Determination

Application for revocation of authorisations 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: 15 July 2016

Authorisation numbers: A91506 and A91507

Commissioners: Schaper
Court
Featherston
Keogh

Summary

The ACCC has decided to re-authorise the *Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement* (MAIF Agreement) and associated guidelines.

The MAIF Agreement, amongst other things, prohibits the advertising and promotion of infant formula by manufacturers and importers directly to the public. The ACCC accepts that this, and other restrictions in the MAIF Agreement, results in public benefits by protecting breastfeeding rates, with significant consequential health benefits. Since 1992, the MAIF Agreement has been the primary means by which the Australian Government has chosen to give effect to the World Health Organisation's *International Code of Marketing of Breast-milk Substitutes,* to which Australia was an early signatory.

Through the re-authorisation process the ACCC heard from many interested parties who submitted that the MAIF Agreement could be improved. The concerns raised by interested parties include that some toddler milk marketing (which is outside the scope of the MAIF Agreement) is effectively marketing infant formula, and that oversight of the MAIF Agreement by the MAIF Complaints Tribunal is ineffective.

Some interested parties called for the MAIF Agreement to be reauthorised for a maximum of two years to increase the prospect of the Government implementing a legislative regime, and to allow for the Government to consider its response to new guidance recently welcomed by WHO member states on this issue (including whether marketing restrictions should extend to toddler milk).

The ACCC considers the issue of whether marketing restrictions should be extended to toddler milk is a policy decision for Government to make. However, in its assessment of this application, the ACCC has given consideration to the potential for toddler milk marketing to also effectively act as marketing of infant formula and thereby negatively impact breastfeeding rates.

The ACCC considers that toddler milk advertising that has the effect of promoting infant formula (in addition to toddler milk), may undermine benefits arising from the MAIF Agreement.

The ACCC understands that the MAIF Complaints Tribunal can currently consider and rule on complaints about toddler milk advertising to the extent they have the effect of marketing infant formula and would be inconsistent with the principles set out in the MAIF Agreement.

In this regard, the ACCC notes a recent decision by the MAIF Complaints Tribunal relating to the marketing of toddler milk (in which the Tribunal found advertising for toddler milk to be in breach of the MAIF Agreement because it used an image of a young infant). The ACCC understands that this and other recent toddler milk decisions by the Tribunal may result in the development of new guidelines and/or changes to industry practice in this area. In any event, any impact of toddler milk marketing on the effectiveness of the MAIF Agreement would be a relevant factor in the ACCC's consideration of any future authorisation application by the Council.

The MAIF Complaints Tribunal currently publishes its decisions in its annual report. The ACCC understands the Tribunal has discretion under its Terms of Reference to publish its decisions in whatever manner it sees fit, and considers it is important to ensure public confidence in the MAIF Agreement that the Tribunal publish its decisions shortly after they are finalised as this will provide transparency and help ensure effective oversight of the MAIF Agreement.

The ACCC also considers that compliance with recommendations of the Tribunal by MAIF Agreement signatories is important to ensure the effective operation of the MAIF Agreement, and expects signatories to adhere to any recommendations made by the Tribunal within the scope of the MAIF Agreement. The ACCC expects to re-examine this issue in any future application for re-authorisation of the MAIF Agreement.

With regard to any future policy changes by the Australian Government as a result of the WHO's considerations of toddler milk marketing, the ACCC notes that there remains uncertainty as to the timing of any such policy decisions, as well as the extent to which any such changes may affect the MAIF Agreement. Re-authorisation does not prevent the Infant Nutrition Council from seeking to vary the authorisation at any time, including as a result of changes in Government policy. Further, the ACCC can initiate a review of the authorisation under the Competition and Consumer Act.

Authorisation of the MAIF Agreement does not preclude the introduction by Government of an alternative regulatory regime for the marketing of infant formula (and/or toddler milk) in Australia.

The Council sought authorisation for a further 10 years, while interested parties submit it should only be granted for two years. On balance, having regard to the significant concerns raised by interested parties, uncertainty about whether the policy environment might change and the cost incurred in seeking re-authorisation, the ACCC considers that granting authorisation for the MAIF Agreement for a further five year period is appropriate.

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. The Council sought 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 Council sought 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 formula for infants up to 12 months. In summary, the MAIF Agreement includes provisions which:

    - require 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

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

- prohibit the distribution of samples of infant formula to health care professionals except when necessary for the purpose of professional evaluation or research at the institutional level

- prohibit the use of any facility of the health care system for the purpose of promoting infant formulas. However, the MAIF Agreement allows for the donation or low-priced sale of infant formula to institutions or organisations for the use of infants who have to be fed on breast milk substitutes.

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

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

- require 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 older than 12 months. 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 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 (**Interpretation Guidelines**)

    - 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 (Terms of Reference for the MAIF Complaints Tribunal (the **Tribunal**).

7. The Interpretation Guidelines were developed by the now-disbanded Advisory Panel.[1] Guidelines regarding electronic media, and samples and interactions with health care professionals were developed by the Council to aid the interpretation of the MAIF Agreement.

8. As these guidelines do not form part of the MAIF Agreement itself, they are not binding upon the Tribunal in making its decisions. However the Council submits that they provide a reference point to companies in seeking to abide by the MAIF Agreement.

9. The Council has sought authorisation for these guidelines and the MAIF Agreement as they may involve agreements between competitors in breach of the competition provisions of the *Competition and Consumer Act* 2010. Authorisation of these guidelines does not in itself make them binding on the Tribunal or MAIF Signatories. The Tribunal remains free to develop its own guidelines on its interpretation and application of the MAIF Agreement.

