Draft Determination

Application for revocation of A90539 and A90540 and substitution with authorisations A91506 and A91507

lodged by

the Infant Nutrition Council

for

the *Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement*

Date: 29 October 2015

Authorisation numbers: A91506 and A91507

Commissioners: Rickard
Cifuentes
Court
Featherston

Summary

The ACCC proposes to re-authorise, for 10 years, the *Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement* (MAIF Agreement) and associated guidelines.

The MAIF Agreement has been authorised in more or less its current form since 1992. An amended form of the MAIF Agreement is proposed to come into force on the date that the ACCC grants authorisation.

The ACCC considers the MAIF Agreement is likely to continue to result in public benefits in the form of promoting and protecting breastfeeding through the restriction of inappropriate advertising of infant formula and avoided regulatory costs, and that these benefits are likely to outweigh detriment arising from the restriction of marketing within the agreement.

The ACCC notes that some interested parties have provided submissions that the MAIF Agreement should be improved and expanded and that re-authorisation for a further 10 years may pre-empt a more effective regulatory response.

The ACCC is aware that there is new guidance being considered internationally in relation to the operation of the World Health Organisation's International Code of Marketing of Breast Milk Substitutes (WHO Code) and subsequent WHA resolutions, and these are what the MAIF Agreement is based on.

However, the ACCC notes that there remains uncertainty as to the timing and outcomes of this work and what, if any, implications it may have for the MAIF Agreement. Any re-authorisation granted by the ACCC would not prevent the Infant Nutrition Council from seeking to vary the authorisation at any time, should it consider alterations are appropriate. Further, ACCC authorisation of the arrangements does not preclude an alternative regulatory response to restrict the marketing of infant formula in Australia.

Next steps

The ACCC invites submissions in relation to this draft determination before making its final decision.

The application for authorisation

1. On 20 July 2015 the Infant Nutrition Council (the **Council**) applied for the revocation of authorisations A90539 and A90540, and the substitution of authorisations A91506 and A91507 for the ones revoked (re-authorisation). The Council made this application on behalf of the current signatories to the MAIF Agreement (which are listed at paragraph 11 below). The Council is seeking re-authorisation for 10 years to make and give effect to the *Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement* (the **MAIF Agreement**) and associated guidelines (together, the **conduct**).

2. The application seeks that authorisation apply to current and future manufacturers in, and importers into, Australia of infant formula that are or become parties to the MAIF Agreement.

3. The MAIF Agreement is a voluntary self-regulatory code which governs the marketing of infant formula for infants up to 12 months. In summary, the MAIF Agreement:

    - requires specified information to be contained in the educational material provided by manufacturers and importers which is intended for pregnant women or parents of young children and which relates to the feeding of infants

    - prohibits the advertising and promotion of infant formula by manufacturers and importers directly to the public

    - restricts the information provided to health care professionals by manufacturers and importers regarding infant formulas to scientific and factual matters, and

    - prohibits health care professionals and persons employed by manufacturers and importers from accepting or offering incentives to promote or sell infant formulas

    - requires internal monitoring and compliance practices by signatories to ensure conduct conforms to the principles and aims of the MAIF Agreement.

4. The MAIF Agreement applies only to starter infant formula (for infants aged 1 to 6 months) and follow-on formula (for infants 6 – 12 months). It does not apply to 'toddler milks' formulated for children aged above one year. The MAIF Agreement also does not apply to retailers (such as supermarkets) or distributors of infant formula.

5. The Council advises there have been two minor amendments made to the MAIF Agreement since 2007 when re-authorisation was last sought. Specifically, the definition of 'infant formula' has been amended in line with changes to the Food Standards Australia New Zealand – Infant Formula Standard 2.9.1, and the reference to the Advisory Panel has been deleted as this no longer applies. It is proposed that an amended form of the MAIF Agreement will come into force on the date that authorisation is granted by the ACCC.

6. In addition to the MAIF Agreement, the conduct for which authorisation is sought includes the following guidelines and policies:

    - interpretation and application of the MAIF Agreement

    - the marketing of infant formula via electronic media

    - interactions with health care professionals

    - the provision of samples to health care professionals

    - the complaints and review process.

Background

Infant formula

7. Infant formula is an industrially produced milk product designed for infant consumption (an infant being a person aged up to 12 months). Formula has added vitamins and enzymes and different fats that infants need.

8. Mandatory compositional and labelling requirements for infant formula in Australia is set out in the Australia New Zealand Food Standards Code – Standard 2.9.1 (FSANZ Standard). Only products which comply with this Standard are permitted to be represented as an infant formula product.

9. In addition, FSANZ Standard 1.2.7 provides that nutrition content and health claims cannot be made about infant formula.

