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Submission in response to the ACCC's draft determination on

Infant Nutrition Council Limited application for authorisation A91506 and A91507, Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement (MAIF Agreement)

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Summary

Disruption to other relevant policy reviews in process

1. Effective implementation of the World Health Organization (WHO) International Code of Marketing of Breast-milk Substitutes (WHO Code) to protect breastfeeding is a crucial element of the implementation of Australian public health policy. The current ACCC process has a much narrower focus on competition policy. Relevant WHO and World Health Assembly (WHA) guidelines are being strengthened. The proposed industry Agreement reflects only the 1981 version of the WHO Code and does not include the subsequent WHA resolutions.[1]
2. Endorsement of the proposed agreement by the ACCC would pre-empt review of the Australian National Breastfeeding Strategy (ANBS) and response to WHO and WHA guidelines.

[1] See WHO document '*WHO Information concerning the use and marketing of follow-up formula 17 July 2013'*. http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf. Accessed 12 November 2015.

Balance of public benefit and public detriment

3. *The Net Public Benefit of protecting breastfeeding is underestimated by ACCC, and alternative feasible determinations yielding higher net public benefit have not been adequately considered.* The ACCC assessment of the net public benefit from protecting breastfeeding is biased downward as it fails to include: (i) the public financial benefit of lower Commonwealth and State government health costs from higher breastfeeding, and (ii) the reduced health and medical costs to households.
4. More effective regulation which better protects breastfeeding, even if more costly or if delayed for two years, would still yield higher public net benefit than the current proposal. The net public benefit of approving the current proposal for ten years may be less than the net public benefit of other available options.

Public benefit

5. *The proposed MAIF is materially different from that in place during 1992-2013, and cannot be assumed to be equally effective*. The ACCC wrongly assumes the proposed MAIF self-regulatory arrangements are the same as those in place since 1992, and therefore equally effective. The current proposal is materially different to the earlier arrangements, including important aspects of governance, transparency and public accountability.
6. *The proposed MAIF Agreement fails to reflect up to date international health guidance particularly recent WHA resolutions and WHO statements addressing the marketing of toddler formulas.* The proposed industry Agreement is outdated, as it does not includes subsequent WHA resolutions since 1981. *The proposed Agreement will be less effective than its predecessor* because there is less public oversight, less transparency and reduced accountability to the public.[2] The proposed Agreement does not clearly demonstrate it addresses changes in the marketing environment since MAIF was developed during the 1980s. The scope of the proposed Agreement does not adequately address the marketing of follow-up and toddler formulas which in effect promote infant formulas.

Length of authorisation

7. *Ten year authorisation by the ACCC legitimises the unsatisfactory status quo, and risks future public health detriment by inhibiting prospective legislative reform to introduce more effective regulatory approaches.* The ACCC determination fails to require regular review of MAIF or its effectiveness, and only the industry have

[2] See comment on the prior role of the Infant Nutrition Council in 2014 by Jan Carey CEO: "*…the council is a strong advocate for, and an active member on, independent government-monitored compliance panels that ensure the ethical marketing of baby formula in Australia and New Zealand is in accordance with World Health Organisation guidelines*" in: 'No denying what is best but formula provides back-up' Canberra Times, 18 February 2014. http://www.canberratimes.com.au/comment/no-denying-what-is-best-but-formula-provides-backup-20140217-32we6 html#ixzz3rLPzbO4n. Accessed 12 November 2015.

standing to initiate future strengthening. More effective regulation may become more vulnerable to future legal challenge under WTO or trade agreement rules.

Public detriment from the proposed Agreement

8. *ACCC fails to recognise the detrimental effect of endorsing the industry practice of providing formula supplies free or at low cost to health care professionals.* This predatory pricing practice reduces financial incentives for Australian health care services to develop or adopt innovations like human milk banking or sharing, which benefits maternal and child health compared to using infant formula.
9. *The proposed Agreement applies only to marketing in Australia by Infant Nutrition Council members.* It excludes marketing activities associated with exports, thereby permitting Infant Nutritional Council members to market overseas in ways which reduce breastfeeding and public health and Australia's reputation for public health leadership in the Asia Pacific region, where regulatory systems are often underdeveloped.[3]

Recommendations

10. *Amendments are required to avoid public detriment and increase net public benefit from endorsing the proposed Agreement.* The ACCC has failed to exercise its power to improve the net public benefit of the proposal or to reduce potential detriments, and should revise its draft determination to make it conditional on amendments which improve its effectiveness.
11. *The proposed Agreement should not be reauthorised for more than two years.*

[3] Marketing activities by companies that do not comply with the WHO Code are published by the International Baby Food Action Network (IBFAN) International Code Documentation Centre http://www.ibfan-icdc.org/index.php/focus/monitoring. Accessed 12 November 2015.

Submission

Disruption to other relevant policy reviews in process

12. The appropriate nutrition for infants and young children is breastfeeding, which also provides maternal and child health and wellbeing and development in all country settings not just in developing countries. In Australia like other developed countries we face an epidemic of obesity and chronic disease including childhood obesity and maternal breast cancer.
13. The harms of inadequate breastfeeding exclusivity and duration are now well understood. Since the ACCC's draft determination was issued, updated systematic reviews and meta-analyses of high quality studies confirm that breastfed children have fewer infections, higher intelligence, lower obesity, type 2 diabetes, asthma, malocclusions and otitis media. Mothers who breastfeed have lower rates of breast and ovarian cancers, type 2 diabetes mellitus and postpartum depression.[4] The strength of this evidence has accumulated over the decades since the MAIF Agreement was developed in 1992.[5] [6] [7]
14. Effective implementation of the WHO Code to protect breastfeeding is a crucial element of the implementation of Australian public health policy. The current ACCC process has a much narrower focus on competition policy. Relevant WHO and WHA guidelines are being strengthened. The proposed industry Agreement reflects only the 1981 WHO Code.
15. Endorsement of the proposed agreement by ACCC pre-empts public consultation on the Australian National Breastfeeding Strategy (ANBS). The ANBS was agreed by Council of Australian Governments (COAG) Health Ministers in 2010. As the ANBS includes review of regulatory arrangements for implementing the WHO Code, it is premature for the ACCC to endorse a 10 year arrangement on regulation of formula marketing until the ANBS review and associated public consultation is completed.
16. The ANBS also states that the ACCC reauthorization would "*allow scope for a review of the MAIF Agreement prior to any reauthorization*…"[8] Thus the ANBS anticipated that the ACCC's process of reauthorization would include a review of the MAIF Agreement.

