David Hatfield
Director, Competition Exemptions Branch
Australian Competition and Consumer Commission

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7 April 2021

Dear Mr Hatfield,

Re: Infant Nutrition Council Limited (INC) application for reauthorisation of Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement (MAIF)

Thank you for the invitation to make a submission on the ACCC Draft Determination on the above application. This submission has been prepared as a collaboration between academic and NGO researchers in Australia and internationally.

Associate Professor Julie Smith (BEc.(hons), BA., PhD) is a former senior official in the Commonwealth Government, now an ARC Future Fellow and holding appointment at the Australian National University, where she has led relevant research for the World Health Organization, and the Australian Department of Health.

Dr Baker (BSc, MHSc, PGDipHSc, PhD) is a Research Fellow at Deakin University and currently leads a multi-country research project, funded by WHO, on the global regulatory and policy responses to protecting breastfeeding from harmful commercial practices.

Our colleagues, Mr Alessandro Iellamo (MPH) and Ms Naomi Hull (RN, IBCLC, MPH) are, respectively, an IYCF specialist and former advisor with UNICEF and WHO, and a lactation consultant, breastfeeding counsellor, and National Coordinator of WBTI Australia.

We would be pleased to elaborate on this and earlier submissions and attend any public hearings held by the ACCC during its deliberations. We are also happy to provide any data and copies of publications referenced in this document.

Yours Sincerely,

Honorary A/Professor Julie Smith
Department of Health Services Research and Policy, College of Health and Medicine

Dr Phil Baker

Mr Alessandro Iellamo

Ms Naomi Hull

SUMMARY

We would like to offer comment on the following:

1. Public benefit, including the extent to which MAIF may have prevented or reduced the promotion of breastmilk substitutes with positive effects on rates of breastfeeding, including on toddler milk marketing as a proxy for infant formula marketing
2. The reauthorisation period and its relation to the MAIF review proposed in the Australian National Breastfeeding Strategy (ANBS)
3. The extent and effectiveness in health professional codes of practice in regulating marketing of breastmilk substitutes (BMS) to health professionals
4. Regulatory costs and the counterfactual to MAIF of fully adopting the International Code into national law
5. The obligations of Australian regulatory agencies regarding the conduct of Australian companies in marketing milk formula products in export markets

Summary recommendations:

1. ACCC impose a condition on any authorisation which applies limitations on advertising set out in Clause 5(a) of the MAIF Agreement to all milk formula products for infants and young children aged 0-36 months. Any future authorisation of MAIF require robust evidence of public benefit on marketing, sales or breastfeeding, and absence of detriment.
2. Authorisation period no longer than 2 years. ACCC formally place this market under review for the period of reauthorisation
3. ACCC require INC to revise guidance documents for health professionals to achieve full compliance with the WHO International Code guidance for health workers, include these guidelines in MAIF authorisation, and encourage health professional organisations to add Code compliance into their ethical and professional codes of practice.
4. Account for the regulatory cost to civil society organisations and individuals of policing MAIF compared with effective legislation to implement the Code in Australia, and against net fiscal benefit of increased breastfeeding.
5. We urge that the ACCC's assessment of public benefit include marketing conduct of INC members in export markets, as required by Australian trade practices law and Australia's international human rights commitments.

BACKGROUND

1. The ACCC proposes to re-authorise the Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement (MAIF Agreement) and associated guidelines for five years, but is considering whether a condition may be required. ACCC is considering whether to grant authorisation subject to a condition extending the restrictions on advertising and promotion of infant formula to include all breast milk substitutes as defined by the

World Health Organisation, which includes toddler milk products sold by infant formula companies, and indeed all milk products marketed for ages 0-36 months. The ACCC has invited comment in particular on whether such a condition is warranted and if so, the form the condition should take, and especially, any additional evidence or information on the extent to which toddler milk marketing is a proxy for infant formula marketing, with the potential to reduce rates of breastfeeding. The ACCC recognises that a condition which extended the marketing restriction in this way would impact all marketing of toddler milk. The ACCC has also invited submissions on whether there is a more targeted way to prevent marketing of toddler milk to the extent it is effectively marketing infant formula including through the use of 'cross-promotion' across entire branded milk formula product lines.

2. At the outset, we would like to draw attention to new evidence that marketing of breastmilk substitutes has increased during COVID 19, and the companies capitalized on fear related to COVID-19 by using health claims and misinformation about breastfeeding. We submit that these companies operate similarly around the world including in Australia. The authors recommend monitoring marketing tactics to inform World Health Assembly actions and targeted Code enforcement including 'efforts to address misinformation about breastfeeding in the context of COVID-19 and prevent spill over of BMS donations to breastfeeding mothers'. Furthermore;

> "Longer-term action includes holding social media platforms accountable, raising public awareness on the Code, and mobilizing community monitoring efforts."

3. This study was led by Ching and published on 1 March 2021 (1). It examined promotional materials and activities from 9 BMS companies in 14 countries since the start of the COVID-19 pandemic. Reported violations of Executive Order 51 in the Philippines (based on the Code) were also examined from January 2019 - July 2020. Eight themes emerged:
    i. Unfounded health claims on immunity that prompt fear;
    ii. Association with public health authorities to gain legitimacy;
    iii. Appeals to public sentiment of solidarity and hope;
    iv. Influxes of BMS product and supply donations related to COVID-19;
    v. Prominent use of digital platforms;
    vi. Promoting uncertainty through breastfeeding endorsements;
    vii. Discounts on BMS products linked to COVID-19; and
    viii. Outreach to health professionals through educational events related to COVID-19 and infant and young child feeding.
4. The authors found a sharp increase of reported marketing violations in the Philippines during the pandemic: 291 during the first months of the outbreak compared with 70 in all of 2019.
5. Also in 2021, important international human rights documents published by the United Nations Committee on the Rights of the Child, have clarified the human rights of children to be protected from digital marketing (2). A recent study of marketing of alcohol to children

under New Zealand's self-regulatory regime, which has important similarities to MAIF, noted the importance of new digital avenues for marketing (3).

6. At para 2.1, ACCC states the aim of the WHO International Code to be 'to protect and promote breastfeeding and to ensure that marketing of breast milk substitutes, feeding bottles and teats is appropriate.' We respectfully submit that this statement is overly narrow and conflates the Code with industry's 'spin' about the aims of its MAIF Agreement. As stated in Article 1 of the 1981 Code resolution and in our previous submission, the stated aim of the WHO International Code is to contribute

> "to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution" (Article 1).

7. At para 2.5. The ACCC states that the 'MAIF Agreement relates only to marketing of infant formula by manufacturers and importers, the WHO Code and WHA resolutions are broader in scope as they recommend that restrictions be placed on the marketing of complementary foods for infants, feed bottles and teats, and on the promotion and price discounting by retailers of all these products.' It is important to also recognise that the scope of the MAIF is much narrower than the WHO Code and WHA resolutions with regard to marketing to health professionals. The manufacturers own policies on responsible marketing are also much narrower, yet are often promoted as demonstrating 'compliance' with the WHO Code and WHA resolutions. This is factually incorrect, and further discussed in section 3 below.

8. At para 2.9 the ACCC has noted that 'FSANZ is currently reviewing the standards applying to infant formula. The aim of the review is to ensure regulation of infant formula is clear and reflects the latest scientific evidence, and to consider harmonising the FSANZ Formula Standard with international regulations. Toddler milk products are not intended to be included in the review.'