Infant Nutrition Council

10. The Infant Nutrition Council (the Council) represents the major manufacturers and marketers of infant formula in Australia and New Zealand as well as local manufacturers producing for export. The Council states its aims are to improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, where needed, infant formula as the only suitable alternative, and to represent the infant formula industry in Australia and New Zealand. All current signatories to the MAIF Agreement are members of the Infant Nutrition Council. Signatories account for the majority of sales of infant formula in Australia.[1]

11. Current signatories to the MAIF Agreement are:

    - Abbott Australasia Pty Ltd
    - Aspen Nutritionals Australia Pty Ltd
    - Australian Dairy Park Pty Ltd
    - Bayer Australia Ltd
    - H J Heinz Company Australia Ltd
    - Nestlé Australia Ltd
    - Nutricia Australia Pty Ltd
    - The a2 Milk Company Limited
    - The Infant Food Co Pty Ltd.

[1] Only two non-signatories appear to have a significant presence in the Australian infant formula market – Bellamy's Organic and Amcal (Department of Health and Ageing, *Review of the effectiveness and validity of operations of the MAIF Agreement: Research Paper*, 13 June 2012, (**Nous Report)** p35).

Implementation of the WHO Code

12. The World Health Organization (**WHO**) established an *International Code of Marketing of Breast-milk Substitutes* (**WHO Code**) in 1981 in response to concerns over a perceived decline in breastfeeding, and as a 'minimum acceptable requirement' for the marketing of breast milk substitutes. The aim of the WHO Code was to protect and promote breastfeeding and to ensure that marketing of breast milk substitutes, feeding bottles and teats is appropriate. Australia was one of the early signatories to the WHO Code.

13. Australia has adopted some elements of the WHO Code through regulatory and quasi-regulatory mechanisms rather than legislation, including through the MAIF Agreement, the FSANZ Standard, and the National Health & Medical Research Council's *Dietary Guidelines for Children and Adolescents in Australia* (2003), which includes guidance for health workers on interpreting the WHO Code.

Previous authorisations

14. The MAIF Agreement has been authorised in more or less its current form since 1992.[2] In August 2007 a minor variation was made to extend authorisation to cover new parties to the MAIF Agreement and to introduce an expiry date of 31 December 2015.[3]

Recent developments

15. A research paper was commissioned by the Commonwealth Department of Health and Ageing (**Department of Health**) in December 2011 to review the effectiveness and validity of operations of the MAIF Agreement in light of the WHO Code. The paper, produced by the Nous Group in June 2012, reports stakeholder consultation revealed that voluntary industry self-regulation remains effective and appropriate while industry coverage remains high, because it encourages industry to take greater ownership of the arrangements.

16. The Nous Report also concluded that the MAIF Agreement should not be extended to cover complementary foods, retailers and pharmacists, or to the marketing of teats and bottles because there was insufficient evidence to warrant such extensions, and there were practicalities and costs associated with extending the scope particularly as bottles and teats were also used by breastfeeding parents for expressed breast milk. The Nous Report concluded that many of the WHO Code recommendations are of particular relevance to developing countries, where issues such as poverty, illiteracy and hygiene present specific challenges to infant feeding and, as such, Australia need not implement the WHO Code in its entirety.

17. However, the Nous Report contained recommendations for some changes to the content and operation of the MAIF Agreement, specifically:

    - that the wording be updated to reflect current legislation, standards, marketing practices and modern health terminology, including that it include specific reference to electronic and social media, provide clear guidance around what constitutes an 'inducement', 'sample' and

[2] See A30146, A90539 and A90540 granted to Abbott Australasia Pty Limited and Nestlé Australia Limited on 23 September 1992.
[3] See minor variation of A90539 and A90540 granted to Nestlé Australia Ltd on 30 August 2007.

'professional evaluation', and refer to current food standards legislation (i.e. Australian Food Standard 2.9.1)

- that the operation of the Advisory Panel in monitoring compliance and dealing with complaints be reviewed to improve efficiency, transparency and timeliness of its operations and governance, and
- that changes be considered in relation to the marketing of toddler milk drinks, as these were often labelled with product identifiers resembling those of infant formula labels, and therefore the marketing of toddler milk drinks (which is not covered by the MAIF Agreement) was being used as de-facto advertising for infant formula as consumers were not necessarily able to distinguish between infant formula and toddler milk drinks.

18. The Department of Health agreed in principle with all but the last of these recommendations.[4]

19. The Advisory Panel (established by the Australian Government to monitor compliance with, and advise the Government on, the MAIF Agreement) was replaced in 2013 with a process by which complaints that fall within the scope of the MAIF Agreement are referred by the Department of Health to a MAIF Complaints Tribunal. The Tribunal was established by the Department of Health in consultation with the Council.

20. The Infant Nutrition Council has developed a policy on the use of formula samples – small quantities of an infant formula provided without cost - which provides that samples are only provided at the request of health care professionals, and has developed guidelines to support the interpretation of the MAIF Agreement as it applies to the marketing of infant formula via electronic media.