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[4] Special Issue: Impact of Breastfeeding on Maternal and Child Health. *Acta Paediatrica*, 2015. 104, S467, http://onlinelibrary.wiley.com/doi/10.1111/apa.2015.104.issue-S467/issuetoc

[5] Grummer-Strawn, L.M. and N. Rollins, Summarising the health effects of breastfeeding. *Acta Paediatrica*, 2015. 104: p. 1-2.

[6] Horta, B. and C. Victora, Short-term effects of breastfeeding: a systematic review on the benefits of breastfeeding on diarrhoea and pneumonia mortality. 2013, Geneva: World Health Organization.

[7] Horta, B.L. and C.G. Victora, The long-term effects of breastfeeding: a systematic review. 2013, Geneva: World Health Organization.

[8] "*The Australian Competition and Consumer Commission's authorisation of the MAIF Agreement will expire on 31 December 2015 (ACCC 2007). This will allow scope for a review of the MAIF Agreement prior to any re-authorisation which may be sought at that time*." page 26, Australian National Breastfeeding Strategy 2010-2015, Commonwealth of Australia, 2010.

17. The onus is on the formula industry (manufacturers, importers and retailers, including pharmacists) to demonstrate how the harms of marketing formula products at a population level are to be prevented. The formula industry must provide evidence that their promotion of infant formula, toddler milk and commercial complementary foods under the MAIF 1992-2013 is appropriate and has no detrimental effect in diverting feeding decisions and practices away from breastfeeding. They have not done so. It is highly unlikely that they will do so given the conflicts of interest stemming from a baby food industry estimated to be worth US61 billion globally in 2015,[9] of which retail sales values for infant formulas in 2013 were US$39 billion globally, and US$0.5 billion in Australia.[10]

Balance of public benefit and public detriment

18. *The Net Public Benefit of protecting breastfeeding is underestimated by ACCC, and alternative feasible determinations yielding higher net public benefit have not been adequately considered.*
19. We appreciate that the public benefit of protecting breastfeeding rates from market failures associated with infant formula marketing is acknowledged in the ACCC draft determination. However the ACCC assessment of the net public benefit from protecting breastfeeding is biased downward because it fails to include: (i) the public financial benefit of lower Commonwealth and State government health costs from higher breastfeeding, and (ii) the reduced health and medical costs to households.
20. More effective regulation which better protects breastfeeding, even if more costly or if delayed for two years, would still yield higher public net benefit than the current proposal involving lower public benefits. This is despite the current proposal possibly having less regulatory cost. ACCC has not demonstrated that the smaller net public benefit of approving the current proposal for ten years exceeds the net public benefit of other available options. Such options include approval for two years followed by a more comprehensive, and more effective mandatory regulatory regime for the subsequent eight years.
21. ACCC authorisation of the proposed formula industry Agreement (91506 and 91507) at this time for a period of ten years is therefore not justified because the ACCC has failed to demonstrate that such authorisation has greater net public benefit and less public detriment than a future without the conduct, that is, than with a shorter authorisation period and/or an amended Agreement which strengthens its effectiveness. The ACCC has not refuted evidence that authorisation for ten years

[9] Euromonitor Passport Market Information Database 2015

[10] Retail sales value of standard milk formula (0-6 months), follow-on milk formula (6-12 months), toddler milk formula (12-36 months) and special baby milk. Source: Baby Food in Australia. Euromonitor Passport Market Information Database 2015.

without amendment could also potentially undermine or delay more effective regulatory arrangements.

Public benefit

22. *The proposed MAIF is materially different from that in place during 1992-2013, and cannot be assumed to be equally effective in the changed circumstances since the previous MAIF was developed and applied*.
23. The ACCC determination is proceeding on the mistaken basis that the proposed MAIF self-regulatory arrangements are 'more or less' the same as those in place since 1992, and therefore equally effective. We argue that to the contrary, the current proposal is materially different to the earlier arrangements in important aspects, including governance, transparency and public accountability.
24. An effective self-regulatory process consists of the formal agreement, its governance and the capacity to monitor its effectiveness by interested parties (those who are affected by it, especially the Australian government and consumers). These broader components of MAIF governance lack sufficient transparency and accountability and all have diminished substantially since 2013 when APMAIF was abolished. It is concerning that the ACCC perpetuates the misrepresentation that the proposed 'MAIF' being considered by the ACCC in 2015 is the same as that in force from 1992 to 2013, because it is not.

    The ACCC in its determination has failed to recognise that the Agreement in place until November 2013 was of the nature of a co-regulatory Agreement not a self-regulatory Agreement. An essential and important element in the previous arrangement was that the Australian Government supervised and appointed members to APMAIF, and provided the chair of the panel which made decisions on complaints by the public, thus providing appropriate assurance on the integrity of panel members such as their independence from industry. In addition, the panel's handling of such complaints was previously subject to transparency and public scrutiny through the requirement of annual reports to parliament on complaints received and how they were handled. This is a crucial difference, and it is a concern that the ACCC perpetuates the misleading impression that the integrity and transparency of the proposed self-regulatory arrangement remain unaffected by the change.
25. For example, the governance of the proposed Agreement is not transparent, does not include input from appropriately recruited experts, and lacks Australian government and public oversight and accountability. Under the proposed 'MAIF', the current MAIF Complaints Tribunal does not have comparable expertise or integrity of appointments and accountability to the public. The complaints mechanism for the proposed Agreement is unclear, and there remains no enforcement mechanism.

26. Since 1992, the complaints mechanism was the subject of criticisms that prompted reviews by Knowles in 2003,[11] the Best Start Parliamentary Inquiry in 2007,[12] and the Department of Health and Ageing in 2012 (the 'NOUS report').[13] These processes resulted in important recommendations for improvement. The complaints process after 2013 has been further weakened with less public oversight of its processes, and has no public or parliamentary accountability (Figure 1). The ACCC should require the complaints mechanism to be improved in any self-regulatory Agreement that it authorises.