9. The history of FSANZ review of toddler milk products is informative to emphasise the urgent need for the ACCC to act on toddler milk formula marketing, because FSANZ has failed its regulatory duty to do so to protect public health. In 2015 following the death of two toddlers fed by their parents on a sole diet of formula, FSANZ was requested to review toddler formulas. However, it subsequently dropped this review from its work program on the grounds of insufficient resources. A disabled toddler starved to death in 2019 in comparable circumstances. It is entirely foreseeable that some parents will confuse different types of milk formula products, and that for some, toddler formula will displace a nutritious diet of solid foods and breastfeeding, or other healthy drinks. This can have tragic consequences.

10. Approximately a third of Australia children are still breastfeeding at aged 12 months (4). Around one in ten are breastfed well into their second year. During that time, breastfeeding provides important nutrition, alongside appropriate complementary foods. Toddler formula products displace appropriate complementary foods as well as breastfeeding.

11. It is important to note that the WHO has long maintained toddler milks are unnecessary and unsuitable as substitutes for continued breastfeeding. Recent Australian studies also find

toddler milks are often high in added sugars, and pose a risk for child overweight and obesity, which can have life-long detrimental effects. By definition of the Australian Dietary Guidelines, toddler milks are discretionary products superfluous to dietary requirements. Despite adding no additional nutritional benefit, toddler milks are also many-fold more expensive for Australian consumers when compared with regular cows or other animal milks.

12. The national importance of breastfeeding in the second year of a child's life, and the economic losses when it is displaced by inappropriate commercial baby foods or milk formula is recognised in a number of studies in Australia, the United States, the United Kingdom, Norway, India and Indonesia, as well as in sub Saharan Africa (5-9). The market value of fresh human milk for well babies in a hospital setting is around $100 a litre in Norway.
13. In Australia alone the economic value of this 'lost milk' amounts to several billions of dollars a year (10). The lack of protection for breastfeeding and the resulting loss of human milk production (including in the second year) is economically inefficient, including because of the demonstrable health cost externalities of unrestrained marketing and distribution of breastmilk substitutes (11-13).

1. THERE IS INSUFFICIENT EVIDENCE TO SUPPORT AN ACCC ASSESSMENT THAT THERE IS PUBLIC BENEFIT FROM MAIF, WHICH MAKES STRONG AND COMPREHENSIVE CONDITIONS ON ANY NEW AUTHORISATION ESSENTIAL

We strongly support that the ACCC impose a condition which applies limitations on advertising set out in Clause 5(a) of the MAIF Agreement to all milk formula products for infants and young children, and recommend robust evidence of net public benefit for any future authorisation based on data collected from detailed market review.

PUBLIC BENEFIT

1. At 4.2. ACCC states that 'consistent with subsection 90(7) and 90(8) of the Act, the ACCC must not grant authorisation unless it is satisfied, in all the circumstances, that the conduct would result or be likely to result in a benefit to the public, and the benefit would outweigh the detriment to the public that would be likely to result (authorisation test).'
2. At para 4.33-4.36, ACCC notes that a number of complaints regarding toddler milk advertising have been considered by the Committee and reported on in recent years. It has been submitted that marketing of toddler milk is generally considered by the Committee to be beyond the scope of the MAIF Agreement, except for some cases where marketing of toddler milk unambiguously has the effect of marketing infant formula – such as when images of infants clearly not over 12 months of age are used, or references are made to "infant formula" within the marketing material. The ACCC understands that issues of cross-promotion through product line marketing have not been found to have been in breach of the MAIF Agreement.
3. At para 4.37 the ACCC states' Given the extent of the marketing and promotion of toddler milk in Australia, and the clear similarities between toddler milk packaging and infant

formula packaging across many product ranges, the ACCC considers there is a risk that the marketing of some toddler milk products communicates indirectly with consumers about infant formula products, and is likely to have much the same effect as the direct marketing of infant formula in that product range. The WHO supports this conclusion in its guidance, as do a number of submissions from interested parties. If this is the case, the impact on consumers of the marketing and promotion of toddler milks may be such that the purpose of the MAIF Agreement is undermined and the public benefit resulting, or likely to result, from the Conduct significantly reduced.

4. Also at 4.74. the ACCC states that it 'considers that there are significant indications that the marketing of toddler milk by infant formula companies in some circumstances has a similar impact on consumers as the direct promotion of infant formula, and this has the potential to undermine the effectiveness of the MAIF Agreement and creates a risk that much of the claimed public benefit may not be realised. The ACCC is considering whether it is necessary to impose a condition in the circumstances to address this risk. Such a condition would extend the advertising prohibitions within the MAIF Agreement to cover all breast milk substitutes, including toddler milk. This is discussed in further detail below.

5. At para 4.75. 'The ACCC also considers that the benefit of the MAIF Agreement may be further limited by:

   - the promotion by infant formula companies of infant formula brands and product ranges which include infant formula
   - the way in which complaints are resolved and the MAIF Agreement is interpreted by the Committee, due to the composition of the Committee and difficulties in processes for lodging complaints
   - incomplete industry coverage of the agreement
   - marketing by third parties not party to the MAIF Agreement, and a lack of transparency over the possible support of signatories for this marketing
   - gifts and donations to health care professionals.'

6. At 4.15 -4.17 ACCC states that 'ACCC has long recognised 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 the best available scientific research indicates that not breastfeeding increases the child's risk of all-cause mortality, diarrhoea, respiratory infection and malocclusion, and likely obesity and type-2 diabetes, and for mothers the risk of breast cancer, and likely ovarian cancer and type-2 diabetes (14) This evidence supports a strong conclusion, that increased rates of breastfeeding among infants and young children will result in improved health outcomes and lower public health costs.

7. 4.16. The WHO considers that inappropriate marketing of products that compete with breastfeeding is an important factor that often negatively affects the choice of a mother to breastfeed her infant optimally. Exposure to such marketing results in increased rates of bottle-feeding, and reduced breastfeeding initiation, exclusivity and duration, irrespective of country context (15). The WHO notes that given the special vulnerability of infants, usual marketing practices are unsuitable for these products.11 4.17. For this reason, the ACCC accepts that the promotion of breast milk substitutes in Australia is likely to negatively influence the

rates of breastfeeding in Australia, and therefore that the MAIF Agreement is likely to result in a public benefit to the extent it prevents or reduces promotion of breast milk substitutes.'

8. Para 4.34. The ACCC considers that, based on the Committee's interpretation guidelines relating to staging information and complaints considered by the Committee, the Tribunal and APMAIF, the MAIF Agreement, as currently drafted, is unlikely to effectively address the concerns of interested parties that the promotion of toddler milk as part of a product line including infant formula may result in the proxy promotion of infant formula.
9. At para 5.3. it is stated that 'under subsections 90(7) and 90(8) of the Act, the ACCC must not grant authorisation unless it is satisfied in all the circumstances that the Conduct is likely to result in a benefit to the public and the benefit would outweigh the detriment to the public that would be likely to result from the Conduct'.

It can therefore reasonably be argued based on the above that it is not open to the ACCC to authorise the MAIF agreement because of a risk that much of the claimed public benefit of MAIF arrangements promoting and protecting breastfeeding is significantly less, due to toddler milk marketing.