21. Currently, the WHO is conducting a consultation process on a series of recommendations on the promotion of foods for infants and young children, in response to growing concern and evidence worldwide that inappropriate promotion of breast milk substitutes, and some commercial complementary foods and beverages for infants and young children, has been undermining progress in infant and young child feeding (i.e. both breastfeeding and nutritionally adequate and safe complementary foods after the age of six months).

22. The recommendations to member states include:

    - introducing all provisions of the WHO Code into domestic law, to implement and enforce these standards
    - to extend implementation to all products within the full scope of the WHO Code, including milk drinks marketed as suitable for children aged up to two years
    - that products manufactured by companies that market breast milk substitutes should not be promoted using similar colour schemes and designs, similar names and similar promotional slogans, mascots or other symbols.

[4] http://www.health.gov.au/internet/main/publishing.nsf/Content/review-effective-infant-formula

23. The WHO recommendations aim to provide guidance to WHO member states, the private sector, health systems, civil society and international organisations on how to meet their obligations under the Code. These recommendations are to be considered by WHO member states at the World Health Assembly meeting in May 2016.

Consultation

24. The ACCC invited submissions from 21 potentially interested parties (including government, industry and non-government organisations) seeking comment on the applications for re-authorisation.

25. Six submissions were received all of which supported granting re-authorisation but a number raised concerns with aspects of the MAIF Agreement in relation to its scope, complaint processes, oversight and the length of authorisation requested.

26. In summary:

- Breastfeeding Coalition Tasmania said the MAIF Agreement should remain in place but needs updating in line with the Nous Report recommendations

- La Leche League NZ submitted the MAIF Agreement should be reauthorised but only for 1 – 2 years, in order to allow a review in light of changes to WHO Code guidelines which is expected next year. It also considers stronger measures need to be taken in interpreting the WHO Code including expansion to cover toddler milks

- Australian Nursing and Midwifery Federation endorses the MAIF Agreement but does not support the commercial promotion of breast milk substitutes by the supply of free or low cost samples

- Dieticians Association of Australia supports the MAIF Agreement in principle but is concerned it has not been updated in response to recommendations in the Nous Report

- Australian Breastfeeding Association (**ABA**) submits re-authorisation should be granted for only one year to allow the Australian Government to consider its response to revised WHO recommendations in 2016. The ABA submits the MAIF Agreement has failed to protect breastfeeding in Australia and a broader, stronger legislative instrument is required, giving full effect to the WHO Code and resolutions

- Associate Professor Julie Smith, Libby Salmon and Dr Phillip Baker of the Australian National University (**Smith et al**) submit that re-authorisation should be granted for a maximum of 2 years on an interim basis, to allow the Australian Parliament to consider its response to revised WHO recommendations and the expiration of the National Breastfeeding Strategy in 2015. Smith et al also argue that the MAIF Agreement is not an effective regulatory instrument given it has not constrained consumption of infant formula or improved rates of optimal breastfeeding, the MAIF Agreement is voluntary and unenforceable, and lacks oversight and clarity about processes around complaints, decisions and outcomes. The submission raises concerns that the MAIF

Agreement does not give effect to the full scope of the WHO Code and provides examples of current marketing practices which fall within the gaps.

27. The concerns raised by interested parties are addressed in further detail as relevant throughout this draft determination.

28. Further information in relation to the applications for re-authorisation, including any public submissions received by the ACCC as this matter progresses, may be obtained from the ACCC's website **www.accc.gov.au/authorisations**.

Scope, content and operation of the Agreement

29. A number of reports and submissions from interested parties have raised concerns about particular aspects of the MAIF Agreement. These issues are discussed in further detail below.

Scope of the MAIF Agreement

30. While the MAIF Agreement relates only to marketing by manufacturers in relation to infant formula, the WHO Code is broader in scope as it includes recommendations that restrictions be placed on the marketing of toddler milks, complementary foods for infants, feeding bottles and teats, and on the promotion and price discounting by retailers of all of these products.

31. The Breastfeeding Coalition Tasmania, La Leche League New Zealand, Australian Breastfeeding Association and Smith et al submit the MAIF Agreement should be extended to cover toddler milks, as marketing for toddler milks may cross-promote infant formula where packaging and the marketing materials do not clearly distinguish between the two products. The submissions note that the WHO is currently consulting on guidance on this issue.

32. The Australian Breastfeeding Association and Smith et al also request that complementary foods be included within the scope of the MAIF Agreement, and that restrictions be applied to the marketing and price promotion of infant formula by retailers.

33. In response, the Council notes that (as outlined at paragraphs 15 – 18 above) the Nous Report did not find sufficient evidence to warrant extending the MAIF Agreement to include complementary foods or retailers. And, while the Nous Report recommended considering options to limit the marketing of toddler milks, the Department of Health did not accept this recommendation.

34. Further, the Council submits the proposed changes being considered by the WHO should not affect re-authorisation of the MAIF Agreement, as it is too early to know what, if any, changes will be made. Any re-authorisation of the MAIF Agreement does not prevent Australia from adapting to those changes, and any changes are unlikely to result in a reduction of the existing restrictions on competition contemplated by the MAIF Agreement.