10. On 29 October 2015 the ACCC issued a draft determination proposing to grant authorisation for a further 10 years. A conference was requested by a number of parties following the draft determination and was held on 14 December 2015. Details of issues raised are discussed in this determination.

11. Due to the expiry of the previous authorisations, on 31 December 2015 the ACCC granted interim authorisation to allow the previously-authorised form of the MAIF Agreement to continue to operate until the ACCC issued its final determination. Interim authorisation remains in place until the date the ACCC's final determination comes into effect or until the ACCC decides to revoke interim authorisation.

Background

Infant formula

12. 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.

13. Mandatory compositional and labelling requirements for infant formula in Australia are 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.

14. FSANZ is currently reviewing the standards applying to infant formula, including: compositional requirements; preparation, use and storage directions; and warning statements (such as those about adding other foods to formula).

[1] See discussion at paragraph 25.

15. Clause 3 of Standard 1.2.7 explicitly prohibits the making of nutrition content claims and health claims about infant formula products. As part of its current review, FSANZ has sought views on whether there is a need for greater clarity about what is permitted in relation to infant formula in this regard (for example, what constitutes a health or nutrition content claim in this context).

Infant Nutrition Council

16. 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.[2]

17. The Department of Health facilitates companies becoming signatories to the MAIF Agreement. The Department maintains a list of current signatories on its website.[3] At the time of writing, these were:

    - Abbott Australasia Pty Ltd
    - Aspen Nutritionals Australia Pty Ltd
    - Australian Dairy Park Pty Ltd
    - Bayer Australia Ltd
    - H J Heinz Company Australia Ltd
    - Murray Goulburn Co-operative Co. Limited (Devondale)
    - Nature One Dairy Pty Ltd
    - Nestle Australia Ltd
    - Nutricia Australia Pty Ltd
    - A2 Corporation Ltd.

Implementation of the WHO Code

18. 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 is 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.

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[2] 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).

[3] **http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-foodpolicy-apmaif.htm**

19. The Department of Health advises that Australia currently implements the WHO Code and related World Health Assembly (WHA) resolutions in a number of ways that are appropriate to Australia's social, legal and economic environments, the primary mechanism being the MAIF Agreement.[4] Other mechanisms include 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

20. The MAIF Agreement has been authorised in more or less its current form since 1992.[5] In August 2007 a variation was made to extend authorisation to cover new parties to the MAIF Agreement and to introduce an expiry date of 31 December 2015.[6]

Developments since authorisation last granted

Review of the MAIF Agreement

21. 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, reported 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.

22. 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.

23. However, the Nous Report recommended some changes to the content and operation of the MAIF Agreement, including:

    - that the wording be updated to reflect current legislation, standards, marketing practices and modern health terminology, including that it make specific reference to electronic and social media, provide clear guidance around what constitutes an 'inducement', 'sample' and 'professional evaluation', and refer to current food standards legislation (i.e. Australian Food Standard 2.9.1)

[4] Submission by the Department of Health to the ACCC regarding A91506 & A91507, 11 December 2015.
[5] See A30146, A90539 and A90540 granted to Abbott Australasia Pty Limited and Nestlé Australia Limited on 23 September 1992.
[6] See variation of A90539 and A90540 granted to Nestlé Australia Ltd on 30 August 2007.

- 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
- while not recommending that the MAIF Agreement be extended to toddler milk, that consideration should be given as to how to best restrict manufacturers' labelling of toddler milk drinks with product identifiers resembling those of infant formula labels. The Nous Report noted that the marketing of toddler milk drinks (which is not covered by the MAIF Agreement) can potentially provide de-facto advertising for infant formula as consumers were not necessarily able to distinguish between infant formula and toddler milk drinks.

24. The Department of Health agreed in principle with all but the last of these recommendations.[7]

Oversight

25. The Advisory Panel (established by the Australian Government to monitor compliance with, and advise the Government on, the MAIF Agreement) was dismantled as a result of a decision of Government in 2013. The Council advises that, in the absence of an independent review body, it approached the St James Ethics Centre to develop and oversee an independent complaints body, as a result of which the MAIF Complaints Tribunal was developed. Complaints under the MAIF Agreement are made to the Department of Health, and those which the Department considers fall within the scope of the MAIF Agreement are referred to the Tribunal.

26. Under its Terms of Reference, the Tribunal's role is to receive and investigate complaints regarding the marketing in Australia of infant formulas, and to develop guidelines on the interpretation and application of the MAIF Agreement. It does not have any specific power to impose penalties or sanctions when it finds a breach. It may publish the reasons for its decision by any means it deems appropriate, and may make recommendations as to how a breach might best be remedied. The ACCC understands that the Tribunal currently communicates its decisions to the complainant and subject of the complaint at the time of its findings, but does not make the decision public until it is published (along with all decisions) in its annual report. The Tribunal's first annual report for 2014/2015 was recently released on the Infant Nutrition Council's website and the ACCC understands it will also be published shortly on the Department of Health's website.

27. 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 supplied 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.

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

WHO process

28. On 28 May 2016, WHO member states welcomed (but did not formally endorse) WHO guidance on ending the inappropriate 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).

29. The recommendations to member states, contained in a report by a Scientific and Technical Advisory Group convened by the WHO,[8] include:

    - introducing all provisions of the WHO Code into domestic law, to implement and enforce these standards (Recommendation 4.1)

    - to extend implementation to all products within the full scope of the WHO Code, and clarifies that this includes milk drinks marketed as suitable for children aged up to two years (Recommendation 4.1)

    - 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 (Recommendation 4.2.3).

30. 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.

Consultation

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

32. Six submissions were initially received from: the Australian Breastfeeding Association (**ABA**); a group of academics from the Regulatory Institutions Network at the Australian National University (**Smith et al**); Breastfeeding Coalition Tasmania; La Leche League NZ; Australian Nursing and Midwifery Federation; and the Dieticians Association of Australia.