10. At para 4.23- ACCC notes 'Numerous interested parties have raised strong concerns regarding marketing of toddler milk, including VicHealth, Rosemary Stanton OAM, the Australian Breastfeeding Association and Breastfeeding Advocacy Australia, and called for the MAIF Agreement to apply to toddler milk products.
11. 4.22. In its 2016 determination, the ACCC considered that the marketing of toddler milk products was likely to, in some circumstances, effectively also act as marketing for infant formula and therefore may potentially undermine the benefit of the MAIF Agreement. At the time of the 2016 determination, the ACCC concluded it was not appropriate to require changes to the MAIF Agreement in relation to toddler milk, because of (then) recent or upcoming expected developments which may have resulted in changed industry practices in the area. In its determination, the ACCC noted that the issue of toddler milk marketing would be a relevant factor in its consideration of any future authorisation applications by the Council.
12. ACCC notes the Infant Nutrition Council Australia & New Zealand (henceforth INC) response to these concerns at para 4.29. In response to these concerns INC submits that issues relating to the marketing of toddler milk have been addressed by a number of developments since the ACCC's 2016 determination, which have improved industry practice. In this regard the Council points to: guidance it has developed and disseminated to its members, which provides practical suggestions to ensure there is no inadvertent promotion of infant formula through the marketing of toddler milk; guidelines developed by the Committee relating to staging information on packaging of infant formula; and a number of determinations issued by the Committee (and formerly the Tribunal) in relation to marketing of toddler milk, which may have had the effect of promoting infant formula. The Council submits that the Federal Government has not given any indication that it considers the MAIF Agreement should be extended to include marketing of toddler milk, and that the inclusion of toddler milk in the MAIF Agreement may deter companies from signing and the withdrawal of existing signatories. At para 4.30. The Council also submits that toddler milk is not a substitute for breast milk and should therefore not be regulated within the same framework as infant formula because:

- toddler milk is intended as an alternative to cow, sheep, goat and other non- human milks in young children over 12 months of age,
- the nutritional composition of toddler milk is different to that of infant formula, and
- toddler milk and infant formula are regulated under separate FSANZ standards.

13. It is notable that these very same arguments (i.e. that distinguish toddler milks from infant formula), further and strongly justify the need to differentiate the packaging the labelling of these product categories, and end the marketing technique of 'cross-promotion' in Australia.

The INC response provides no evidence to support a contention about what the industry has actually done, rather than what INC says it does.

14. At para 2.18 the ACCC states that 'the Breastfeeding Strategy also noted that research suggests that Australian consumers fail to distinguish between the advertising of infant formula and toddler milk, and that there has been an increase in toddler milk and other baby food advertising in Australia.

15. At para 4.73 it is stated that the ACCC considers that the Conduct has resulted, and has the potential to continue to result in a significant public benefit in the form of:
    - protecting and promoting breastfeeding leading to improved health outcomes, and
    - avoided regulatory costs from alternative solutions.

16. The 'significant public benefit' in the form of protecting and promoting breastfeeding is considered in the following paragraphs, while the issue of regulatory costs is considered in a later (Section 4).

INC has submitted that since the ACCC's 2016 determination, industry has improved its practice. Available evidence is to the contrary. In recent years, the share of toddler formula in the Australian market has continued the rise that we reported in our submission in 2015.(16) Sales continue to rise. It is our submission that there is no evidence of public benefit from approving the INC application for reauthorisation of INC as the MAIF is ineffective.

17. A short history of infant formula marketing in Australia including through health facilities, and industry's counter regulatory response, is summarised in previous submissions to the ACCC on this issue and in our academic publications (17-19). Recent comprehensive reviews of the international literature also exist, including our recent publication explaining how commercial marketing shapes 'first-food systems' to undermine breastfeeding and drive milk formula consumption on a global-scale (20, 21).

18. Here we point again to the well-known fact, that the industry started marketing follow-up formulas and toddler milks more intensively from the mid-1980s onwards, in direct response to the International Code of Marketing of Breast-milk Substitutes and tightening national regulations on the marketing of infant formula (20). This not only cultivated new markets and revenue growth for the industry, but also as one industry report frames it, was essentially the renaming of products '…primarily to avoid regulation and restrictions on advertising' applying to infant formula only (22).

19. Since then, 'cross-promotion' has become a standard industry marketing technique used to promote entire branded product ranges, including milk formula categories where regulations prohibit this (20). This technique has been remarkably effective. For example, studies from Australia and Italy found that 67% and 81% respectively of mothers surveyed reported

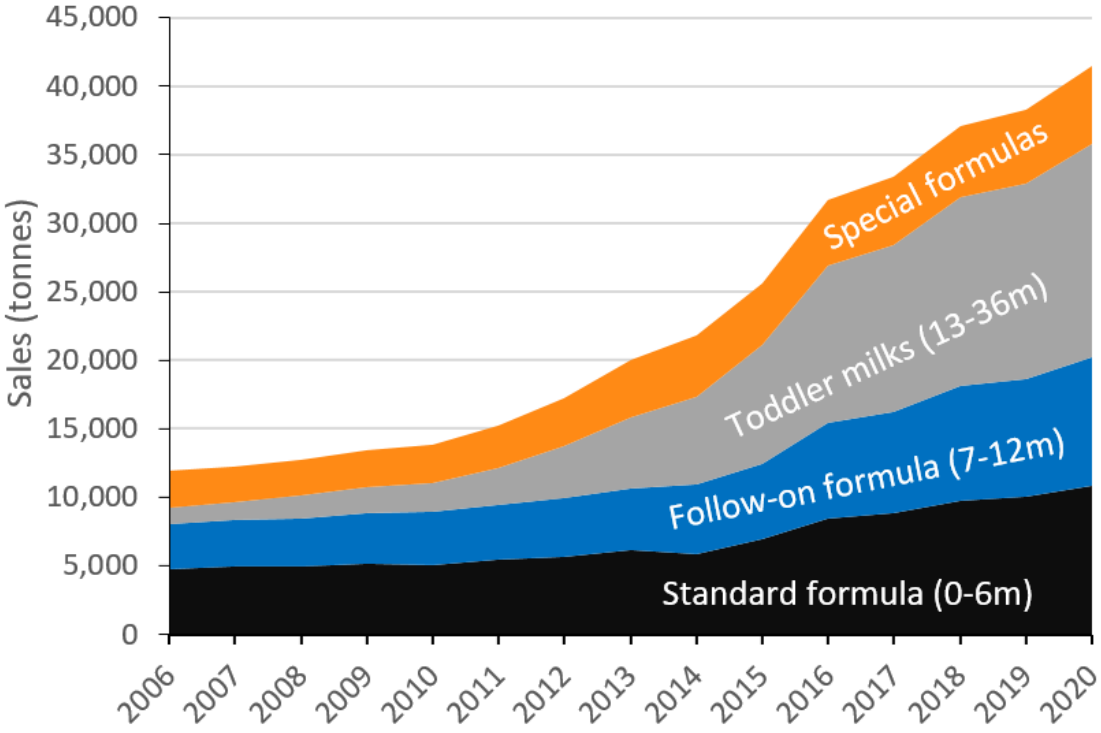
having seen an infant formula advertisement, despite such advertisements should technically not exist under the regulatory arrangements currently in place, including the MAIF (23-25).

