The Secretariat:

- a) advises the Company that a complaint has been received by the APMAIF alleging a breach of the MAIF Agreement. The relevant clause of the MAIF Agreement and a copy of the original complaint (identity of the complainant is withheld) are provided to the Company;
- b) invites the Company to provide a response for consideration by the APMAIF; and
- c) may seek expert advice where appropriate.

2. Complaint and supporting documentation considered

All complaints that are within the scope of the MAIF Agreement are considered by the APMAIF. All available information concerning the complaint is provided to the APMAIF before its meeting. At the meeting, the APMAIF considers each complaint and makes a finding that the complaint:

- a) **does not reveal a breach of the MAIF Agreement**—the APMAIF determines that the conduct to which the complaint relates is not a breach of the MAIF Agreement based on the evidence at hand.

Complaints found not to reveal a breach are classified as 'closed' and both the Company and the complainant are informed of the APMAIF's decision in writing and the reasons for the decision.

or

- b) **requires further consideration**—the APMAIF has insufficient information to determine that there has been no breach. The complaint is carried over to the next APMAIF meeting pending further investigation and consideration of the response received from the relevant Company.

3. Company informed that there is insufficient information to determine that there has been no breach and invited to respond

For complaints where there is insufficient information to determine that there has been no breach of the MAIF Agreement, the APMAIF:

- a) advises the Company that the complaint has been considered and, based on the evidence at hand, there is insufficient information to determine that there has been no breach of the MAIF Agreement;
- b) provides the Company with a written explanation of any preliminary view that APMAIF has reached together with the evidence or other material upon which that view has been reached; and
- c) invites the Company to respond within 21 days with any further relevant information which is in addition to that provided at paragraph 1 and considered at paragraph 2.

4. APMAIF's Final consideration

The APMAIF considers any additional relevant information provided by the Company and makes a final decision:

- a) the APMAIF makes a decision that the conduct that is the subject of the complaint is **'In Breach'** of the MAIF Agreement based on the evidence at hand.

or

- b) the APMAIF makes a decision that the conduct that is the subject of the complaint is **'Not in Breach'** of the MAIF Agreement based on the evidence at hand.

*Complaints about conduct found to be **'Not in Breach'** are classified as 'closed' and both the company and the complainant are informed of the APMAIF's decision in writing and the reasons for the decision.*

5. Notification of an 'In Breach' Decision

Following an **'In Breach'** decision by the APMAIF:

- a) the Company is advised that the APMAIF has determined the conduct that is the subject of the complaint to be **'In Breach'** of the MAIF Agreement and provides the reasons for this decision;
- b) the Complainant is advised of the outcome and the reason/s for this decision;
- c) the Parliamentary Secretary to the Minister for Health and Ageing is advised that the APMAIF has determined conduct considered by APMAIF as a result of a complaint to be **'In Breach'** of the MAIF Agreement and the reason/s for this decision; and
- d) the **'In Breach'** decision is recorded in the APMAIF Annual Report.

Appendix D: The MAIF Agreement FAQ

The MAIF Agreement *What is it and what does it mean for you?*

APMAIF Secretariat
Department of Health and Ageing
Mail Drop Point 802
GPO Box 9848
CANBERRA ACT 2601

Phone: (02) 6289 7358
Fax: (02) 6289 4235
Website: www.health.gov.au/apmaif

For a copy of the **Dietary Guidelines for Children and Adolescents in Australia incorporating The Infant Feeding Guidelines for Health Workers** and other related information, visit the following website: <http://www.nhmrc.gov.au/PUBLICATIONS/synopses/dietsyn.htm>

Background

Q. What is the MAIF Agreement?

A. It is the Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement (1992).

The MAIF Agreement is a voluntary self regulatory code of conduct between manufacturers and importers of infant formula in Australia. It is Australia's response to becoming a signatory to the World Health Organization's International Code of Marketing of Breast-milk Substitutes (WHO Code). It sets out the obligations of manufacturers and importers of infant formulas in Australia who are signatories to the Agreement and gives effect to the principles of the WHO Code.

Q. What is the aim of the MAIF Agreement?

A. The aim of the MAIF Agreement is to help ensure safe and adequate nutrition for infants:

- through the protection and promotion of breastfeeding;
- 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.

*Note: The word 'necessary' is used here to include mothers who have made an informed choice to use breast milk substitutes.

Q. What does the MAIF Agreement cover?

A. The MAIF Agreement covers the marketing in Australia of infant formulas by manufacturers and importers when such products are marketed or represented to be suitable for use as a partial or total replacement to breast milk.