Social media

35. The Nous Report in 2012 recommended amending wording in the MAIF Agreement, including to specifically include reference to electronic media and social marketing. While these recommendations have not been adopted in the

updated MAIF Agreement, the Council has adopted a guideline on *Marketing of Infant Formulas via Electronic Media* which was endorsed by the Department of Health. This guideline forms part of the current authorisation application. The ACCC understands that, while breaches of this guideline are not able to be considered by the Tribunal in its consideration of complaints in relation to the MAIF Agreement, the Tribunal can nonetheless consider potential breaches of the MAIF Agreement which occur via social media and other forms of electronic marketing.

36. Both the Breastfeeding Coalition Tasmania and Smith et al raise concerns that the current MAIF Agreement does not explicitly cover electronic marketing. Smith et al identified examples of online marketing by manufacturers which it identified as falling outside of the scope of the MAIF Agreement, but within the scope of the WHO Code and subsequent WHA resolutions.

37. In response, the Council said the MAIF Agreement operates as a high level instrument to be supplemented by more specific guidelines, principles and policies, which can be regularly reviewed to ensure currency of the operation of the MAIF Agreement, and that the specific inclusion of social media marketing is more properly addressed through these guidelines and principles.

38. In relation to the content of the guideline, the ACCC notes that it suggests signatories "should adopt reasonable measures to monitor social media forums…. which are within their control." The ACCC expects signatories would not only monitor content but also take appropriate actions to ensure content on social media is compliant with their obligations under the MAIF Agreement and the Australian Consumer Law.[5]

Oversight and complaints

39. Smith et al and the ABA raised concerns about the replacement of the Advisory Panel with the Tribunal in 2013. Smith et al argue this has weakened oversight of the MAIF Agreement and says the Tribunal's terms of reference, procedures and expertise have been questioned by the Public Health Association of Australia.

40. However, the Council advises the Advisory Panel was disbanded by the Department of Health in 2013. The Tribunal was established by MAIF signatories in collaboration with the Department of Health and key stakeholders. In December 2014 the Assistant Minister for Health, Senator the Hon Fiona Nash, stated the Tribunal "meets Australia's obligations under the [WHO Code]."[6]

41. While the Council submits that low complaints are evidence of the success of the MAIF Agreement, the La Leche League submits this is due to the narrow scope and non-compulsory nature of the MAIF Agreement. The Nous Report found that, since 2007-08, 80% of complaints to the Advisory Panel had been deemed to be out of scope, and noted that some stakeholders indicated that they had stopped submitting complaints as a result of their complaints repeatedly being deemed to be out-of-scope.[7]

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[5] See ACCC guidance on this issue at **http://www.accc.gov.au/business/advertising-promoting-your-business/social-media**.
[6] **www.infantnutritioncouncil.com/code-compliance/australia/**
[7] Nous Report, pp33-34.

42. Smith et al and the ABA also raised concerns that the MAIF Agreement was not enforceable as the Tribunal has no power to impose penalties. The Nous Report also raised the issue that stronger consequences for breaches may be required to ensure the voluntary, self-regulatory model remains effective.[8]

43. The ACCC has previously noted that any public benefits associated with substantive provisions of a code of conduct will only arise to the extent that the code is effective in its operation.[9] In the case of the MAIF Agreement, while the dispute resolution measures do not seem particularly robust, the ACCC is not aware of significant unresolved issues arising within the scope of the MAIF Agreement.

Industry coverage

44. Smith et al and the ABA argue that the voluntary nature of the MAIF Agreement undermines its effectiveness as a regulatory instrument, because it misses major industry players that would otherwise be required to comply if a legislative regulatory instrument were adopted.

45. The ACCC notes that the Nous Report found that the voluntary, self-regulatory nature of the MAIF Agreement remained the most appropriate option providing industry coverage levels remain high. The report notes it is difficult to determine the exact coverage of the MAIF Agreement in Australia due to limited public information, but that signatories to the agreement accounted for the majority (perhaps up to 95 per cent[10]) of market sales, and that only two non-signatories appeared to have a significant presence in the Australian infant formula market (being Bellamy's Organic and Amcal).

Health claims

46. Smith et al argue that health claims in relation to infant formula can be made on weak grounds. Breastfeeding Coalition Tasmania submits that Standard 1.2.7 within the Australia New Zealand Food Standards Code (relating to nutrition and health claims) should be incorporated into the MAIF Agreement.

47. While infant formula is not currently subject to the requirements within Standard 1.2.7, the ACCC notes that adaption of the scope of the Food Standards Code to include infant formula may be more appropriate than its inclusion within the MAIF Agreement, should the Australian Government be concerned at health or nutrition claims made in relation to infant formula. Additionally, the marketing of infant formula remains subject to the Australian Consumer Law prohibitions of misleading and deceptive conduct and false representations.

ACCC view

48. The ACCC notes many of the issues raised by interested parties have been, or continue to be, under review both domestically and internationally.