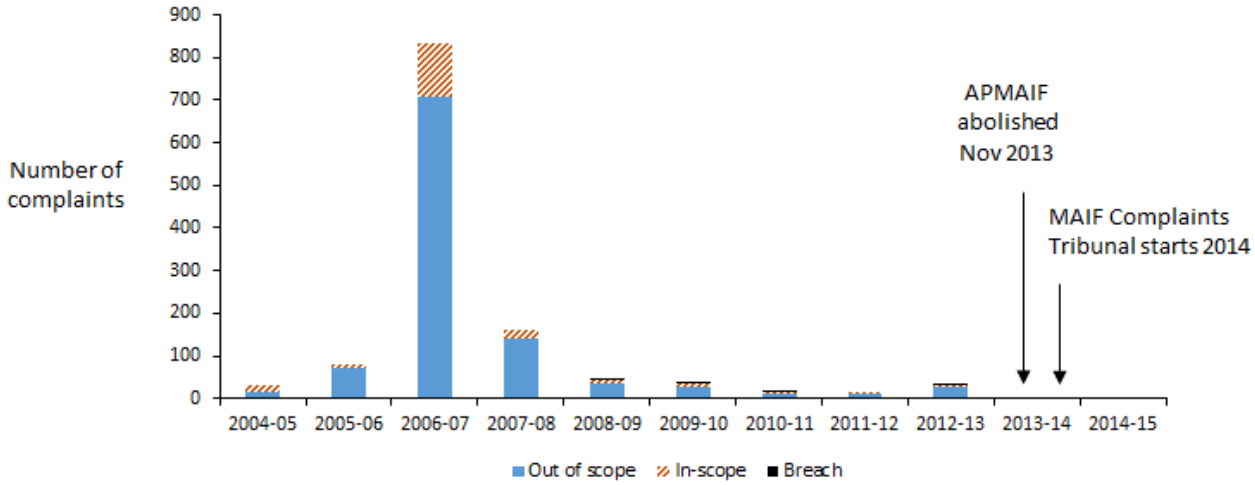

Figure 1. Number of complaints about MAIF Agreement compliance 2004-2015. Reports are not available after 2012-13, when the Advisory Panel on the MAIF Agreement (APMAIF) was abolished, and replaced by the MAIF Complaints Tribunal. Source: Department of Health http://www.health.gov.au/apmaif Accessed 5/11/2015.

27. Particularly in the light of the major change to the critical aspect of review, reporting and compliance enforcement, the ACCC draft determination at paragraph 14 is therefore incorrect to state that the Agreement has previously been approved 'more or less its current form' since 1992. Changes to the handling of complaints is not a minor matter as indicated in the ACCC draft determination (paragraph 5). We also note that in its draft determination the ACCC has not addressed whether the MAIF current complaints handling processes and reporting meet international standards[14],

[11] Knowles, R., Independent advice on the composition and modus operandi of APMAIF and the scope of the MAIF Agreement. 2003: Canberra.
[12] House of Representatives Standing Committee on Health and Ageing. The Best Start. Report on the inquiry into the health benefits of breastfeeding. 2007, Canberra: Commonwealth of Australia.
[13] Department of Health and Ageing, Review of the Effectiveness and Validity of Operations of the MAIF Agreement: Research Paper. Vol. 13 June. 2012, Canberra: Department of Health and Ageing.
[14] https://www.standards.org.au/InternationalEngagement/InternationalUpdates/Documents/International%20update%20October%202012.pdf

the current Australian standard AS3806-2006[15], or refer by analogy to the Professional Standards Council reporting requirements.[16]

28. In its draft determination, the ACCC recognizes deficiencies in the MAIF Agreement that could be addressed to better ensure net public benefit or avoid public detriment, but has not required these be addressed. For example:
    a. The operation of the Complaints Tribunal has not been evaluated. Has the ACCC received reports from the Department of Health and the Complaints Tribunal? If so, these should be made publically available, noting that no reports of complaints against the MAIF Agreement have been available since the report dated 2012-13 was published by the Department of Health. It is imperative that any complaints and review mechanism should operate with transparency to be effective.
    b. The legal status of the policies and guidelines appended to the MAIF Agreement are not clear. These guidelines refer to key elements of the MAIF Agreement, namely: interpretation, use of electronic media, interactions with health professionals, distribution of samples to health care professionals, and promotion through retailers. In reference to the 'Guideline on Marketing of Infant Formulas via Electronic Media' it is not clear what is meant in the following statement by the ACCC:

        '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.' (ACCC Draft Determination, Paragraph 35)

29. *The proposed MAIF Agreement fails to reflect up to date international health guidance particularly recent WHA resolutions and WHO statements addressing the marketing of toddler formulas.* The proposed industry Agreement reflects only the 1981 WHO Code and does not include any of the many subsequent WHA resolutions since 1981.
30. *The proposed Agreement also does not address changes in the marketing environment* and likely increased market concentration since 1992; nor has it kept up with changing technology including online and electronic marketing. Marketing through electronic and social media also form a large, pervasive, intrusive and covert part of the environment in which parents and care-givers make infant and young child feeding decisions. It is a concern that the ACCC does not insist that the MAIF Agreement is amended to include relevant appended guidelines and policies, (as recommended in the 2012 NOUS report), if they are considered to improve the

[15] AS3806-2006 https://www.saiglobal.com/PDFTemp/Previews/OSH/as/as3000/3800/3806-2006.pdf
[16] http://www.psc.gov.au/sites/default/files/A%20framework%20for%20compliance.pdf

effectiveness and operation of the MAIF Agreement. Would infant formula manufacturers and importers provide direct-to-consumer electronic access, advice and information and 'help lines' (which are directly contrary to the WHO International Code) if these did not increase promotion of and loyalty to their brands and product sales?

31. The scope of the proposed Agreement does not adequately address the marketing of follow-up and toddler formulas which are often mistaken for infant formulas because of the way they are marketed. The share of toddler formulas in the market has increased dramatically since 1992, when the Agreement was introduced, especially in the last 5 years (Figure 2).