In relation to products, the MAIF Agreement applies to:

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

It also covers the quality and availability of such products and the provision of information concerning their use.

Q. Who is involved in the MAIF Agreement?

A. The MAIF Agreement was developed by the Australian Government, the infant formula industry, breastfeeding advocates and other stakeholders and was authorised in 1992 under the *Trade Practices Act 1974*. The infant formula manufacturers and importers who are signatories have voluntarily entered into the MAIF Agreement in the interests of the health and development of infants in Australia. The MAIF Agreement is not legally binding.

Q. Which organisations are involved in the MAIF Agreement?

A. The signatories to the MAIF Agreement are:

- Abbott Australasia Pty Ltd;
- Bayer Australia Ltd;
- H J Heinz Company Australia Ltd;
- Nestlé Australia Limited;
- Nutricia Australia Pty Ltd; and
- Pfizer Australia Pty Ltd.

The MAIF Agreement & the WHO Code

Q. What is the difference between the MAIF Agreement and the WHO Code?

A. The WHO Code applies to the marketing and related practices of the following products: breast milk substitutes including infant formula, other milk products, feeding bottles and teats and foods and beverages—including bottle-fed complementary foods, when marketed to be suitable for use as a partial or total replacement for breast milk. It also applies to retailers and health professionals.

The MAIF Agreement operates in Australia only and is Australia's main response to becoming a signatory to the WHO Code. It applies to manufacturers and importers of formulas for infants up to 12 months of age. In this respect it differs from the WHO Code which only applies to infant formula up to the age of 6 months. The MAIF Agreement does not include other milk products, foods, beverages or feeding bottles and teats. The activities of retailers of infant formula are excluded from the MAIF Agreement unless there is involvement by manufacturers or importers.

Further information including full details of the MAIF Agreement and APMAIF Annual Reports are available on the APMAIF website www.health.gov.au/apmaif.

Work of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF)

Q. What does the APMAIF do?

A. The APMAIF's terms of reference are to:

- receive and investigate complaints regarding the marketing in Australia of infant formulas;
- act as a liaison point for issues relating to the marketing in Australia of infant formulas;
- develop guidelines on the interpretation and application of the MAIF Agreement; and
- provide advice to the Australian Government Minister for Health and Ageing, on the operation of the Agreement.

Complaints

Q. Who can lodge a complaint?

A. Anyone can lodge a complaint about an alleged breach of the MAIF Agreement.

Complaints should be submitted on an APMAIF Complaint Form which can be downloaded from the APMAIF website www.health.gov.au/apmaif. You will need to provide the following information:

- Details of the product and the company that promoted the product.
- If relevant, the title of the material and the date of publication.
- Date when the alleged breach was identified.
- Where and how the material was obtained.
- A brief description of the complaint, itemising specific claims and issues.
- The section/s of the MAIF Agreement alleged to be breached (if known).
- Details of any attempts to resolve the matter with the company involved.

- Supporting data for medically and scientifically based complaints, if available.
- A photocopy or original of the relevant promotional material.
- Your contact details and signature.

If these criteria are not met the APMAIF may return the complaint for further information.

Send your complaints to the APMAIF Secretariat—contact details on front cover

The Panel Members

The APMAIF has five members and is a non-statutory body appointed by the Australian Government to monitor the MAIF Agreement.

Independent Chair—Ms Venessa Tripp

Appointed as Chair of the APMAIF in March 2008, Ms Tripp is the principal of her own executive coaching business, with expertise in leadership, communication and dealing with stakeholders.

Member with legal expertise—Prof Bill Lane

Appointed to the Panel in January 2009, Prof Lane is the Clayton Utz Professor of Public Law at the Queensland University of Technology.

Industry Representative—Ms Jan Carey

CEO of the Infant Nutrition Council Ltd (formerly the Infant Formula Manufacturers' Association of Australia Inc) Ms Carey was nominated by the industry and appointed to the Panel in 2007.

Community & Consumer Representative—Ms Margaret Grove

Appointed to the Panel in January 2009, Ms Grove was National President of the Australian Breastfeeding Association (ABA) from 2006–2008 and has been a breastfeeding counsellor since 1983.

Public Health and Nutrition Expert—Associate Prof Heather Yeatman

Appointed to the Panel in January 2009, Prof Yeatman is Associate Professor in Public Health Nutrition at the School of Health Sciences, University of Wollongong.