20. According to data from Euromonitor, a market research service provider, the overall volume of milk formula sales in Australia expanded 248% between 2006-20, a compounding annual growth rate (CAGR) of 8.7%.(26) The toddler milk category, typically marketed for ages 13-36 months, has led this growth with an expansion of 1116% over the period, equivalent to a CAGR of 18.1%. Toddler formula sales continue to grow much faster than sales of infant formula, although all milk formula product segments continue to rise.

21. We note the rapid market expansion continues from approximately 2010 onwards. This cannot be explained by secular trends that influence infant and young child feeding in Australia, for example, changes in the birth rate, income or labour market.

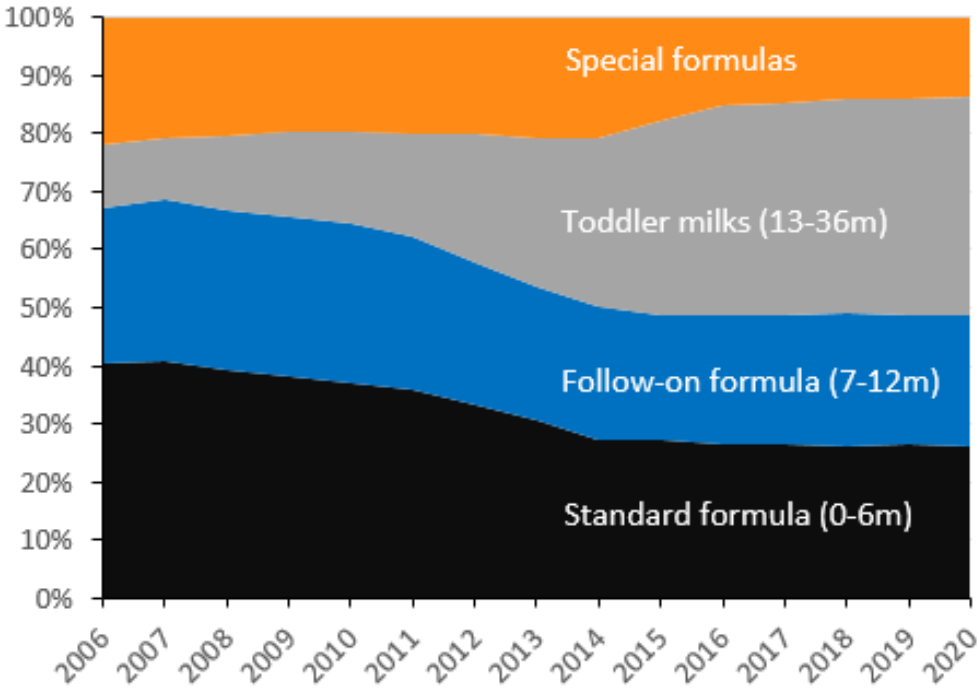
22. These continuing trends are evident in Figure 1 below. Figure 1 shows that the INC response to the concerns raised in 2015 have not been effective in protecting breastfeeding from inappropriate marketing of milk formula products, and judging by our data sourced from Euromonitor, sales of milk formulas have in fact escalated.

Figure 1. Trends in milk formula category retail sales (tonnes) in Australia, 2006-2020



Source: Euromonitor Passport

Figure 2. Changes in the proportionate share of milk formula category retail sales (tonnes) in Australia, 2006-2020



Source: Euromonitor Passport

23. Around 90% of the growth in baby food sales during the period 2015 to 2020 was from increased sales volumes of toddler formula ("growing up milk"). See Table 1 and Appendix A. The share of toddler formula in the Australian market has thus continued the rise that we reported in our submission in 2015.(16)

Table 1. Volume of milk formula products sold at retail in Australia, 2015 to 2020

Categories	2015	2020	% growth
Milk formula	25.6	41.4	62%
Standard milk formula	6.9	10.9	58%
Follow on milk formula	5.5	9.3	69%
Growing up milk formula	8.6	15.6	81%
Special baby milk formula	4.5	5.6	24%
All baby food	41.5	58.9	42%

Source: Euromonitor, Baby Food in Australia, 2020

24. At para 2.19 ACCC states that 'the Department of Health advises it is currently developing an implementation plan and governance arrangements for the Breastfeeding Strategy, and relevantly, anticipates undertaking a review of the MAIF Agreement in 2021.

25. ACCC notes the INC response to concerns about toddler milk marketing at para 4.29. In response to these concerns the Council submits *inter alia* that the Federal Government has not given any indication that it considers the MAIF Agreement should be extended to include marketing of toddler milk, and that the inclusion of toddler milk in the MAIF Agreement may deter companies from signing and the withdrawal of existing signatories.

26. We submit that the Breastfeeding Strategy presents clear evidence of a change in policy that includes that the MAIF should be extended to include marketing of toddler milk. The stated objectives of the Strategy include (p.28):

> *"Strengthen the regulatory arrangements for marketing of infant formula and breastmilk substitutes so that inappropriate marketing and distribution ceases.*
>
> *Increase the proportion of health professionals who receive adequate, evidence-based breastfeeding education and training that is free from commercial influence."*

27. Firstly it should be noted that the stated objective is that inappropriate marketing and distribution ceases. This is a change of policy agreed by all Australian governments. Secondly that this applies to infant formula and breastmilk substitutes. The wording of this objective leaves no doubt that the Strategy objectives relate to infant formula and other breastmilk substitutes, which according to the World Health Organization, includes toddler milks. Likewise, the policy has been agreed by all Australian governments.

MAIF COVERAGE AND PUBLIC DETRIMENT

28. At Para 4.51 ACCC says 'Many interested parties argue that the voluntary nature of the MAIF Agreement undermines its effectiveness as a regulatory instrument, because it does not extend to major industry players that would otherwise be required to comply if a legislative solution was adopted. At Para 4.51 ACCC also says 'Some interested parties have raised concerns that the MAIF Agreement no longer covers all significant players in the infant formula market, and that many new entrants are not signatories and are marketing aggressively. The ACCC states at para 2.12. that it 'does not have information as to what proportion of sales of infant formula, by volume, is covered by signatories to the MAIF Agreement.

29. A recent systematic review and document analysis of the market strategies used by processed food manufacturers to increase and consolidate their power documented the global market strategies of the food industry, and is relevant to assessing the varied nature of potentially detrimental conduct of the milk formula industry in Australia. The study noted six themes (27). We invite the ACCC to consider the role of MAIF in relation to each of these strategies.

    i. reduce intense competition with equivalent sized rivals and maintaining dominance over smaller rivals;

    ii. raise barriers to market entry by new competitors;

    iii. counter the threat of market disruptors and drive dietary displacement in favour of their products;

    iv. increase firm buyer power over suppliers;

    v. increase firm seller power over retailers and distributors; and

    vi. leverage informational power asymmetries in relations with consumers

30. The INC submits that signatories include all of Australia's major manufacturers and importers, and that signatories account for the majority of sales of infant formula in Australia. Infant formula brands not covered by the MAIF Agreement include those manufactured by Royal Australia New Zealand, Munchkins, Blackmores, and some supermarket brands'. Further, at Para 4.52 it is reported that 'The Council understands that