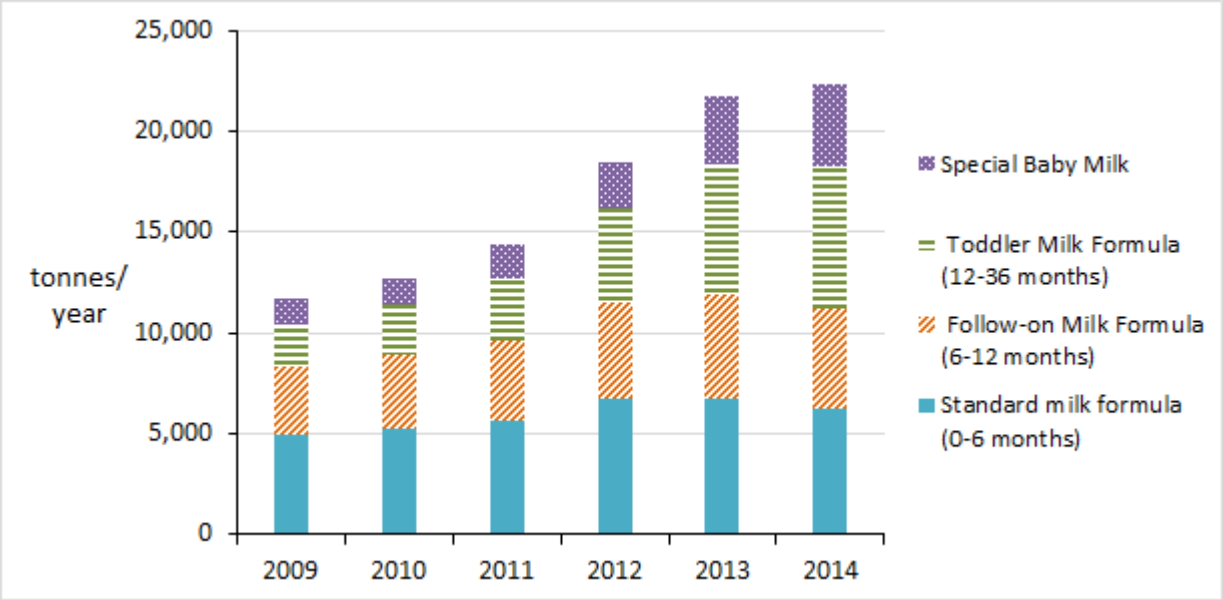

Figure 2. Annual volume of milk formula for children aged 0-36 months sold in Australia 2009-2014. Source: Baby Food in Australia. Euromonitor International 2014

In Australia in 2014, toddler milks were worth AUD$150 million which was approximately one third of the total milk formula market of AUD$546 million in that year.[17] However, under the proposal no data is provided on the changing composition of products covered by the WHO Code. This is of considerable importance to whether the proposed Agreement has adequate coverage of food products marketed for infants and young children, to be effective. In the interests of administrative fairness, those affected by the MAIF Agreement (public health authorities, consumers and non-government organizations) need access to information about market share of infant

[17] Euromonitor International. Baby Food in Australia. Euromonitor Passport Market Information Database. London 2014

formulas and toddler milks. It is also unclear how the ACCC can make its determination without such information, and rely only on the assurances of the Infant Nutrition Council, in whose interest it is to withhold such information.

32. There have also been changes in the concentration of the market with mergers in recent years. No information is provided by industry to the ACCC or the public market on share in sales volume and value for all categories of baby foods relevant to the WHO Code to verify the industry coverage claimed by the Infant Nutrition Council. Infant Nutrition Council membership has changed through mergers of dairy companies and new entrants in recent years, with some involved only in formula packaging and labelling or manufacturing private brands for pharmacies or supermarkets. Some of these large and expanding players are not Infant Nutrition Council members: Bellamy's Organic increased market share of baby food from 4.6% in 2013 to 6.9% in 2014[18]; Aldi stores which sell their private label formula *Mamia*[19] and other baby foods increased from 1.4% in 2013 to 2.2% in 2014, and Coles supermarkets which sell their private label infant formula *Nutriforme.*[20] [21]
33. Requiring the setting up of procedures for the supply of relevant information to stakeholders including consumers, competitors and the ACCC has considerable precedent[22], and should be required as a condition of the proposed authorisation.
34. *The ACCC determination did not fully assess the public benefits of restraining marketing.* The public benefit of protection of breastfeeding rates from infant formula marketing is acknowledged in the ACCC draft determination. We are concerned however, that the ACCC's evaluation of achieving higher breastfeeding rates through effective regulation, did not incorporate a full consideration of:
    a. the economic resource savings of higher breastfeeding and breastmilk production, or
    b. the reduced health costs to the public sector, and
    c. reduced households' out of pocket costs.

    We note on the other hand, that avoided regulatory financial costs are counted towards the net public benefit of the MAIF. As a result, the exclusion of these other economic benefits biases downward the ACCC assessment of the magnitude of

[18] Euromonitor International. Baby Food in Australia. Euromonitor Passport Market Information Database. London 2014. www.who.int/nutrition/publications/code_english.pdf.
[19] Aldi Stores. Baby Care https://www.aldi.com.au/en/groceries/baby-care/
[20] Coles shop online: Baby Formula http://shop.coles.com.au/online/SearchDisplay?storeId=10601&catalogId=10576&langId=-1&beginIndex=0&browseView=false&searchSource=Q&sType=SimpleSearch&resultCatEntryType=2&showResultsPage=true&pageView=image&searchTerm=baby+formula&gclid=Cj0KEQiAyIayBRDo4vjdqJrgxZ0BEiQAhOYCYCcfEfepfDLmXWyO56gLwSELOVnZSZucgXVk3vfXGacaArL28P8HAQ&KEYWORD=+coles%20+infant%20+formula&MATCHTYPE=Search&AD_ID=96373183447&REFFER=#pageNumber=2&currentPageSize=20 Accessed 11 November 2015
[21] Euromonitor International. Baby Food in Australia. Euromonitor Passport Market Information Database. London 2014. www.who.int/nutrition/publications/code_english.pdf. Euromonitor International 2014
[22] Nagarajan, V., Co-opting for governance: the use of the conditions power by the ACCC in authorisations. *UNSW Law Journal*, 2011. 34(3): p. 785-810.

public benefit from protecting breastfeeding rates with regard to any offsetting regulatory financial costs.