[8] Nous Report, p35.
[9] eg. See ACCC determination relating to A91436 – A91440, lodged by Medicines Australia Limited, at [294].
[10] As estimated by some interviewed stakeholders. Nous Report, p34.

49. However, it is not the role of the ACCC as part of the authorisation process to redraft the MAIF Agreement to seek to create an ideal agreement. Rather, the role of the ACCC is to assess whether the public benefits of the current MAIF Agreement for which the parties have sought authorisation are likely to outweigh the detriments.

50. While the ACCC considers an alternative regulatory regime is likely to ultimately be imposed if there was no MAIF Agreement, the ACCC notes there is considerable uncertainty as to the extent or nature of such a regulatory regime. This means that, even if the changes to the MAIF Agreement (or contained in a possible alternative legislative regime) suggested by interested parties could be said to increase rates of breastfeeding, it is not clear that this benefit would be achieved in the absence of the arrangements for which authorisation is sought.

ACCC assessment

51. The ACCC's assessment of the conduct is in accordance with the relevant net public benefits tests[11] contained in the *Competition and Consumer Act* 2010 (the **CCA**).

52. In its assessment of the applications the ACCC has taken into account:

    - the application and submissions received from the applicant and interested parties;[12]
    - other relevant information available to the ACCC, including information from consideration of previous matters and the ACCC's previous consideration of the MAIF Agreement; and
    - the relevant areas of competition likely to be affected by the MAIF Agreement, particularly competition between manufacturers of infant formula.

Future with and without the conduct

53. To assist in its assessment of the conduct against the public benefit tests, the ACCC compares the likely future with the conduct for which authorisation is sought to the likely future without the conduct the subject of the authorisation. The ACCC will compare the public benefits and detriment likely to arise in the future where the conduct occurs against the future in which the conduct does not occur.

54. The Applicants did not make a submission on the likely future without the conduct.

55. A number of interested parties submit that a regulatory approach would be an alternative to the MAIF Agreement. A number of these parties called for such a regulatory regime to give effect to the full scope of the WHO Code, beyond that covered by the MAIF Agreement.

56. The ACCC considers that, in the absence of the MAIF Agreement, a form of regulatory response by the Australian Government is likely to give effect to

[11] Subsections 90,(5A), 90(5B), 90(6), 90(7), 90(8) and 91C(7) of the CCA.
[12] Please see the ACCC's Public Register for more details, including a list of parties consulted.

Australia's obligations under the WHO Code. Restrictions imposed under such a regulatory regime may be similar or more restrictive than under the current MAIF Agreement, and would likely take a number of years to develop and implement. Additionally, there would be costs associated with developing, implementing and operating a regulatory regime.

57. However, in the interim, the marketing of infant formula in Australia would not be subject to any restriction and members of the Council would be free to market as they see fit (subject to the requirements outlined in paragraph 58 and Australian Consumer Law). Due to the reputational risk of advertising infant formula, it is possible that Council members would voluntarily abide by the same restrictions without an agreement. However, the ACCC considers there would be some incentive for members to actively and directly market infant formula.

58. The ACCC notes that, even without the MAIF Agreement, members of the Council would still be subject to the labelling requirements for infant formula set out in food standards legislation (as amended from time to time), including FSANZ Standard 2.9.1,[13] and any other applicable legislation.

Rationale for the conduct

59. Generally, marketing is designed to increase demand for a firm's product and/or to differentiate the firm's products from those of its competitors and as such is a part of efficient competitive rivalry in most markets.

60. While there is no commercial incentive for the marketing and promotion of breastfeeding, infant formula manufacturers, importers and retailers have an incentive to market and promote their product. However, the promotion of infant formula and resulting increase in demand could be expected to reduce rates of breastfeeding because consumers will have access to greater information about the benefits of infant formula than they will breastfeeding. This in turn undermines the health benefits associated with breastfeeding and the public policy aims of promoting breastfeeding.

61. One way to address this market failure is to restrict the marketing of infant formula, as set out in the WHO Code. Without any general restrictions on marketing, formula manufacturers do not individually have an incentive not to market their products unless they all agree not to do so, for fear of losing market share to competitors.

62. For this reason, restricting the marketing of infant formula may protect rates of breastfeeding and protect public health and policy outcomes. This restriction may be achieved through an agreement between competitors (as is currently the case in the MAIF Agreement) or through government regulation.

Public benefits

63. The Council submits the MAIF Agreement has resulted, and will continue to result, in significant public benefit through promoting and protecting

[13] At the current time, Standard 2.91 sets (among other things) labelling requirements such as a statement that breast milk is best for babies, and prohibiting the use of pictures of infants or idealising the use of formula.

breastfeeding as the best form of nutrition for the health, growth and development of infants, whilst also ensuring that appropriate information is provided to women who are unable to (or make an informed choice not to) breastfeed. The MAIF Agreement achieves this through:

- restricting promotional activities which could undermine these objectives
- setting consistent standards for the information to be provided to health care professionals
- limiting the potential for conflicts of interest in relationships between manufacturers of infant formula and health care professionals
- requiring manufacturers and importers of infant formula to have internal compliance procedures which promote compliance by all company employees.