33. The ACCC invited further submissions in response to its draft determination. A large number of interested parties provided submissions, including more than 100 submissions from individuals (largely health professionals and parents), and from six organisations (specifically, the ABA, the Public Health Association of Australia, the International Code Documentation Centre, the International Board of Lactation Consultant Examiners, and Smith et al).

34. The Department of Health lodged submissions in November and December 2015, saying it supports re-authorisation of the MAIF Agreement, and that its re-

[8] <**http://www.who.int/nutrition/events/stag-report-inappropriate-promotion-infant-foods-en.pdf**>

authorisation is paramount as the primary mechanism by which Australia currently implements the WHO Code.

35. On 12 November 2015, a number of parties[9] requested that the ACCC hold a pre decision conference to discuss the draft determination. The conference was held on 14 December 2015 at ACCC offices in Canberra, Sydney, Melbourne and Brisbane.[10] The vast majority of submissions and conference attendees, while supporting re-authorisation, requested the ACCC grant authorisation for only 1 – 2 years to allow the government to reconsider the scope, complaint processes and oversight of the MAIF Agreement, or to develop and implement a legislative regime to replace it.

36. On 8 April 2016, Greens Senators Richard Di Natale, Larissa Waters and Rachel Siewert submitted they were concerned with the proposed re-authorisation period of 10 years, as this may discourage alternative government regulation and full implementation of the WHO Code and subsequent WHA resolutions.

37. On 22 April 2016, Labor Shadow Ministers Catherine King, Dr Andrew Leigh, and Claire Moore also urged any re-authorisation be limited to no more than two years to allow the issue to be considered by parliamentarians.

38. On 12 May 2016, Independent Senator Nick Xenophon wrote to the ACCC encouraging it to impose a requirement that any milk formula provided to hospitals or health care professionals be supplied at retail price (due to concerns that the provision of free or low cost formula to the health system leads to lower breastfeeding rates), and that a review be conducted within two years.

39. The Council provided submissions in September 2015, February 2016 and May 2016 responding to issues raised by interested parties.

40. The ACCC has also spoken with the Tribunal in order to fully understand its role and scope.

41. The concerns raised by interested parties, and the response to these by the Council, are addressed in further detail as relevant throughout this Determination.

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

Scope, content and operation of the Agreement

43. A number of reports and submissions from interested parties have raised concerns about particular aspects of the MAIF Agreement, including some which

[9] The ABA, the Public Health Association of Australia, and US-based organisations International Code Documentation Centre and the International Board of Lactation Consultant Examiners requested the conference. A late conference request was also made by Smith et al from the Regulatory Institutions Network at the ANU.

[10] Further information about the conference, including a record of proceedings, is available at: **http://registers.accc.gov.au/content/index.phtml/itemId/1188093/fromItemId/278039/display/preDecisionConference**.

the ACCC considers to be outside the scope of its current consideration of this authorisation application. These issues are discussed in further detail below.

Scope of the MAIF Agreement

44. While the MAIF Agreement relates only to marketing of infant formula by manufacturers, 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. The ACCC understands the scope of the current agreement to be in line with current Government policy following its consideration of the Nous Report (see paragraphs 21 – 24 above).

45. Some interested parties requested 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.

46. The issue of including toddler milks within the scope of the MAIF Agreement was also raised by many interested parties, and will be discussed in further detail in the Public Benefits section of this Determination.

47. In response to concerns raised regarding retailers and complementary foods, the Council notes that the Nous Report did not find sufficient evidence to warrant extending the MAIF Agreement to include complementary foods or retailers.

48. The ACCC considers that the extension of the MAIF Agreement to include retailers and manufacturers of complementary foods is beyond the scope of its assessment of this authorisation application, as a voluntary agreement between manufacturers and importers of infant formula. Such an extension could be achieved either through a separate agreement between retailers or between manufacturers of complementary foods (which may also require authorisation), or through a legislated mechanism. In any case, the ACCC considers that the scope of products and parties covered by marketing restrictions is ultimately a matter for Government policy.

49. The ACCC notes that, in some recent decisions, the MAIF Complaints Tribunal has found that some manufacturers had breached the MAIF Agreement by providing funding, wording and pictorial material for a retailer's promotion in a magazine. The Tribunal considered that manufacturers must bear some responsibility for retailer promotions in these circumstances. The ACCC considers that, to the extent manufacturers may indirectly engage in marketing of infant formula to the public through retailers or other products, it is possible for this to be captured within the scope of the current MAIF Agreement. For example, complaints have been considered by the Tribunal relating to manufacturers funding and providing content for retailer advertisements, which have been found to be in breach by the Tribunal.

Social media

50. The ACCC understands that there have been concerns raised for some years that marketing practices have changed with increased use of social media, and that these may not be adequately captured by the MAIF Agreement as it does not specifically refer to marketing via social and electronic media.

51. The Nous Report in 2012 recommended amending wording in the MAIF Agreement, including to specifically incorporate reference to electronic and social media 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.

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

53. 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.

54. At the pre-decision conference the Council confirmed that all forms of marketing (including those conducted via social media) are captured by the MAIF Agreement, and said the marketing of products within the scope of the MAIF Agreement does not occur via social media.

55. The ACCC understands that, while the social media guideline is not binding on 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.

Industry coverage

56. Many interested parties 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 solution was adopted.

57. 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 on sales volumes, but that signatories to the agreement accounted for the majority (perhaps up to 95 per cent[11]) of market sales, and that only two non-signatories appeared to have a presence in the Australian infant formula market (being Bellamy's Organic and Amcal).