35. Health costs from inadequate breastfeeding duration which are wrongly excluded from the ACCC assessment of public benefit from regulating marketing of breastmilk substitutes include the costs of 250 avoidable maternal breast cancer cases in Australia in 2010.[23] A study in the Australian Capital Territory in 2002 found the Australia-wide costs of infectious illnesses among young children which were attributable to premature weaning from exclusive breastfeeding was over $100 million a year.[24] In the United States, inadequate breastfeeding is estimated to have cost US$17.4 billion a year from premature deaths and treatment of maternal breast cancer.[25] [26] In 2014 a study in the United Kingdom reported that increased breastfeeding rates would save £17-38 million in health costs, including from lower rates of infectious illness, and maternal breast cancer.[27] Restraint of marketing which reduces these public costs has a public benefit which act to more than offset any regulatory costs.
36. The ACCC agrees that it is likely that in the absence of the proposed Agreement there would be a regulatory response by Government to give effect to the WHO Code (paragraph 68). It also states that '*in the absence of the authorisation, it is possible that Council members would voluntarily abide by the same restrictions without an agreement*', however, '*there would be some incentive for members to actively and directly market infant formula*' (paragraph 57).[28]
37. We also submit that the Council members are not currently voluntarily abiding by restrictions on marketing infant formula, as there is good quality evidence that they are actively promoting infant formula products through their promotion of toddler

[23] Jordan, SJ, LF Wilson, CM Nagle, AC Green, CM Olsen, CJ Bain, N Pandeya, DC Whiteman, and PM Webb. "Cancers in Australia in 2010 attributable to total breastfeeding durations of 12 months or less by parous women." *Australian and New Zealand Journal of Public Health* 39, no. 5 (2015): 418-21.
[24] Smith, JP, JF Thompson, and DA Ellwood. "Hospital system costs of artificial infant feeding: estimates for the Australian Capital Territory." *Australian and New Zealand Journal of Public Health* 26, no. 6 (2002): 543-51.
[25] Pokhrel, S, MA Quigley, J Fox-Rushby, F McCormick, A Williams, P Trueman, R Dodds, and MJ Renfrew. "Potential economic impacts from improving breastfeeding rates in the UK." *Archives of Disease in Childhood* (December 4, 2014).
[26] Bartick, M, AM Stuebe, EB Schwarz, C Luongo, AG Reinhold, and EM Foster. "Cost analysis of maternal disease associated with suboptimal breastfeeding." *Obstetrics & Gynecology* 122, no. 1 (Jul 2013): 111-9.
[27] Renfrew, M.J., et al., Preventing Disease and Saving Resources: the Potential Contribution of Increasing Breastfeeding Rates in the UK. 2012: UNICEF UK.
[28] These two possibilities were raised by the Infant Nutrition Council in its Application dated 25 November 2015 to the New Zealand Commerce Commission in its notice seeking authorisation under Section 58 of the New Zealand *Commerce Act* 1986: Restrictive Trade Practices. Paragraph 12: "However, for a period of time before the Ministry of Health is able to impose the restrictions, it would be clear to all members of the Infant Nutrition Council that they would not, and could not, be bound by relevant restrictions in the INC Code of Practice. Non-members, perceiving the potential for more active marketing, may be incentivised to increase their own marketing with the overall effect of a reduction in the rate of breastfeeding of infants." Paragraph 13. "While INC members have been committed to restrictions of the type embodied in the INC Code of Practice and its predecessor (the NZIFMA Code of Practice) for some time, in the event that there was any increase, however small, in marketing by an industry participant, each INC member would have to reassess its position. For example, while members would not expect there to be a massive increase in advertising to the general public, a number of the other restrictions present less of a clear distinction between actions that would be consistent or inconsistent with the INC Code of Practice or WHO Code."

formulas. It has been shown that promotion of infant formula is occurring via cross branding and cross marketing of toddler formulas.[29] [30] [31] Therefore Infant Nutrition Council members are not complying with the Agreement to restrict their marketing of infant formula and the current Agreement does not have the public benefit claimed. As a result, the proposed Agreement does not address market failure by restricting marketing of infant formula alone and needs to also restrict toddler milk marketing to achieve public benefit.

38. In consideration of the points above, the superior effectiveness of the proposed Agreement in generating public benefit has not been demonstrated. In addition, it can be predicted that it will be even less effective in protecting breastfeeding than the Agreement in place since 1992. This is because it is not the 'more or less the same', 'longstanding' Agreement that was in place 1992 to 2013. The ACCC assessment has mistakenly accepted Infant Nutritional Council assertions that the proposal is materially the same as the previous MAIF Agreement, when the abolition of the APMAIF panel and related changes means that it is not in substance the same as the previous MAIF Agreement, so its effectiveness is unknown. As stated earlier, the Commonwealth Health Minister no longer appoints most members of the MAIF Panel or its chair, does not oversight its processes for handling complaints, and does not require accountability to Parliament for the handling of complaints in the form of an annual report. In contrast, the proposed Agreement is also likely to be substantially less effective than that relatively more effective earlier Agreement, because marketing has changed to focus heavily on electronic means which has not been regulated effectively under the previous Agreement, and because the market for infant and young child food products including milk formula has changed. Major players in the infant formula market such as Bellamy's and AMCAL remain outside the Agreement, and other IYC food products including toddler formulas are now a much higher proportion of the IYC food product market. As noted above, these are used to market infant formula by Infant Nutritional Council members.
39. The costs and therefore cost-effectiveness of the MAIF Agreement in the current Australian context have not been adequately substantiated. The ACCC assessment that the proposed Agreement is more cost effective than alternatives is therefore speculative. In New Zealand the regulatory costs of its comparable arrangement, the *Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand*[32]*,* may be lower. The ACCC has not estimated the cost effectiveness of

[29] Department of Health and Ageing, Review of the Effectiveness and Validity of Operations of the MAIF Agreement: Research Paper. Vol. 13 June. 2012, Canberra: Department of Health and Ageing.
[30] Berry, N.J., S.C. Jones, and D. Iverson, Toddler milk advertising in Australia: infant formula advertising in disguise? *Australasian Marketing Journal* (AMJ), 2012. 20(1): p. 24-27.
[31] See paragraph 8.54 in House of Representatives Standing Committee on Health and Ageing. The Best Start. Report on the inquiry into the health benefits of breastfeeding. 2007, Canberra: Commonwealth of Australia.
[32] Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand. Infant Nutrition Council. http://www.infantnutritioncouncil.com/marketing-codes/code-in-new-zealand/. Accessed 12 November 2015.

regulatory options in the Australian context. The ACCC relies solely on the unsubstantiated assertions in the NOUS report[33] or the NZ Commerce Commission;[34] these do not report studies which would meet current WHO or National Health and Medical Research Council standards for good quality evidence.