64. The ACCC accepts that there is likely to be a public benefit resulting from arrangements that promote and protect breastfeeding. The link between improved health outcomes and breastfeeding is undisputed, and scientific research has indicated there is a relationship between breastfeeding and diseases including breast cancer, gastrointestinal infection, necrotising enterocolitis, lower respiratory tract infection and acute otitis media.[14] Therefore increased rates of breastfeeding in infants will lead to improved health outcomes and lower public health costs.

In addition, the ACCC considers the benefits of the MAIF Agreement should be assessed against the costs of industry self-regulation compared to government regulation and enforcement.

Impact on breastfeeding rates

65. Submissions from the Australian Breastfeeding Association and Smith et al expressed concerns that the MAIF Agreement had not been an effective regulatory instrument because it had not constrained the consumption of breast milk substitutes or improved the rates of optimal breastfeeding in the period of its operation.

66. The ACCC notes that it is difficult to draw definitive conclusions regarding the effectiveness of the MAIF Agreement from rates of breastfeeding and/or consumption of formula within a population, as these rates will be affected by a number of factors such as lifestyle, cultural and institutional factors which are beyond the reach of the MAIF Agreement.

67. Nonetheless, to the extent marketing by MAIF Agreement signatories were to increase in the absence of the MAIF Agreement, the ACCC considers the restrictions in the MAIF Agreement are likely to protect and promote breastfeeding and result in a significant public benefit compared to the future without it for at least the period until an alternative regulatory regime took effect.

[14] Mary Renfrew et al, "Preventing disease and saving resources: the potential contribution of increasing breastfeeding rates in the UK" (report commissioned by UNICEF UK, October 2012).

Reduced Regulatory costs

68. In the absence of the MAIF Agreement it is likely that there would be a regulatory response by Government to give effect to the WHO Code. This would incur costs in terms of the time and resources required to develop the regulatory regime and the ongoing enforcement of the regime.

69. As such the ACCC considers that the MAIF Agreement results in a public benefit through avoiding these regulatory costs, including the time and resources of Parliament and policy agencies, and the lower operating costs of a voluntary self-regulatory code compared with regulatory alternatives. The New Zealand Commerce Commission quantified the avoided net regulatory costs, within the New Zealand context, at approximately $NZ3.2 million over two years.[15] In this regard the ACCC also notes the finding of the Nous Report that "the voluntary, self-regulatory nature of the MAIF Agreement is the most cost effective regulatory mechanism."[16]

Conclusion on public benefits

70. The ACCC considers that the MAIF Agreement has resulted, and is likely to continue to result, in public benefits in the form of:

    - protecting and promoting breastfeeding
    - avoided regulatory costs.

Public detriments

71. The Council submits the MAIF Agreement does not result in any material anti-competitive or other public detriment, because:

    - the restrictions are directed to meeting important public health goals
    - the benefits normally attributed to direct advertising (namely, ensuring best quality and the lowest cost and creating an informed public) do not appear to be applicable to the advertising of infant formula, and
    - a decision on whether to use infant formula should not depend upon the effectiveness of commercial advertising but on objective and consistent advice, and appropriate supervision.

72. The ACCC considers that the restrictions in the MAIF Arrangement are likely to result in minimal detriment because:

    - retailers of infant formula are not prevented from engaging in inter- and intra-brand price competition
    - Australia is a small consumer of infant formula in a global context, and as most infant formula is imported, the conduct is unlikely to influence product innovation

[15] New Zealand Commerce Commission, Determination: Infant Nutrition Council Limited [2015] NZCC 11, p18.
[16] Nous Report, p28.

- similar or stricter restrictions on the marketing of infant formula are likely to be imposed via a regulatory regime after a period, in the absence of the MAIF Agreement.

Balance of public benefit and detriment

73. For the reasons outlined in this draft determination, on balance, the ACCC considers that the conduct is likely to result in public benefit from promoting and protecting breastfeeding and avoiding regulatory costs. These benefits outweigh any public detriment, including from any lessening of competition caused by the restrictions on marketing. Accordingly, the ACCC is satisfied that the relevant net public benefit tests are met.

Length of authorisation

74. The CCA allows the ACCC to grant authorisation for a limited period of time.[17] This enables the ACCC to be in a position to be satisfied that the likely public benefits will outweigh the detriment for the period of authorisation. It also enables the ACCC to review the authorisation, and the public benefits and detriments that have resulted, after an appropriate period.

75. In this instance, the Council seeks re-authorisation for a further 10 years. The Council submits this is appropriate given the MAIF Agreement has been authorised since 1992 with only minor amendments in this time.