Health claims

58. At the current time, the applicable standard for infant formula under the Food Standards Code is Standard 2.9.1. Health and nutrition claims relating to infant formula are prohibited under Standard 1.2.7, but FSANZ is currently engaged in a process to consider whether there is a need for greater clarity about what

[11] As estimated by some interviewed stakeholders. Nous Report, p34.

constitutes a health or nutrition content claim in this context and what is permitted.

59. 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.

60. 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. The ACCC notes that FSANZ is currently reviewing the Food Standards Code as it applies to infant formula (see paragraphs 14 - 15 above).

61. Regardless of the content of the MAIF Agreement, all manufacturers of infant formula will continue to be required to adhere to all mandatory requirements relating to infant formula set out in the Food Standards Code as these are amended from time to time.

62. Additionally, the marketing of infant formula remains subject to the Australian Consumer Law prohibitions of misleading and deceptive conduct and false representations.

ACCC view

63. The ACCC notes the above issues have been, or continue to be, under review both domestically and internationally, and a number of the concerns do not appear to fall directly within the scope of the ACCC's current consideration.

64. Specifically, 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 likely public benefits of the current MAIF Agreement for which the parties have sought authorisation will outweigh the likely public detriments.

65. The ACCC notes there is considerable uncertainty as to any alternative regulatory regime which might be imposed in the absence of the MAIF Agreement, including the extent or nature of any such regime. This means that, even if the changes to the MAIF Agreement (or contained in a possible 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. This issue is addressed in more detail in the *Future with and without the conduct* section below.

Assessment

66. The ACCC cannot revoke and substitute the existing authorisations of the MAIF Agreement unless the ACCC is satisfied that sections 90(5A), 90(5B), 90(6), 90(7) and 90(8) of the *Competition and Consumer Act* 2010 (the **CCA**) would not prevent it from granting a new authorisation.[12] Those sub-sections require the

[12] Section 91C(7) of the CCA.

ACCC, in assessing an application for authorisation, to apply what is generally referred to as a "net public benefits test": the ACCC weighs public benefits likely to arise from the MAIF Agreement against likely public detriment.[13]

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

    - the application and submissions received from the applicant and interested parties;[14] and
    - other relevant information available to the ACCC, including information from consideration of previous matters and the ACCC's previous consideration of the MAIF Agreement.

Relevant areas of competition

68. In its draft determination, the ACCC considered that competition at the level of manufacturers and importers of infant formula is particularly likely to be affected by the MAIF Agreement.

69. Following the pre-decision conference, Smith et al lodged a submission arguing that there is a market for infant and young child food, which includes breastfeeding and related goods and services, human breastmilk (such as milk banks), and commercial products such as infant formula.

70. The ACCC considers that it is not necessary to precisely define the relevant markets in this matter in order to examine the likely public benefits and detriments.

71. The ACCC considers that breastfeeding, human breast milk and commercial infant formula have some functional overlap (as foods suitable for meeting the nutritional needs of infants). However, for the purpose of assessing the conduct the ACCC considers it appropriate to:

    - assess the effect of the conduct on competition between manufacturers and importers of infant milk formula; and
    - assess any flow-on effects on breastfeeding rates in Australia that may result from the conduct.

Future with and without the conduct

72. 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 application. 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.

73. The Council submits that, if the MAIF Agreement is not authorised, it considers it unlikely the Federal government will introduce legislation in its place.

[13] Under sub-sections (5A), (5B), (6) and (7), the relevant detriment is that arising from any lessening of competition likely to arise from the agreement

[14] Please see the ACCC's Public Register for more details, including a list of parties consulted.

74. 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. Others submit that infant formula should be sold with plain packaging and risk messaging, or only under medical guidance.

75. The ACCC considers that, in the absence of the MAIF Agreement, 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 of food standards legislation and Australian Consumer Law), at least in the short to medium term. Due to the reputational risk of advertising infant formula, it is possible that Council members would voluntarily abide by much the same restrictions without an agreement. However, the ACCC considers there would be an increased incentive for members to actively and directly market infant formula.

76. Any alternative regulatory response by the Australian Government to give effect to Australia's obligations under the WHO Code would likely take a number of years to develop and implement. It is not possible to know what form any response by Government would take, and whether restrictions imposed under such a regulatory regime may be more or less restrictive than under the current MAIF Agreement. The ACCC notes there would be costs associated with developing, implementing and operating a regulatory regime.

77. 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,[15] and any other applicable legislation.

78. With or without the MAIF Agreement the marketing of infant formula remains subject to the Australian Consumer Law prohibitions of misleading and deceptive conduct and false representations.

Rationale for the conduct

79. Marketing is intended 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.

80. 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. This in turn undermines the health benefits associated with breastfeeding and the public policy aims of promoting breastfeeding.

81. 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 individually have an incentive to market their

[15] 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.

products unless they all agree not to do so, for fear of losing market share to competitors.

82. For this reason, restricting the marketing of infant formula may protect rates of breastfeeding and promote 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

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

84. 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 lower incidence of diseases including breast cancer, gastrointestinal infection, necrotising enterocolitis, lower respiratory tract infection and acute otitis media.[16] Therefore increased rates of breastfeeding in infants will lead to improved health outcomes and lower public health costs. Accepting that there is a likely public benefit in promoting breastfeeding, the MAIF Agreement is likely to result in a public benefit if it leads to increased breastfeeding rates or materially mitigates a decline in breastfeeding due to the use of breast milk substitutes.

85. In addition, the ACCC considers the MAIF Agreement may result in benefits if the costs of industry self-regulation are lower than government regulation and enforcement (for a similar outcome).