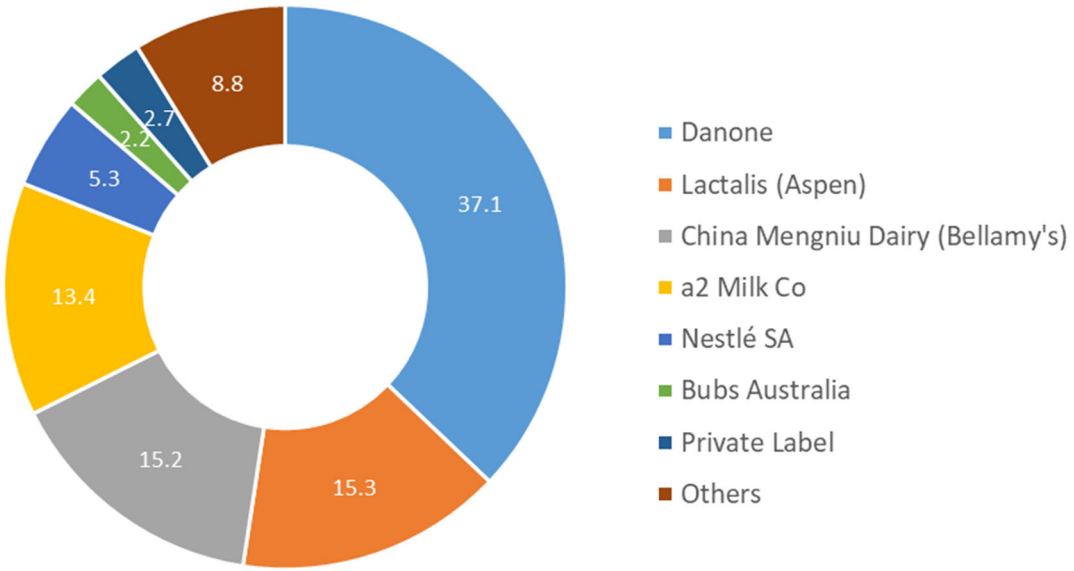
the MAIF Agreement covers the majority of the infant formula market in Australia and considers that only a small number of manufacturers and importers are not signatories, including Royal Australia New Zealand, Munchkins and Blackmores. At Para 4.53. ACCC notes that (in addition to the companies named by the Council) some major supermarket brands (which act as both manufacturer/importer and retailer due to vertical integration) are also not signatories.

31. At para 2.13 INC advised that the current signatories at the time of lodging the application were as follows:

INFANT NUTRITION COUNCIL MEMBER SIGNATORIES TO MAIF
Abbott Australasia Pty Ltd
Australian Dairy Park Pty Ltd
Bayer Australia Ltd
Bellamy's Organic
The Infant Food Co. Pty Ltd
The LittleOak Company Pty Ltd
Nature One Dairy Pty Ltd
Nestlé Australia Ltd
Nuchev Ltd
Nutricia Australia Pty Ltd
Reckitt Benckiser (Australia) Pty Limited
Sanulac Nutritional's Australia Pty Ltd
Spring Sheep Milk Company
Sprout Organic
Swisse Wellness Pty Ltd
The a2 Milk Company Ltd
Wattle Health Australia Limited.

32. We offer the following information to assist the ACCC in assessing MAIF Agreement coverage of the milk formula market in Australia. Figure 3 below shows the market share of corporations in the Australian milk formula sector in 2020.

Figure 3. Market share of corporations in the Australian milk formula sector, 2020



Source: Euromonitor Passport

33. The market leaders are Danone (France), Lactalis (France; which recently acquired Aspen), China Mengniu Dairy Company (China; which recently acquired Bellamy's), the A2 Milk Company (Australia and New Zealand), Nestle (Switzerland), and Bubs Australia (Australia). Private label brands sold by Australia's largest supermarket retailers also comprises a significant market share.

34. The Euromonitor report on the Australian baby food market shows a shift in the distribution of sales to discounters and to e-commerce between 2015 and 2020. Other retail distribution channels became less important. Further details are provided at Appendix B.

35. In our previous submission in 2015 in response to the ACCC draft determination on a previous application by INC, we called for the ACCC to require better information to define the market and the products and companies involved in it. This would allow comparison of the conduct of companies who are signatories to the INC MAIF Agreement, with those who are not. We propose that the commercial milk formula market for infants and young children, applies to all milk drink products marketed for ages 0-36 months, to be consistent with the best available evidence and WHO definition. This market definition is further supported by the fact that INCANZ itself, which is one of many similar trade associations representing the industry worldwide, recognises these products fall within their scope of remit.

36. We note that the above information on companies market share coverage of MAIF (which it seems has not been available to the ACCC) relates to the market for milk formula, including both infant formula and toddler formula. Due to cross product marketing (and brand marketing), the baby food market and specifically the milk formula product category is the more relevant market for assessing coverage of MAIF than the market for standard infant formula.

37. In the absence of detailed information relating the market share of milk formula product categories of INC members, compared with non-members, we submit that it is not possible for the ACCC or the public to accurately judge the coverage of the MAIF or the conduct of INC signatories to it. Nor is it possible to assess the conduct of INC members and signatories to the MAIF with regard to their restraint or otherwise of their marketing activities.

38. Hence the ACCC statement at para 4.54 'that the majority of infant formula manufacturers and importers in Australia are signatories' is unsupported by evidence, and furthermore the evidence available cannot reliably support a judgement on the 'likely public benefits arising from the Conduct'.

SUMMARY

39. There is no evidence that the MAIF prevents or reduces promotion of breast milk substitutes, or its negative effects on breastfeeding, including in particular since the ACCC's determination in 2016. Sales of toddler milk continue to rise, driven by industry marketing.

40. Detrimental effects are a considerable risk in this industry. The ACCC has no independent evidence of the extent of MAIF coverage of the market, and which companies are involved in it.

RECOMMENDATIONS

1. We recommend the ACCC impose a condition on any authorisation which applies limitations on advertising set out in Clause 5(a) of the MAIF Agreement to all milk formula

products marketed for infants and young children aged 0-36 months. Any future authorisation of MAIF require robust evidence of public benefit on marketing, sales or breastfeeding, and absence of detriment.

2. We again request the ACCC publicly indicate its intention to place this market under formal review, as in our previous submission.

2. THE DURATION OF ANY MAIF REAUTHORISATION SHOULD NOT EXCEED 2 YEARS

We support a shorter authorisation than INC has requested. We recommend the reauthorisation period should be for no more than 2 years.

GREATER AND MORE CERTAIN PUBLIC BENEFIT FROM SHORTER REAUTHORISATION PERIOD

1. We strongly support the ACCC draft determination to not approve authorisation for ten years as sought by INC. However, the arguments put by the ACCC for a shorter authorisation period of 5 years apply even more strongly in support of authorising the MAIF agreement for a shorter period, say, 2 years. There is no evidence that previous reviews of the MAIF resulted in any change that has delivered a public benefit to justify granting the exemption.
2. At 4.2. the ACCC states the legal test to grant an authorisation, 'Consistent with subsection 90(7) and 90(8) of the Act,8 the ACCC must not grant authorisation unless it is satisfied, in all the circumstances, that the conduct would result or be likely to result in a benefit to the public, and the benefit would outweigh the detriment to the public that would be likely to result (authorisation test).'
3. However, as set out above, the ACCC draft determination does not apply this test, because the finding of 'likely public benefit against detriment' is based on future uncertain, possible and improbable changes to the MAIF, its implementation and enforcement. The potential public benefit from granting the authorisation is made even more improbable, the longer the period of any authorisation because of the weak and uncertain, or absence of significant evidence of public benefit from the existing arrangements and the uncertainty regarding possible future reviews. The material findings of the ACCC report notes the uncertainty of public benefit.