76. The La Leche League NZ, the ABA and Smith et al submit re-authorisation should only be granted for a period of 1 – 2 years, given anticipated changes to the WHO Code and guidelines in 2016, to allow the Australian Government to consider its response to any changes. The Dieticians Association of Australia also raised concerns at the length of time for which authorisation was sought.

77. The ACCC notes that there remains uncertainty as to the timing and implications of any future WHA guidance, including whether or how this might be implemented within the Australian context.

78. Further, authorisation does not prevent changes to the MAIF Agreement or associated arrangements. Neither does it lock in the current provisions. If these were to change, the parties may need to seek to vary the authorisation through a process of minor variation or revocation and substitution.

79. And ultimately, if at any time during the period of authorisation the ACCC reached the view that circumstances had changed and the benefits of the arrangements no longer outweighed the detriments, the ACCC could decide to commence a process to revoke the authorisation.

80. Given the uncertainty regarding changes and the longstanding nature of the MAIF Agreement, the ACCC considers that granting authorisation for a further 10 year period (with flexibility to vary the arrangements as noted above) is appropriate.

[17] Subsection 91(1)

Draft determination

The application

81. The Infant Nutrition Council lodged an application under subsection 91C(1) of the CCA for the revocation of authorisations A90539 and A90540 and the substitution of authorisations A91506 and A91507 for the ones revoked. The Council made this application on behalf of the current signatories to the MAIF Agreement (which are listed at paragraph 11 above).[18] The application was made using a Form FC. Authorisation is sought to make and give effect to the *Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement* and associated guidelines, as set out in Annexure 1.

82. The amended form of the MAIF Agreement set out in Annexure 1 is proposed to come into force on the date that authorisation is granted by the ACCC.

83. The application seeks that authorisation apply to current and future manufacturers in, and importers into, Australia of infant formula that are or become parties to the MAIF Agreement.

The net public benefit test

84. For the reasons outlined in this draft determination, the ACCC is satisfied, pursuant to sections 90(5A), 90(5B), 90(6) and 90(7) of the CCA, that in all the circumstances the conduct for which authorisation is sought is likely to result in a public benefit that would outweigh any likely detriment to the public constituted by any lessening of competition arising from the conduct.

85. The ACCC is satisfied, pursuant to section 90(8) that the conduct for which authorisation is sought is likely to result in such a benefit to the public that the conduct should be allowed to take place.

Conduct which the ACCC proposes to authorise

86. The ACCC proposes to revoke authorisations A90539 and A90540 and grant authorisation A91506 and A91507 to the Infant Nutrition Council on behalf of the manufacturers in, and importers into, Australia of infant formula that are currently parties to the MAIF Agreement (as listed at paragraph 11 above) to make and give effect to the *Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement* and associated guidelines as set out in Annexure 1, which:

    - requires specified information to be contained in the educational material provided by signatories which is intended for pregnant women or parents of young children and which relates to the feeding of infants

    - prohibits the advertising and promotion of infant formula by signatories directly to the public

    - restricts the information provided to health care professionals by signatories regarding infant formulas to scientific and factual matters

[18] Including Nestle Australia Ltd, to whom authorisations A90539 and A90540 were granted.

- prohibits health care professionals and persons employed by signatories from accepting or offering incentives to promote or sell infant formulas

- requires internal monitoring and compliance practices by signatories to ensure conduct conforms to the principles and aims of the MAIF Agreement.

87. The ACCC proposes to grant authorisation for a further 10 years.

88. Under section 88(10) of the CCA, the ACCC proposes to extend the authorisation to future parties to the MAIF Agreement.

89. This draft determination is made on 29 October 2015.

Next steps

90. The ACCC now seeks further submissions on this draft determination. In addition, the applicant or any interested party may request that the ACCC hold a conference to discuss the draft determination, pursuant to section 90A of the CCA.

Annexure 1.

Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement

The MAIF Agreement

Preamble

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

Clause 1: Aim

The aim is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary,[2] on the basis of adequate information and through appropriate marketing and distribution. (WHO Code Article 1)

Clause 2: Scope

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

Clause 3: Definitions

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

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

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

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

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

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

(e) 'Infant formula' - any food described or sold as an alternative for human milk for the feeding of infants up to the age of twelve months and formulated in accordance with all relevant clauses of the Australia New Zealand Food Standards Code, including Infant Formula Products Standard 2.9.1.