Impact on breastfeeding rates

86. Submissions from interested parties 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.

[16] 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).

87. The Department of Health told the pre-decision conference that it considers it is not possible to be definitive about whether breastfeeding rates are increasing, decreasing, or remaining static in Australia, due to a lack of appropriate data sources. It follows that it is not possible to determine the precise impact of the MAIF agreement on breastfeeding rates.

88. The Council submits that sales of infant formula in Australia are not representative of demand in Australia, because of an increase over recent years in the 'unofficial export' of infant formula purchased through Australian retailers and subsequently sent overseas.

89. The ACCC considers 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 (even if reliable data were available). The rates of breastfeeding will also be affected by a number of other factors such as lifestyle, cultural and institutional factors which are beyond the reach of the MAIF Agreement.

90. Nonetheless, the ACCC takes the view that marketing of infant formula can be assumed to increase consumption of infant formula which (as a breast milk substitute) is likely to have a corresponding effect of decreasing rates of breastfeeding.

91. Therefore, 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 any alternative regulatory regime took effect.

Reduced Regulatory costs

92. In the absence of the MAIF Agreement the ACCC considers it is likely that there would ultimately be some form of regulatory response by Government to give effect to the WHO Code. This would incur costs in terms of the time and resources of Parliament, regulatory agencies and industry to develop, implement and enforce a regulatory regime.

93. The New Zealand Commerce Commission, in considering the broadly-similar Infant Nutrition Council Code of Practice, quantified the avoided net regulatory costs, within the New Zealand context, at approximately $NZ3.2 million over two years.[17] 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."[18]

94. The ACCC accepts that the operating costs of a voluntary self-regulatory code are likely to be lower than the costs associated with regulatory alternatives. Consequently, the ACCC considers that the MAIF Agreement is likely to result in a public benefit by avoiding these regulatory costs, at least in the short to medium term.

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

Factors which may undermine the benefits

95. A number of issues have been raised by interested parties which they consider undermine the benefits potentially achieved by the MAIF Agreement.

Marketing of toddler milk

96. Many interested parties submit the marketing of toddler milks effectively cross-promotes infant formula because packaging and the marketing materials do not clearly distinguish between the two products.

97. Interested parties have submitted that:

- toddler milk is promoted by manufacturers as forming part of a "range" of products which include starter and follow on formula, and these are sequentially numbered and packaged very similarly (sharing logos, graphics, package type, colour, shape and product name)

- there is a strong emphasis on branding (which is shared with infant formula products) in the marketing of toddler milk. Branding and product-range elements are considerably more prominent in advertising and on packaging than the text clarifying the appropriate age at which the product should be offered.

- studies indicate that consumers do not distinguish between the marketing of toddler milk and the marketing of infant formula.[19] Researchers found:

    - the majority of parents viewing toddler milk advertisements understood they had seen advertisements for infant formula (or, for a range of products which included infant formula and toddler milk)

    - parents transfer what they learn about toddler milk through advertising to infant formula products. This includes health-related claims which echo the public health messaging used to support breastfeeding, such as improved immunity, improved brain development, etc.

    - the findings were consistent with those of British and Italian researchers in those jurisdictions.[20]

[19] Berry, Nina J, Sandra C Jones, Don Iverson, *Toddler milk advertising in Australia: infant formula advertising in disguise?*, Australasian Marketing Journal, 2012; Berry, Jones and Iverson, *It's all formula to me: women's understandings of toddler milk ads*, Breastfeeding Review, 2009.

[20] National Childbirth Trust/UNICEF UK, *Follow-on Milk Advertising Survey: Topline Results,* **www.unicef.org.uk/press/pdf/nct_unicef.pdf**, 2005; Adriano Cattaneo et al, *Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy*, Disease in Childhood, 2014.

- toddler milk advertisements appeared more frequently in Australia (where infant formula and follow on formula advertising is prohibited) than they did in countries where direct to consumer infant formula and/or follow on formula advertising is permitted.[21]

- in Australia in 1992 with the introduction of the MAIF Agreement, there was an immediate reduction in infant formula marketing in Australia but a corresponding increase in toddler milk marketing.[22] A similar effect can be seen in other jurisdictions in which restrictions have been placed on the marketing of infant formula.[23]

98. Interested parties argued that advertising of toddler milk was effectively advertising infant formula, and that manufacturers were undermining the intent and effectiveness of the MAIF Agreement in supporting breastfeeding by preventing direct to consumer advertising of infant formula products.

99. The issue of toddler milk marketing has previously been considered in the Australian context in the 2012 Nous Report which recommended considering options to limit the marketing of toddler milks to ensure labelling of products was sufficiently different to enable consumers to clearly and quickly distinguish between infant formula and toddler milk drinks. However, the Department of Health did not accept this recommendation.

100. As a result of concerns globally that complementary foods are being marketed inappropriately so as to undermine progress in achieving breastfeeding targets, the WHO recently welcomed (but did not formally endorse) guidance on this issue. These guidelines recommend member states act to end “inappropriate” promotion of foods for infants and young children (such as, for example, using brands, labels or logos that are the same as those used for infant formula, portraying products as being equivalent to or superior to breastmilk, or making health claims unless specifically approved by national authorities.

101. The Council has responded to the concerns of interested parties, submitting that:

- there is no evidence that sales of infant formula have increased as a result of the promotion of toddler milks

- the same informational pop-up (setting out the benefits and superiority of breastfeeding) appears when a person seeks to access information about infant formula on a manufacturer’s website, whether or not the viewer accesses the page from a toddler milk page or an advertisement on social media

[21] Berry, Nina, Sandra Jones & Don Iverson, *Circumventing the WHO Code? An observational study*, Disease in Childhood, 2011.