40. It is a concern that there is no industry data submitted to substantiate Infant Nutritional Council's claim that the MAIF Agreement is a 'high level document'. This creates legal uncertainty about the detail contained in associated attachments, policies and guidelines. A very substantial share of milk formula sales is not covered by the proposed MAIF Agreement, and the legal status and content of the Agreement could be contested at law.
41. In the interests of transparency in decision making regarding review of the implementation of the ANBS, it is also disappointing that Commonwealth and State Departments of Health did not make public submissions. It would be useful for the public to know of any inter-agency consultation on MAIF reauthorisation between the ACCC and the Commonwealth Department of Health. Despite the evidence-based recommendations of inquiries into breastfeeding and formula marketing in Australia over the past few decades, in the past the Commonwealth Department of Health has failed to implement recommended changes to strengthen regulation such as the MAIF Agreement. The Health Department's rejection of NOUS consultant recommendations to restrict marketing of toddler milks in 2012[35] misrepresented the WHO position by stating it did not include toddler milks in the WHO Code;[36] this is incorrect, confirmed most recently by WHO in July 2013.[37] It is also disappointing that the ACCC's determination on public benefit does not include input from the authorities responsible for public health, the Commonwealth and State Departments of Health, accompanied by a full economic analysis in the Australian context, as indicated in this submission.
42. *In the light of the above, the proposed Agreement will be less effective than its predecessor*:[38] No assumption can be made that the proposal will be comparably

[33] Department of Health and Ageing, Review of the Effectiveness and Validity of Operations of the MAIF Agreement: Research Paper. Vol. 13 June. 2012, Canberra: Department of Health and Ageing.

[34] New Zealand Commerce Commission. Determination- Infant Nutrition Council Limited [2015] NZCC 11. 2 April 2015. .Paragraph 60: http://www.comcom.govt.nz/business-competition/anti-competitive-practices/anti-competitive-practices-authorisations-register/infant-nutrition-council-restrictive-trade-practice-application/

[35] Department of Health and Ageing, Review of the Effectiveness and Validity of Operations of the MAIF Agreement: Research Paper. Vol. 13 June. 2012, Canberra: Department of Health and Ageing.

[36] Ibid. The 2012 NOUS consultants recommended that the MAIF Agreement include constraints on the marketing of toddler milks, which were also called for by four of the six submissions to the ACCC.

[37] World Health Organization 2013. Information concerning the use and marketing of follow-up formula www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf

[38] See comment on the prior role of the Infant Nutrition Council in 2014 by CEO Jan Carey:
"…*the council is a strong advocate for, and an active member on, independent government-monitored compliance panels that ensure the ethical marketing of baby formula in Australia and New Zealand is in accordance with World Health Organisation guidelines*" in: 'No denying what is best but formula provides back-up' Canberra Times, 18 February 2014. http://www.canberratimes.com.au/comment/no-denying-what-is-best-but-formula-provides-backup-20140217-32we6 html#ixzz3rLPzbO4n. Accessed 12 November 2015.

effective to the Agreement in place since 1992. It is likely to be less effective than previous arrangements due to lack of public oversight, less transparency and reduced accountability to the public.

Length of authorisation

43. *Ten year authorisation by the ACCC legitimises the unsatisfactory status quo, and risks future public health detriment by inhibiting prospective legislative reform to introduce more effective regulatory approaches.* There are legitimate reasons for concern that ACCC or other regulatory endorsement of the proposed Agreement could limit Australia's capacity to introduce more effective public legislation on marketing of infant and young child food products in the future.
44. Full implementation of the WHO Code was recommended by the Best Start Parliamentary Inquiry in 2007. Regular review of MAIF and its effectiveness was recommended by the NOUS report.[39] The ACCC determination fails to require regular review of MAIF or its effectiveness, and under current arrangements only the industry have standing to initiate future strengthening. It is irrelevant to defend the ten year authorisation by stating that parties to the proposed Agreement have standing to vary the authorisation, as there is close to zero probability the Infant Nutritional Council would initiate this in order to allow regulation to be strengthened, yet non-parties including the public would NOT have standing to initiate this. In addition, parties to the Agreement could challenge ACCC processes to revoke the Agreement, and delay more effective regulatory policy for many years.
45. There are valid concerns that authorising the proposed industry self-regulatory Agreement for ten years rather than for a shorter period of less than two years may be used to undermine Australian governments putting in place more effective regulatory arrangements consequent to the WHO/WHA process in 2016. If the ACCC approves the proposed Agreement this may prejudice the likelihood of implementing more effective regulation as this may become more vulnerable to future legal challenge under WTO or trade agreement rules.[40] [41] If the proposed industry Agreement is endorsed by ACCC for ten years, industry could be given greater recourse to World Trade Organisation processes to challenge new, broader and more effective regulatory arrangements. Thus it is important to establish the precedent of regular review, and any necessary amendment (as outlined in this submission), as part of Australia's commercial environment. Experience implementing WHO Code legislation in Hong Kong provides a reasonable basis for concerns that ACCC authorisation would assist companies to make legal challenge against stronger future

[39] Department of Health and Ageing, Review of the Effectiveness and Validity of Operations of the MAIF Agreement: Research Paper. Vol. 13 June. 2012, Canberra: Department of Health and Ageing.
[40] Kogan, L., Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 2 of 3). LexisNexis *Emerging Issues Analysis* 7048, 2013. August.
[41] Friel, S., et al., A new generation of trade policy: potential risks to diet-related health from the Trans Pacific Partnership agreement. *Globalization and Health*, 2013. 9: p. 46.

regulation, such as legislation of the WHO Code or mandatory industry participation. This might go forward, for example, with argument that regulatory restrictions on marketing which affect the use of logos and trademarks contravene international trade agreements regarding protection of intellectual property and trade restrictions.[42]

46. On the other hand, the ACCC asserts that authorisation of the proposed Agreement for ten years does not preclude more effective regulatory responses in the future. ACCC has provided no evidence or argument to substantiate this or to refute concerns raised. Hence the ACCC is unable to provide the public with assurance that re-endorsement of the Agreement will not undermine Australia's ability to defend more effective regulatory arrangements from challenge under international trade agreements, including in WTO processes.
47. We submit that the draft determination has a reasonable likelihood of pre-empting or inhibiting alternative more effective regulation with higher public net benefit, and is therefore of uncertain public benefit at this time.