UNKNOWN AND PROBABLY IRRELEVANT OUTCOME OF REVIEW

4. At para 2017-2.19 the ACCC refers to the Australian National Breastfeeding Strategy (ANBS): 'The strategy made a number of recommendations, including an independent review to determine:
    - the effectiveness of the MAIF Agreement in restricting inappropriate marketing of breastmilk substitutes
    - the feasibility of including all manufacturers of infant formula and all retailers in the scope of the MAIF Agreement, and

- the transparency of the complaints process and outcomes of the Committee meetings.'

5. Anticipation of a possible review being conducted, or of it being 'independent', is not a relevant basis for assessing that there is a public benefit in reauthorising MAIF for five years. We submit that, in law, this is an irrelevant consideration.
6. There have been multiple such 'independent reviews' since 1992. For example, "independent reviews" of MAIF were conducted in 2001 by former Victorian Health Minister Knowles (28), and in 2007 by the cross parliamentary Best Start Parliamentary Committee Inquiry (29). Knowles recommended the Code be legislated, and the Best Start Inquiry recommended full implementation of the Code.
7. In 2010 the Australian National Breastfeeding Strategy (30) included actions which included a review of Australia's implementation of the WHO International Code. Such a review was conducted by NOUS in 2012 (31); it concluded that companies should not be permitted to use common branding of infant formula and toddler formula products. No action was taken by the Department of Health, which stated inaccurately on its website at the time,[1] that the WHO Code did not cover toddler formulas. In 2017 a further review of the operation of the MAIF was conducted by NOUS with minimal evident change to its effectiveness. (32)
8. That is, none of these reviews resulted in meaningful strengthening of Code implementation in Australia or most relevantly, addressed the recommendations of the 2007 Parliamentary 'Best Start' Inquiry for 'full implementation' of the Code.

We submit that no significant changes to the effective operation of MAIF have been implemented as a result of previous reviews, and that the ACCC cannot rely on anticipation of the possible beneficial outcomes of a possible future review in its determination.

1. Furthermore, the ANBS 2019 has no budget for implementation, no publicly available implementation plan, and has not met its promised timelines for reporting to ministers or the public 22. No details for the proposed review are publicly available, including its terms of reference, approved budget, public consultation, or processes and timelines for reporting and publication. The ANBS is not law. It is merely a statement of policy. It is, we submit, an irrelevant consideration for the ACCC decision to grant an authorisation based on the proposed review of MAIF. An 'anticipated' review in a policy document that is already not meeting its stated timelines, and has not informed the public of the nature of such a review or about its processes, cannot be a relevant consideration for ACCC in its current assessment of whether there is a public benefit from reauthorising MAIF. It is a mere unenforceable political promise of probable continued inaction.

We submit that a shorter period of MAIF authorisation is more likely than a longer period to generate public benefit, as the review itself is uncertain.

2. The ACCC concludes on the length of authorisation that (para 4.94) 'Given the number of issues (described above) which the ACCC considers may reduce the benefits of the MAIF Agreement, and the uncertainty of outcome as a result of the Department of Health's planned review of the effectiveness of the arrangement, the ACCC proposes to grant reauthorisation for a period of five years.'
3. The main relevance of the advice from the Department of Health to the ACCC assessment is to reinforce the need for a shorter period of authorisation. The counter view put forward by

[1] See previous evidence on WHO guidance in this regard, and its timing.

the proponents of a five year authorisation (INC and the federal Dept of Health) - that a longer authorisation period is needed to allow sufficient time for a review and implementation - is astonishing.

4. As noted above, previous, serial reviews have each failed to result in significant strengthening of MAIF. Maintaining the status quo in the context of a significantly changed marketing environment has thus over time watered down any public benefit that might have justified the original 1992 authorisation of APMAIF arrangements. Despite claims that industry or government would gather information to provide material evidence of public benefit this has not occurred, and yet the ACCC has continued to grant authorisations. Delay has not seen any significant change in industry behaviour.

   The industry tactic of delaying stronger marketing regulation (such as through seeking a long authorisation period for the MAIF) is well documented in relevant global studies (33-35).

SUMMARY

5. The issues which the ACCC considers 'may reduce the benefits of the MAIF Agreement, and the uncertainty of outcome as a result of the Department of Health's planned review of the effectiveness of the arrangement can only lead to the conclusion that the ACCC cannot be confident of public benefit from approving the application, and hence it should not be approved.
6. The MAIF review should not be a relevant consideration in the ACCC's decision-making about public benefit of reauthorising MAIF, and potential 5-year delay in improving MAIF reduces its public benefit if any. A delayed response means yet another generation of infants and young children (around a million every year 0-36 months) miss out on protection. Similarly, even if the ACCC chooses to approve the application despite the possibly reduced benefits and uncertainty of outcome, these are grounds for the ACCC to only reauthorise MAIF for 2 years rather than 5. A short period for reauthorisation would provide an opportunity for those who assert there is a public benefit from the status quo to substantiate the claim with evidence that is currently lacking.

RECOMMENDATION

1. If the MAIF is reauthorised, the reauthorisation period should be for 2 years or less.

3. HEALTH PROFESSIONAL CODES OF CONDUCT ARE NOT A SUFFICIENT RESPONSE TO MARKETING TO HEALTH PROFESSIONALS

We recommend that the ACCC require all INC guideline documents on relationships with health professionals to fully incorporate the WHO International Code guidance for health workers and be considered part of the MAIF, and urge that all relevant health professional organisations be encouraged to add Code compliance into their ethical and professional codes of practice.

MARKETING INFLUENCE ON HEALTH PROFESSIONALS IN AUSTRALIA

1. The ACCC states (para 4.70.) that it does not consider there is currently sufficient evidence 'that health care professionals are being influenced by gifts or donations of infant formula companies to undermine the aims of the MAIF Agreement for the purpose of this assessment.'

2. We submit to the contrary that there is relevant strong evidence of health care professionals being influenced by gifts or donations, sponsorships, continuing medical education, or other rewards, in the field of pharmaceuticals (36). Our review of the recent international literature found ample evidence that companies are using digital de-learning platforms for this purpose, among other strategies to influence health professional associations and clinical prescribing behaviours, which is especially relevant to the marketing of specialised (or therapeutic) formulas (20, 37) Given this evidence, the ACCC cannot use a purported lack of direct evidence on health professionals being influenced such as by gifts or donations of infant formula to determine that they are not so influenced.

3. The onus is on those asserting that health professionals in Australia are not being influenced by marketing of milk formula products to justify such an assessment based on evidence. An influential major study by the US Institute of Medicine has documented ongoing harms from commercial influence on medical research, education, and practice (38, 39).

4. This issue was also investigated in a global context by our 2015 rapid evidence review of marketing of complementary foods for infants and young children conducted for the WHO (40). There is considerable overlap between the pharmaceutical industry and the baby food industry (20).[2] Our review found high quality evidence from well conducted systematic reviews that for example, prescribing behaviour is affected by marketing of pharmaceutical products to health professionals. The review concluded that this evidence on the effectiveness of marketing was likely to apply in the case of baby food marketing to health professionals.