[22] Smith, Julie and Miranda Blake, *Infant food marketing strategies undermine effective regulation of breast milk substitutes: trends in print advertising in Australia, 1950 – 2010*, Australian and New Zealand Journal of Public Health, 2013.

[23] eg. Dickinson, Roger, Barrie Gunter, Julian Matthew and Jennifer Cole, *The impact of amended controls on the advertising of infant formula in the UK: findings from a before and after study*, International Journal of Health Promotion and Education, 2013.

- the inclusion of toddler milks would be a significant departure from the current agreement and may have an adverse impact on signatories' incentives to continue to be bound by the agreement

- imposing a condition regarding toddler milk would inappropriately pre-empt the WHO's decision

- toddler milk is not advertised in order to circumvent restrictions on marketing infant formula and there has been no evidence put forward that this is the case.

102. The Council has also said that it understands that MAIF Signatories do not promote toddler milk as "toddler formula" and that the term "formula" is not used in connection with toddler milk.[24]

103. The ACCC understands that the Tribunal has recently made a decision regarding toddler milk marketing which has not yet been publicized, including a finding that a toddler milk advertisement was in breach of the MAIF Agreement because it used an image of a young infant. In a different matter recently published in the Tribunal's 2014/2015 annual report, the Tribunal made a recommendation that the industry develop guidelines about the placement of infant formula adjacent to toddler milk and toddler milk advertising in retail outlets.

104. The ACCC considers it is likely that a significant proportion of consumers would recognise toddler milk as part of a staged range of products which include infant formula, as a result of:

- the use of similar (or near identical) packaging of infant formula and toddler milk products, which display a number for each "stage"

- the prominence of branding and branding elements (such as colour) on packaging and some marketing materials

- the positioning of toddler milk products and marketing adjacent to infant formula in retail outlets

- in at least one case, the use of the terms "toddler formula" and even "infant formula" on toddler milk packaging

- the use of images of infants who appear to be younger than 12 months in some advertisements.

105. As a result of this perception of a "range" of products, it is likely that marketing of toddler milk could in some circumstances effectively also act as marketing for infant formula. Toddler milk marketing could therefore increase brand and product awareness in relation to infant formula, and could be used to communicate with consumers indirectly about infant formula products (including to promote infant formula to the detriment of breastfeeding).

[24] See Record of Pre-Decision Conference, p8, available at **http://registers.accc.gov.au/content/index.phtml/itemId/1188093/fromItemId/278039/display/preDecisionConference.**

106. The ACCC considers there is potential for some current toddler milk marketing practices to undermine the benefits of the MAIF Agreement. There are no specific restrictions on the advertising of toddler milk, and manufacturers are entitled to market it to consumers. However, to the extent such advertising has the effect of promoting infant formula (in addition to toddler milk), it may be in breach of the MAIF Agreement.

107. The ACCC understands the Tribunal has the scope to consider complaints that marketing of toddler milk is having the effect of marketing infant formula, and to potentially find such conduct in breach of the MAIF Agreement. Indeed, there are recent decisions of the Tribunal which contain such findings, and which may result in the development of new guidelines and/or changed industry practices in this area.

108. The ACCC considers the issue of whether marketing restrictions should be extended to toddler milk is a policy decision for Government to make. The ACCC also notes that the Australian Government will need time to consider whether and how it wishes to respond to the WHO guidance. As discussed at paragraphs 144 to 147 below, a material change in the policy environment is likely to provide a basis for the ACCC to review the authorisation should it consider it appropriate to do so.

109. On this basis the ACCC does not consider it appropriate, as part of the re-authorisation process, to require changes to the MAIF Agreement in relation to toddler milk at this time, but notes this would be a relevant factor in its consideration of the likely benefits arising in relation to any future authorisation application by the Council, or any consideration by the ACCC if there has been a material change in circumstances.

Oversight and complaints

110. Interested parties raised concerns about the replacement of the Advisory Panel with the Tribunal in 2013, arguing it has weakened oversight of the MAIF Agreement and that the Tribunal's terms of reference, procedures and expertise have been questioned by the Public Health Association of Australia.

111. 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]."[25]

112. While the Council submits that low complaints are evidence of the success of the MAIF Agreement, some interested parties submit 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 (mostly on the basis that they related to activity by retailers), 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.[26]

[25] **www.infantnutritioncouncil.com/code-compliance/australia/**
[26] Nous Report, pp33-34.

113. Interested parties 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.[27]

114. The Department of Health supports reauthorisation of the MAIF Agreement and has not raised any concerns with the operation of the Tribunal.

115. 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.[28]

116. In the case of the MAIF Agreement and the operation of the Tribunal, there are no sanctions within the Agreement or Tribunal Terms of Reference in the case of a breach. The only available mechanism to ensure effective operation of the Agreement is the adverse publicity likely to result from the publication of findings of a breach by the Tribunal. The ACCC understands that the prospect of adverse publicity is a significant discipline on the conduct of signatories to the agreement. For this reason, the ACCC considers that the transparency of decisions by the MAIF Complaints Tribunal is important.

117. The Tribunal is relatively new in its operation and has only recently released its first annual report for the 2014-2015 financial year. The report indicates that the MAIF Tribunal has found some signatories in breach since it began operation, but that the publication of these decisions only occurred with the release of the annual report. The ACCC understands the Tribunal has discretion under its Terms of Reference to publish its decisions in whatever manner it sees fit, and considers it is appropriate to ensure public confidence in the MAIF Agreement that the Tribunal publish its decisions shortly after they are finalised as this will provide transparency and help ensure effective oversight of the MAIF Agreement.