Public detriment from the proposed Agreement

48. *ACCC fails to recognise the detriment from authorising the industry practice of providing formula supplies free or at low cost for use by health care professionals.* The proposed Agreement permits free or discounted formula supplies to health care professionals. These practices contravene WHO-UNICEF guidelines[43] and may be considered in some circumstances to be akin to monopolistic pricing such as price discrimination or predatory pricing. Such pricing practices reduce financial incentives for Australian health care services to develop or adopt innovations like human milk banking or sharing using improved technologies and business models which have emerged in Australia in the past five years.[44] [45] [46] [47] Human milk banking and sharing can provide substantial additional benefits for maternal and child health and save

[42] Hong Kong Legislative Council Panel on Health Services, The Draft Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children: Results of Public Consultation and Way Forward. LC Paper No. CB(2)2048/13-14(05). 21 July 2014. 2014. http://www.gov hk/en/theme/bf/consultation/pdf/Archive2013_10067A_hs0721cb2-2048-5-e.pdf. Accessed 11 November 2015.

[43] See section 1.2 in WHO/UNICEF, Baby-friendly Hospital Initiative: revised, updated and expanded for integrated care. Section 1, Background and implementation. 2009, World Health Organization, UNICEF and Wellstart International: Geneva

[44] In 2015 Australia has five milk banks. Four hospital-associated and one community milk bank provide pasteurized donor milk to babies who sick, premature or multiple births (PREM Bank at the King Edward Memorial Hospital in Perth; Mercy Health Breastmilk Bank in Melbourne; Royal Brisbane Hospital for Women in Brisbane; Mothers' Milk Bank in South East Queensland; King George V in Sydney). Commonwealth of Australia, Donor Human Milk Banking in Australia- Issues and Background Paper. 2014, Canberra: Department of Health.

[45] Mackenzie, C., S. Javanparast, and L. Newman, Mothers' knowledge of and attitudes toward human milk banking in South Australia: a qualitative study. *Journal of Human Lactation*, 2013. 29(2): p. 222-229.

[46] Mumme, R., J. Miller , and K. Mehta, Attitudes and perceptions of women using an informal human milk sharing website, in Dietitians Association of Australia 32nd National Conference. May 2015. 2015: Perth, Australia.

[47] Palit, V. and G.F. Opie, Breastmilk banking and the Mercy Health experience. *Medical Journal of Australia*, 2015. 203(9): p. e357-258.

health costs compared to using infant formula, particularly for hospitalised or sick babies or babies who cannot be breastfed by their mothers.[48] [49] [50]

49. Undocumented and non-transparent arrangements for free or low cost supplies and incentives to be provided to health care professionals or health services allowed by are a public detriment arising from the proposal, unnecessary to its effectiveness, and likely to undermine the cost effectiveness of innovative human milk banking or milk sharing arrangements.[51] Such predatory pricing of commercial infant formula products is a substantial detriment to beneficial new entry into the infant feeding industry and to the significant detriment of the health of women and especially vulnerable babies
50. ACCC should amend the MAIF Agreement to prohibit free or low cost supplies to health care professionals for research or evaluation unless this is essential to research conducted under a protocol approved by a registered Human Research Ethics Committee (HREC) at a Certified Institution applying the relevant NHMRC ethical guidelines.
51. *The proposed Agreement applies only to marketing in Australia by Infant Nutritional Council members.* The Agreement also should be amended to explicitly apply to the export marketing activities of Australian formula manufacturers. The proposed Agreement excludes marketing activities associated with exports, thereby permitting Infant Nutritional Council members to market in ways which reduce breastfeeding and public health in the Asia Pacific region, [52] [53] despite assurances that Infant Nutritional Council members comply with the WHO Code.[54] WHO Code

[48] Gribble, K.D., "I'm happy to be able to help:" why women donate milk to a peer via internet-based milk sharing networks. *Breastfeeding Medicine*, 2014. 9(5): p. 251-256.
[49] WHO/UNICEF, Baby-friendly Hospital Initiative: revised, updated and expanded for integrated care. Section 1, Background and implementation. 2009, World Health Organization, UNICEF and Wellstart International: Geneva.
[50] Simmer, K. and B. Hartmann, The knowns and unknowns of human milk banking. *Early Human Development*, 2009. 85(11): p. 701-704.
[51] In Australia in 2012 a hospital-associated milk bank cost up to AUD$250,000 to establish and $150,000 - $250,000 annually to run. Cashin-Garbutt, A., Breast milk banks: an interview with Dr. Pieter Koorts, in News-Medical.net. 2012, ZoM.com Limited. http://www.news-medical net/news/20121205/Breast-milk-banks-an-interview-with-Dr-Pieter-Koorts.aspx
[52] For example, the 2012 report '*Nestle Creating Shared Value (CSV) and Meeting our Commitment*s' on page 3, records 22 breaches of WHO Code in 'high-risk' countries (based on infant mortality rates). No breaches were recorded in the 2014 report '*Nestle in Oceania Creating Shared Value (CSV)*'. http://www nestle.com.au/creating-shared-value Accessed 12 November 2015.
[53] As in Australia, the transparency, governance and accountability of corporate marketing activities in other countries also relies on evidence from the public and non-government organizations (NGOs). Marketing activities by companies that do not comply with the WHO Code are documented by the non-government organization the International Baby Food Action Network (IBFAN) International Code Documentation Centre '*Breaking the Rules, Stretching the Rules 2014*' http://www.ibfan-icdc.org/index.php/focus/monitoring. Accessed 12 November 2015
[54] See comments by Infant Nutrition Council CEO Jan Carey*: "…the council is a strong advocate for, and an active member on, independent government-monitored compliance panels that ensure the ethical marketing of baby formula in Australia and New Zealand is in accordance with World Health Organisation guidelines"* and *"…council members have not only made a commitment to this ethical behaviour in Australia and New Zealand but in all the countries we export to and market in. We agree the industry in Australia should be taking the lead and that is what we are doing."* in 'No denying what is best but formula provides back-up' Canberra Times, 18 February 2014. http://www.canberratimes.com.au/comment/no-denying-what-is-best-but-formula-provides-backup-20140217-32we6.html#ixzz3rLPzbO4n. Accessed 12 November 2015.

implementation in Australia should provide leadership[55] [56] and assurance for exported infant formula, toddler milks and complementary foods into other countries in the Asia Pacific region where regulatory systems are often underdeveloped. Thus the form and effectiveness of WHO Code implementation in Australia is part of and, in turn, influences the infant feeding environment globally. As stated by the Infant Nutrition Council in its submission to the New Zealand Competition Commission in 2015, export markets affect the profitability of domestic formula manufacturers (whether they are local or transnational corporations), as highlighted by media coverage of the shortage of infant formula on Australian supermarket shelves in November 2015.[57] The consequences for the Australian public of marketing for export markets is increased investment in and exposure to advertising in Australia, especially via the internet and internet sales webpages of manufacturers and importers, supermarkets, chemists, as noted in our previous submission to the ACCC.