5. In a research study presently being revised for publication in 2021, Baker et al (33) investigate and document the strategies and tactics used by the baby food industry to shape first-food systems on a global scale. It shows how the industry makes large investments in fostering favorable policy, regulatory and knowledge environments to enable and sustain its

[2] 'A small number of transnational corporations, originating in either the food or pharmaceutical sectors of Europe and the United States, dominate milk formula manufacturing and own the major brands. According to Euromonitor data, just five controlled 57% of global market share in 2018: Nestlé (Switzerland), Danone (France), Reckitt Benckiser (UK; recently acquired Mead Johnson Nutrition), Abbott Laboratories (US) and Royal FreislandCampina (Netherlands). These 'Big Formula' companies are the end result of intensive merger and acquisition activity over recent decades, with most markets controlled by a small number of these players.'

marketing. Co-option of healthcare professionals in the marketing of their products is one of the diverse market and political practices that the industry uses to drive continued expansion of milk formula markets, including in Australia. This includes co-opting health professionals to secure product recommendations.

6. Australian research shows the activities of pharmaceutical companies in marketing to health professionals(41, 42). Research in Australia looking at the concept of conflict of interest in the education of health professionals by the pharmaceutical industry found a double standard exists. It found that health professionals do not see themselves as being able to be influenced by gifts and industry-provided education. Conversely the companies themselves were very aware of the impact and risk of conflict of interest within their own employees and had policies in place to eliminate them wherever possible. Grundy et al also concluded that in the case of interactions between health professionals and industry, a self-regulatory approach to eliminating potential conflict of interest was unlikely to be successful (41).
7. Against this background of global and Australian evidence on relevant marketing to health professionals, the question has to be addressed, why would the situation regarding marketing of milk formula to health professionals be different in Australia?
8. Health facilities and services and health professionals are a key marketing channel for milk formula and other baby food products (33, 43). Introduction of infant formula in the first month and especially during the hospital stay reduces breastfeeding success and increases retail demand for infant formula throughout the first year (44). According to WHO Guidance for maternity and newborn care facilities (44), "avoiding supplementation of newborns with products other than breast milk (step 6) is a crucial factor in determining breastfeeding outcomes." Indeed,

"Giving newborns any foods or fluids other than breast milk in the first few days after birth interferes with the establishment of breast-milk production. Newborns' stomachs are very small and easily filled. Newborns who are fed other foods or fluids will suckle less vigorously at the breast and thus inefficiently ***stimulate*** *milk production, creating a cycle of insufficient milk and supplementation that leads to breastfeeding failure.*

Babies who are supplemented prior to facility discharge have been found to twice as likely to stop breastfeeding altogether in the first 6 weeks of life (45)[emphasis added].

9. This means that there is a very high payback to company investments in health channels for marketing. Approximately a third of newborns in New South Wales and Victoria (jurisdictions where such data is readily available) are given formula in the few days before they leave hospital (46). This means that there is a very high payback to company investments in health channels for marketing. Based on our informal analysis of baby food sales in Australia, it is plausible that some 20% of the total retail market for milk formula may be determined by infant feeding practices during the first month.
10. Surveys of mothers such as the ANBS consultation documents (47) (see also our previous submission on this application) demonstrate that formula is heavily promoted in Australian hospitals and health services by health professionals. This is also impacted by the fact that health professionals receive very little pre-service or in-service education on breastfeeding and supporting the breastfeeding mother. The lack of appropriate and sufficient education

makes it very difficult for the health professional to support the breastfeeding mother adequately. Given the presence of industry in educational opportunities provided on site or at conferences the knowledge of formula products is more readily accessible to the health professional than knowledge about supporting breastfeeding. (WBTi, 2018)

HEALTH PROFESSIONAL ETHICS AND STANDARDS

11. In para 4.70 the ACCC notes 'that health care professionals are subject to a number of obligations under their own professional ethics and standards'.

We challenge the ACCC assumption that these professional ethics and standards regulate health professional behaviour in any significant way regarding the WHO International Code.

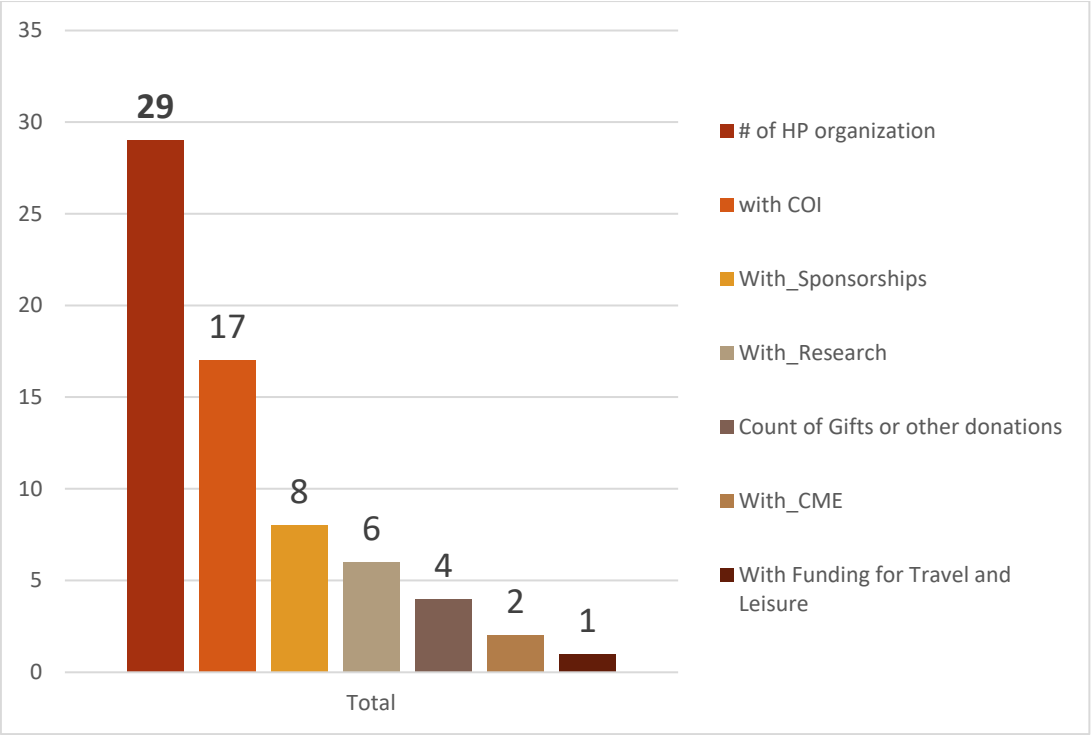
12. In 2021, our team conducted a review of health professional codes of practice and similar guidelines in Australia and internationally. This was presented to an international webinar on 15 February 2021. We identified 29 relevant health professional organisations in Australia, and retrieved their professional code of ethics or similar relevant documents to assess whether professional ethics and standards regulate health professional behaviour regarding the International Code. WHO has recently prepared specific guidance for health workers on their longstanding responsibilities under the WHO International Code, and this provides a useful checklist for evaluating the extent to which health professional association codes cover health worker behaviour on key elements of the Code (48).