118. Further, the ACCC notes that, although the Terms of Reference provide for the Tribunal to make recommendations, it does not contain any requirement that the parties comply with them. The ACCC considers that compliance with recommendations of the Tribunal is important to ensure the effective operation of the MAIF Agreement, and understands that, where appropriate, the Council will implement recommendations of the Tribunal by working with its members and the Tribunal to develop guidelines for MAIF Agreement signatories.

119. The ACCC understands that the Tribunal has made two recommendations since it commenced operation. One is a breach finding in which the Tribunal recommended that the Council consider an industry code under which manufacturers exercise approval of publications to which they contribute. In a separate matter (in which the Tribunal did not ultimately find a breach), the Tribunal noted it would assist it if industry developed guidelines about the placement of infant formula adjacent to toddler milk and advertising within retail premises. The ACCC is not aware of any steps taken to implement these recommendations as yet.

[27] Nous Report, p35.
[28] eg. See ACCC determination relating to A91436 – A91440, lodged by Medicines Australia Limited, at [294].

120. The ACCC expects MAIF Agreement signatories to adhere to any recommendations made by the Tribunal within the scope of the MAIF Agreement. The ACCC will take account of the extent that failure to do so reduces the effectiveness of the MAIF Agreement in any future application for reauthorisation.

121. The ACCC expects that failure to comply with recommendations made or guidelines developed by the Tribunal is likely to result in additional breach findings by the Tribunal, and the publicity associated with these is likely to encourage compliance. The ACCC encourages the Tribunal (with financial and potentially other forms of assistance from the INC) to develop guidelines to assist MAIF signatories to comply with the MAIF Agreement.

122. Authorisation to give effect to the MAIF Agreement includes MAIF signatories complying with associated guidelines, decisions and recommendations of the MAIF Complaints Tribunal provided they are within the scope of the MAIF Agreement, including – for example – toddler milk advertising which a reasonable person may believe to be advertising infant formula.

Conclusion on public benefits

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

- protecting and promoting breastfeeding leading to improved health outcomes
- avoided regulatory costs from alternative solutions.

124. While the ACCC is concerned that current practices around the marketing of toddler milk may be undermining these benefits to some extent (by effectively cross-promoting infant formula), it considers that the making and publication of Tribunal decisions in this regard are likely to result in changes to such industry practices in the future. Any material future change in the policy environment regarding marketing of toddler milk (including as a result of recent WHO deliberations) is likely to provide a basis for the ACCC to review the authorisation should it consider it appropriate to do so.

125. The ACCC notes that the benefits of the agreement will only be achieved to the extent it is effective in its operation, and considers that transparency of Tribunal decisions and the development of guidelines by the Tribunal are key elements of this which will help to ensure compliance with Tribunal decisions. The ACCC considers that it is important for the Tribunal to publish its decisions as soon as possible after they are made to maintain public confidence in the MAIF Agreement.

Public detriments

126. 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.

Health system

127. During and following the pre-decision conference, interested parties raised concerns that formula is provided to hospitals on a low-cost or free basis, which results in detriment by discouraging (presumably by reducing the incentive to invest in) the development by health systems of models which support breastfeeding and breast milk, such as milk pumps, lactation consultants, and human milk banks.

128. Further, interested parties expressed concern that samples given to the public by a health professional take on greater significance because of the trust placed in the advice of a health professional. Interested parties are concerned that manufacturers are therefore effectively marketing their product to the public through health professionals.

129. Senator Nick Xenophon requested the ACCC require infant formula to be provided to hospitals or health care professionals at retail price, as he is concerned the provision of free or low cost formula leads to fewer women breastfeeding exclusively.

130. The Council responded to the concerns raised, stating that:

- infant formula is supplied to hospitals predominantly through competitive tender processes and always at above-cost prices. Requiring signatories to provide formula at a higher price would disadvantage signatories, as not all manufacturers are signatories

- it is important that hospitals have access to infant formula at competitive prices, as it is the only suitable and safe alternative to breastmilk in circumstances when infants are not breastfed

- health care professionals exercise considerable care in providing infant formula to women in a hospital setting, as required by the Infant Feeding Guidelines (developed by the National Health and Medical Research Council to provide advice and recommendations for health workers)

- the 'harm' claimed by creating a disincentive for health systems to develop or focus on alternatives is overstated at best and largely speculative

- the circumstances under which signatories can distribute infant formula samples to health care professionals is very limited (i.e. for the purpose of professional evaluation or research, and where it was requested in writing by the professional). There is no evidence that the provision of samples in this way discourages breastfeeding.

131. The ACCC notes that interested parties appear to have two separate but related concerns with regard to infant formula and the health system. The first concern is that parents are being effectively exposed to marketing of infant formula through the recommendations of health professionals who receive free samples from manufacturers. The ACCC notes that the infant feeding advice

provided by health care professionals is ultimately subject to the professional care and judgement of the health professionals concerned, informed by the Infant Feeding Guidelines as developed by the National Health and Medical Research Council. This remains the case regardless of the basis on which infant formula is provided to hospitals and health professionals.

132. The second concern is that the provision of low cost formula to the health system is inhibiting the development of breastfeeding-friendly alternatives such as milk banks. That is, if hospitals have access to formula at low cost this may reduce their incentive to spend resources developing breastfeeding-friendly alternatives.

133. The ACCC notes that hospitals require infant formula as it is necessary for some infants. Formula supplied to the health system on a competitive basis provides a benefit in the form of cost savings. The ACCC recognises that it may also result in a detriment to the extent that it disincentivises the establishment of other, more efficient means of supporting breastfeeding. However, this seems unlikely. There is a very large difference in cost between hospitals seeking to address problems new mothers may be having establishing breastfeeding by spending resources to support breastfeeding (such as employing lactation consultants or establishing breastmilk banks) or alternatively just providing them with infant formula. To the extent hospitals make such decisions based on cost, it is hard to see those decisions being significantly influenced by a reduction in the cost of infant formula, when any saving is such a small proportion of the overall difference in cost.