Way forward

52. The regulation of marketing of foods including formula for infants and young children is in urgent need of improvement in Australia and worldwide, and the role of the ACCC should be to improve, not weaken it. The ACCC has failed to exercise its power to improve the net public benefit of the proposal or to reduce potential detriments. By the ACCC requiring amendments it could ensure the proposed Agreement delivers much larger public benefit at little additional regulatory cost (see below), and with no significant additional detriment.
53. Therefore ACCC should require *amendments to avoid public detriment and increase net public benefit from endorsing the proposed Agreement*. ACCC should not authorise provisions for free or low cost supplies to health care professionals for research or evaluation which are to the public detriment. Public benefit should be increased by requiring the MAIF to include all formulas for infants and young children, including toddler formulas in its scope. The ACCC should require amendments which improve provision of information such as information on MAIF decision-making processes and company price-marketing practices, for example incentives to retailers and health professionals. It should also introduce more transparent and accountable processes for complaints and disputes, and provide for greater independent external oversight and monitoring of MAIF effectiveness and public health benefit for the duration of any Agreement. It should also require amendments in accordance with (i)

[55] ibid
[56] Galtry, J.A., Improving the New Zealand dairy industry's contribution to local and global wellbeing: the case of infant formula exports. *New Zealand Medical Journal*, 2013. 126(1386): p. 82-89.
[57] Han E. 2015 'Child genius claims in China driving baby formula demand and hurting Australia's supply' Sydney Morning Herald. 12 November 2015 http://www.smh.com.au/business/china/child-genius-claims-in-china-driving-baby-formula-demand-and-hurting-australias-supply-20151111-gkwvh1.html

recommendations of the NOUS report[58] that were accepted by the Department of Health and (ii) evidence that WHO Code implementation should include toddler formulas and complementary foods.[59]

Conclusions

54. Effective implementation of the WHO Code to protect breastfeeding is a crucial element of the implementation of Australian public health policy including the Australian National Breastfeeding Strategy. The current ACCC process must not compromise future regulatory options to strengthening WHO Code implementation in line with WHA resolutions since 1981 and updated evidence based guidelines for regulation of marketing of food products for infants and young children.

Balance of public benefit and public detriment

55. ACCC authorisation of the proposed Agreement at this time for a period of ten years is not justified because the ACCC has failed to demonstrate that such authorisation has greater net public benefit and less public detriment than a future without the conduct, than a shorter authorisation period and/or an amended Agreement which strengthens its effectiveness. The ACCC is unable to refute evidence that authorisation for ten years without amendment could also potentially undermine or delay more effective regulatory arrangements.

Public benefit

56. In the absence of the proposed Agreement there would most likely be a regulatory response by Government to give effect to the WHO Code,[60] and it is not clear whether there would be more active direct marketing of infant formula in the short term because of reputational risk and incomplete industry coverage. Although the proposal may have a net public benefit, the likely Government response to the absence of an authorised Agreement is likely to be at least as effective as the proposed Agreement, and hence the public benefits would be substantially greater. However currently Infant Nutritional Council members are not voluntarily abiding by restrictions on marketing infant formula, as they are actively promoting infant formula products through cross branding and cross marketing of toddler formulas, hence the purported public benefits of the current Agreement do not exist. The proposed Agreement is not demonstrated to generate public benefit, and will be even less effective in protecting breastfeeding

[58] Department of Health and Ageing, Review of the Effectiveness and Validity of Operations of the MAIF Agreement: Research Paper. Vol. 13 June. 2012, Canberra: Department of Health and Ageing.
[59] See WHO document '*WHO Information concerning the use and marketing of follow-up formula 17 July 2013'*. http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf. Accessed 12 November 2015
[60] In 2015 the New Zealand Commerce Commission considered that legislation was likely in the absence of the Infant Nutrition Council Code (INC Code) in New Zealand: "*The Commission agrees that indefinite, unimpeded advertising and marketing is an unlikely scenario. In the absence of the INC Code, the Commission considers that the MOH would ultimately put in place legislated restrictions comparable to (or more restrictive than) the INC Code*." New Zealand Commerce Commission. Project no. 11.04/14863. Draft Determination 3 March 2015.

than the Agreement in place since 1992 as it is not the 'more or less the same', 'longstanding' Agreement that was in place 1992 to 2013. The ACCC is mistaken that the proposal is materially the same as the previous MAIF Agreement . The proposed Agreement is also likely to be substantially less effective than the relatively more effective earlier Agreement, because marketing has changed to focus heavily on electronic means which has not been regulated effectively under the previous Agreement, and because the market for infant and young child food products including milk formula has changed. Major players remain outside the Agreement, and other IYC food products are now a much higher proportion of the IYC food product market. As noted above, these other products such as toddler formula are used to market infant formula by Infant Nutritional Council members. The costs and therefore cost-effectiveness of the MAIF in the current Australian context have also not been adequately substantiated, so the ACCC conclusion that the proposed Agreement is more cost effective in Australia than alternatives is therefore speculative.

Length of authorisation

57. There are reasonable grounds for concerns that ACCC authorisation for a longer period of ten years would reduce Australia's ability to defend more effective regulatory arrangements of marketing from challenge. The draft determination is likely to pre-empt more effective regulation with higher public net benefit. Therefore the proposed Agreement is of uncertain public benefit at this time. It is not an adequate response to say that parties to the proposed Agreement can vary the authorisation, or that the ACCC could commence processes to revoke it.

Public detriment from the proposed Agreement

58. The draft determination fails to fully take into account public detriments as allowing free or low cost supplies and incentives to be provided to health care professionals or health services that will reduce innovation and entry by new players into human milk banking or milk sharing arrangements. This a substantial detriment to the health of women and specially vulnerable babies.

Recommendations

59. The regulation of marketing of foods including formula for infants and young children has important public health implications. The ACCC should exercise its authority to improve, not weaken restrictions on marketing, and address market failure to the maximum public benefit. To maximise the likelihood of effective regulation in the immediate and longer term future (2015-2025), the ACCC should:

    a) not authorize the proposed new, and different, MAIF Agreement for any longer than two years,

    b) require amendments to the proposal which significantly improve the public oversight, integrity, transparency, external review, marketing activities to the public, and

    c) require such improvements to a level which is at least no less rigorous than the MAIF Agreement up to 2013 under the co-regulatory Agreement with the APMAIF Panel.