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

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

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

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

Clause 4: Information and Education

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

(i) the benefits and superiority of breastfeeding;

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

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

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

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

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

(c) Manufacturers and importers of infant formulas should not donate informational or educational equipment or materials unless it is at the request of, and with the written approval of, the appropriate government authority or within guidelines given by the

Commonwealth, State or Territory Governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary infant formula, and should be distributed only through the health care system. (WHO Code Article 4.3)

Clause 5: The general public and mothers

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

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

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

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

Clause 6: Health care system

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

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

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

(d) Manufacturers and importers of infant formulas should be aware that feeding with infant formulas, whether manufactured or home prepared, should be demonstrated only by

health care professionals. Such demonstrations should be made only to the parents or other persons who need to use it, and the information given should include a clear explanation of the hazards of improper use. (WHO Code Article 6.5)

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

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

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

Clause 7: Health Care Professionals

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

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

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

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

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

Clause 8: Persons employed by manufacturers and importers

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

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

Clause 9: Quality and Labelling

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

(b) Manufacturers and importers of infant formulas must ensure that labels provide the information required to be provided by the Australia New Zealand Food Standards Code Part 1.2 and Infant Formula Products Standard 2.9.1., and also provide the necessary information about the appropriate use of infant formula and should not discourage breastfeeding. (WHO Code Article 9.1)

Clause 10: Implementation and monitoring

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

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

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

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

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

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

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

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

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

Inclusion of information

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

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

Pictures on informational or educational material for health professionals

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

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

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

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

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

Advertisements to the general public

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

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

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

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

Interpretation of the term 'scientific'

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

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

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

Access to health professionals

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

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

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

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

Inducements

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

Advertising

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

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

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

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

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

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

Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

MARKETING OF INFANT FORMULAS VIA ELECTRONIC MEDIA

Overall Principles

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

2. These guidelines are to be read with the aim of the MAIF Agreement and the INC Code of Practice in mind and as an overarching principle: that is, to contribute to the safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information and through appropriate marketing and distribution.

Consumer-based websites

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

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

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

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

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

Frequently Asked Questions

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

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

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

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

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

Other electronic communications and social media

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

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

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

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

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

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

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

Guidance on Interactions with Healthcare Professionals

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

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

1. Visits with Company Representatives

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

2. Educational Events

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

3. Sponsorship of Healthcare Professionals

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

Approved by the Board – 31 January 2012

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

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

4. Consultancy Arrangements

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

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

5. Sponsorship of Healthcare Professional Practice Activities

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

6. Entertainment

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

7. Travel

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

8. Venue / Accommodation

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

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

Approved by the Board – 31 January 2012

9. Hospitality

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

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

10. Gifts

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

Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

Policy – Distribution of Infant Formula Samples to Health Care Professionals

Aim

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

Scope

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

Definitions

'Samples'

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

'Professional Evaluation' and 'Research'

The words *'professional evaluation'* apply to:

- Analysis of products (ingredients, taste, nutritional profile);
- Trial preparation and mixing of infant formula products (includes preparation and mixing instructions to mothers);

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

- Investigative or development projects, using sound methodology and involving a number of infants;

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

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

The word *'research'* applies to:

- Clinical research carried out at the institutional level.

'Health Care System'

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

'Health Care Professional'

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

Policy

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

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

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

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

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

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

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

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

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

Complaints Tribunal

Terms of Reference

Background[1]:

1. The MAIF Agreement is a voluntary self-regulatory code of conduct between the manufacturers and importers of infant formula in Australia. It is Australia's response to the World Health Organization's *International Code of Marketing of Breast-milk Substitutes 1981* (WHO Code). The MAIF Agreement applies to those Australian manufacturers and importers of infant formula who are signatories to the MAIF Agreement. The MAIF Agreement aims to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information through appropriate marketing and distribution.

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

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

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

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

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

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

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

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

MAIF Complaints Tribunal

Terms of Reference

Purpose:

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

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

Proceedings:

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

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

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

Composition:

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

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

Appointment:

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

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

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

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

Conflicts of Interest

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

Term of appointment

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

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

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

Termination of Appointment

13) Appointment to the Tribunal may be terminated by:

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

Casual Vacancies

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

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

Chair of the Tribunal

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

Remuneration

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

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

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

Basis for a determination

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

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

Process

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Appeals

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

Residual Rights

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

Observer

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

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

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

APPENDIX 1

REMUNERATION OF COMPLAINTS TRIBUNAL MEMBERS

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

Chair	$922 per day
Member	$794 per day

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

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

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

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

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

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

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

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

KEY FEATURES OF THE MAIF AGREEMENT

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

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

MAIF AGREEMENT SIGNATORIES

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

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

FURTHER INFORMATION

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

CONTACT US

For further information or questions:

Phone: 02 6273 8164

Email: info@infantnutritioncouncil.com

www.infantnutritioncouncil.com

Infant Nutrition Council

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

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

Information for Retailers

Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

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

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

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

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

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

It is based on the World Health Organisation International Code of Marketing of Breast Milk Substitutes (WHO 1981) and is Australia's official application of the WHO Code within the context of our legal and economic environment. Both the MAIF Agreement and the WHO Code have the same aim which is:

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

The MAIF Agreement was developed by the Australian government, the infant formula industry, breastfeeding advocates and other stakeholders and implemented in 1992.

MONITORING CODE COMPLIANCE

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

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

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

APPLICATION OF THE MAIF AGREEMENT

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

In relation to products, the MAIF Agreement applies to:

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

The MAIF Agreement does not apply to:

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

MAIF AGREEMENT AND RETAILERS

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

PRICE PROMOTIONS

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