134. The ACCC therefore considers that this aspect of the MAIF Agreement is unlikely to provide a significant disincentive to the establishment of non-formula alternatives to breastfeeding. To the extent such a disincentive occurs, the government remains free to support the development of alternatives through health policy and funding.

135. The ACCC also notes that it is unlikely that the above concerns of interested parties would be eliminated in the absence of the MAIF Agreement, that is, the future without the conduct for which authorisation is sought. The uncertainty surrounding any alternative regulatory response, in the absence of the MAIF Agreement, is discussed above at paragraphs 72 to 78.

ACCC assessment of detriments

136. Generally speaking, an agreement of this sort between manufacturers is likely to result in detriment in the form of reduced competition particularly in relation to product innovation, because manufacturers will have less incentive to invest to improve their products if they cannot capture the benefit of this by differentiating their product through advertising. However, 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

- without the MAIF Agreement, manufacturers would nonetheless have significant restrictions on product innovation and their ability to market these, under food standards legislation (see paragraphs 12 – 15 above)
- restrictions on the marketing of infant formula may be imposed via a regulatory regime after a period, in the absence of the MAIF Agreement.

Balance of public benefit and detriment

137. For the reasons outlined in this determination, on balance, the ACCC considers that the conduct is likely to result in significant 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

138. The CCA allows the ACCC to grant authorisation for a limited period of time.[29] 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.

139. In this instance, the Council sought 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.

140. In the draft determination the ACCC proposed granting re-authorisation for 10 years.

141. The ACCC notes the concerns raised by a large number of interested parties (including Members of Parliament and Senators) in submissions and at the pre decision conference, calling for re-authorisation to be granted for a period of only 1 – 2 years. They submit that this shorter time frame is appropriate to allow the Australian Government to consider its response to the WHO guidelines.

142. The ACCC is concerned that due to uncertainty around the timing and outcome of the Australian Government's response to the WHO's recommendations, granting re-authorisation for only two years may result in the Council unnecessarily having to apply for re-authorisation again in 18 months' time, at significant cost to all involved.

143. The Council advises it would be willing to accept a condition on authorisation that the ACCC can withdraw authorisation if the Department of Health determines during the period of authorisation that the MAIF Agreement no longer meets community expectations or is no longer the most appropriate application of the WHO Code for Australia.

144. Under the CCA the ACCC may review and potentially revoke an authorisation at any time if there has been a material change in circumstances such that the benefits of the conduct no longer outweigh the detriments.[30]

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[29] Subsection 91(1)
[30] Section 91B(3)

145. Any significant change in the policy environment during the period of authorisation – including as evidenced by a concern expressed to the ACCC by the Department of Health that the MAIF Agreement no longer reflects the Government's policy position or community views - is likely to provide a basis for the ACCC to review the authorisation should it consider it appropriate to do so.

146. The ACCC notes that authorisation does not prevent changes to the MAIF Agreement or associated arrangements during the period of authorisation. Neither does it lock in the current provisions. If these were to change, the parties may seek to vary the authorisation through a process of minor variation or revocation and substitution.

147. For the above reasons, the ACCC does not consider the imposition of a condition in this regard to be appropriate.

148. In seeking to balance the significant concerns raised by interested parties and the uncertainty of the policy environment with the cost of undertaking a reauthorisation process, the ACCC considers that granting authorisation for a further five year period is appropriate.

Determination

The application

149. 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 17 above).[31] 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.

150. The parties propose that the amended form of the MAIF Agreement set out in Annexure 1 will come into force on the date that authorisation is granted by the ACCC.

151. The Council 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

152. For the reasons outlined in this 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.

153. 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.

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

Conduct authorised by the ACCC

154. The ACCC revokes authorisations A90539 and A90540 and grants 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 17 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
    - prohibits the distribution of samples of infant formula to health care professionals except when necessary for the purpose of professional evaluation or research at the institutional level
    - prohibits the use of any facility of the health care system for the purpose of promoting infant formulas. However, the MAIF Agreement allows for the donation or low-priced sale of infant formula to institutions or organisations for the use of infants who have to be fed on breast milk substitutes
    - restricts the information provided to health care professionals by signatories regarding infant formulas to scientific and factual matters
    - prohibits health care professionals and persons employed by signatories from accepting or offering incentives to promote or sell infant formulas, and
    - requires internal monitoring and compliance practices by signatories to ensure conduct conforms to the principles and aims of the MAIF Agreement.

155. Authorisation to give effect to the MAIF Agreement includes MAIF Agreement signatories complying with associated guidelines, recommendations and decisions of the MAIF Complaints Tribunal provided they are within the scope of the MAIF Agreement.

156. To the extent any associated guidelines, recommendations or decisions of the MAIF Complaints Tribunal go beyond the scope of the MAIF Agreement, the applicants may seek a minor variation or a revocation and substitution as applicable.

157. The ACCC grants authorisation until 8 August 2021.

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

Interim authorisation

159. The ACCC granted interim authorisation under subsection 91(2) of the CCA on 31 December 2015, due to the expiration of A90539 and A90540, to allow the form of the MAIF Agreement authorised under A90539 and A91540 to continue to operate until the ACCC issued its final determination.

160. Interim authorisation will remain in place until the date the ACCC's final determination comes into effect or until the ACCC decides to revoke interim authorisation.

Date authorisation comes into effect

161. This determination is made on 15 July 2016. If no application for review of the determination is made to the Australian Competition Tribunal it will come into force on 6 August 2016.