13. The investigation found that all professions identified had general conflict of interest provisions in the relevant documents (see Figure below). However, for most health professional societies in Australia the professional code of ethics or code of practice documents include no specific provisions relating to International Code guidance (48) on key provisions set out in WHO guidance regarding sponsorships, continuing medical education, research or industry funding for travel and leisure.

14. Only one health professional organisation out of 29 identified as relevant organisations in Australia comprehensively covered International Code components relating to health professional responsibilities, and one other organisation covered most areas. Midwifery, nursing, paediatric, obstetric and gynaecology health professional organisations all had little or no content regulating compliance with International Code standards for protecting and supporting breastfeeding in healthcare facilities and services.

15. The preliminary findings of our research are therefore that the International Code is not implemented in Australia through ethics and standards set down in health professional organisation codes of practice.

Figure 4: Australian health professional organisation ethical codes or standards on International Code



Source: see text

16. Further details on the organisations identified and the nature of these provisions are provided in Appendix C.

17. Our study provides evidence that obligations under their own professional ethics and standards do not reflect WHO guidance and are not sufficient to prevent health care professionals being influenced by formula company marketing. Furthermore, only around 20% of Australian maternity care facilities are accredited as Baby Friendly Hospitals which includes Code compliance and staff training on the Code as a requirement for accreditation (44, 49). In the absence of evidence to the contrary it is reasonable to assume that the marketing of breastmilk substitutes to health professionals contrary to WHO and NHMRC guidance is likely to significantly undermine the aims of the MAIF Agreement for the purpose of this assessment.

GIFTS, DONATIONS AND INDUCEMENTS

18. In para 4.69. The ACCC acknowledges that 'the MAIF Agreement, in prohibiting "inducements" to health care professionals, does not go as far as WHO recommendations, which extend to prohibiting all gifts or donations. Further, that the use of the term "inducement" within the MAIF Agreement potentially permits a broad interpretation of gift giving and donations permitted. We note in this regard that Transparency International UK guidelines (50) do not distinguish inducements and bribery. Inducements can take the form of money, gifts, loans, fees, rewards or other advantages (taxes, services, donations, favours etc'.) Bribery is:

> *'... the offering, promising, giving, accepting or soliciting of an advantage as an inducement for an action which is* illegal*, unethical or a breach of trust.'*

SUMMARY

19. In summary, firstly, there is evidence that health professionals are influenced in their practice by pharmaceutical marketing, and there is specific evidence that Australian health professionals, facilities and services are perceived by mothers to promote giving formula to newborns. To our knowledge there is no published Australian research evidence on the question of whether health professionals are being influenced by gifts or donations from INC members. Nevertheless, the balance and tendency of available evidence on formula marketing to health professionals in Australia is that influence on health professional practice such as through gifts and donations is likely to be occurring. The ACCC cannot therefore be confident that MAIF is providing public benefit by preventing or restraining marketing of milk formula products to health professionals in Australia. Secondly there is Preliminary research evidence that health professional codes of practice and standards do not regulate interactions with health professionals on the international code In line with specific who Guidance.
20. On this basis, voluntary MAIF guidelines on marketing via interactions in health channels cannot support an ACCC determination to re-authorise MAIF on the grounds of supposed public benefit from the Agreement preventing or reducing negative marketing effects on breastfeeding via this channel. Similarly the existence of health professional codes of practice and standards cannot support an ACCC determination that potentially adverse influence of formula marketing via health channels including health professionals is sufficiently prevented or restrained by such codes.

RECOMMENDATIONS

1. In light of the above, we recommend that the ACCC make it a condition of authorisation that all INC guideline documents on relationships with health professionals fully incorporate the WHO International Code guidance for health workers.
2. As in our previous submission, INC guidelines should be formally part of the MAIF.
3. We further urge that the ACCC strongly encourage all relevant health professional organisations seeking ACCC authorisations to add Code compliance into their ethical and professional codes of practice.

4 WHO CURRENTLY BEARS THE COST OF REGULATING MILK FORMULA MARKETING, AND WHAT IS THE REAL COUNTERFACTUAL TO MAIF – IS IT REALLY MORE RAMPANT MARKETING?

We request that the ACCC take account of the regulatory cost to civil society organisations and individuals, collect evidence on such costs, and compare these costs with the regulatory cost of effective legislation to implement the Code in Australia, and the net fiscal costs of effective regulation that increases breastfeeding and reduces health costs.

1. At para 4.10 ACCC states its opinion 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 infant formula as they see fit, subject to the requirements of food standards legislation and the Australian Consumer Law’. At para

4.12. ACCC again states its assumption 'that in the future without the Conduct, the signatories to the MAIF Agreement are likely to promote the sale of infant formula alongside their promotion of toddler milk and other breast milk substitutes'. However, we note that in para 4.12, the ACCC also acknowledges that,

due to the reputational risk of advertising infant formula, it is possible that some Council members may voluntarily abide by much the same restrictions without an agreement.

2. At para 4.71, the ACCC states that

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 its obligations under the WHO Code. While the nature and scope of such a response is uncertain, the ACCC accepts that any regulatory response would impose regulatory costs on industry, government and regulatory agencies to develop, implement and enforce a new regime.

3. At para 4.72. the ACCC states that 'Although a compulsory regulatory approach may address more of the concerns raised by interested parties in relation to the ACCC's assessment, the ACCC is of the view 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 to the extent that it leads to avoiding these regulatory costs, at least in the short to medium term.'

It appears from the above that the ACCC views the main counterfactual as being regulatory costs on industry, government, and regulatory agencies. We submit that this should not be a decisive consideration in the ACCC determination.

4. Furthermore, we note that the current model imposes regulatory costs on civil society, and request the ACCC to acknowledge these regulatory costs, as elaborated later in this section.

EVIDENCE ON VARIOUS COSTS OF IMPLEMENTING PUBLIC HEALTH REGULATION

5. Evidence of regulatory cost in this area is very limited, and low quality as indicated in our previous submission. Reliable evidence is needed. Members of this team estimated the cost of implementing the WHO International Code using a validated international tool at around US$1.1 million in 2020 (51).
6. The WHO Framework Convention on Tobacco Control (WHO FCTC) potentially provides relevant precedent on implementing effective public health regulation (52), as well as relevant Australian information about time frames and regulatory costs of legislation. Experience with tobacco control and plain packaging in Australia shows that a relatively short time frame for implementing such legislation is possible (53). The major public costs of plain packaging of cigarettes in Australia are likely to be the significant legal costs incurred in order to resist industry attempts at 'regulatory chill' to delay public health measures, via litigation invoking international trade treaties (53).
7. Also a number of countries strongly legislate the Code such as India and the Philippines. No data is available on the regulatory cost of such interventions but neither are high income countries like Australia. China and Indonesia are comparable countries but with weaker implementation hence regulatory costs are unlikely to be higher than in India or Philippine's.

8. On the other hand, data is available on the growth in sales of milk formula in these countries. This information is presented in the presentation slide below (54). It suggests that the regulatory cost of implementing an alternative regulatory arrangement to the INC MAIF is not a substantial cost in relation to the public benefit of restraining milk formula marketing and protecting breastfeeding. The data in the graph are sourced from Euromonitor International.
9. There is strong evidence from many countries (15, 55) including Australia (11, 12) that the health cost savings from increased breastfeeding are substantial, so the costs of regulation must be considered against these potential fiscal savings.

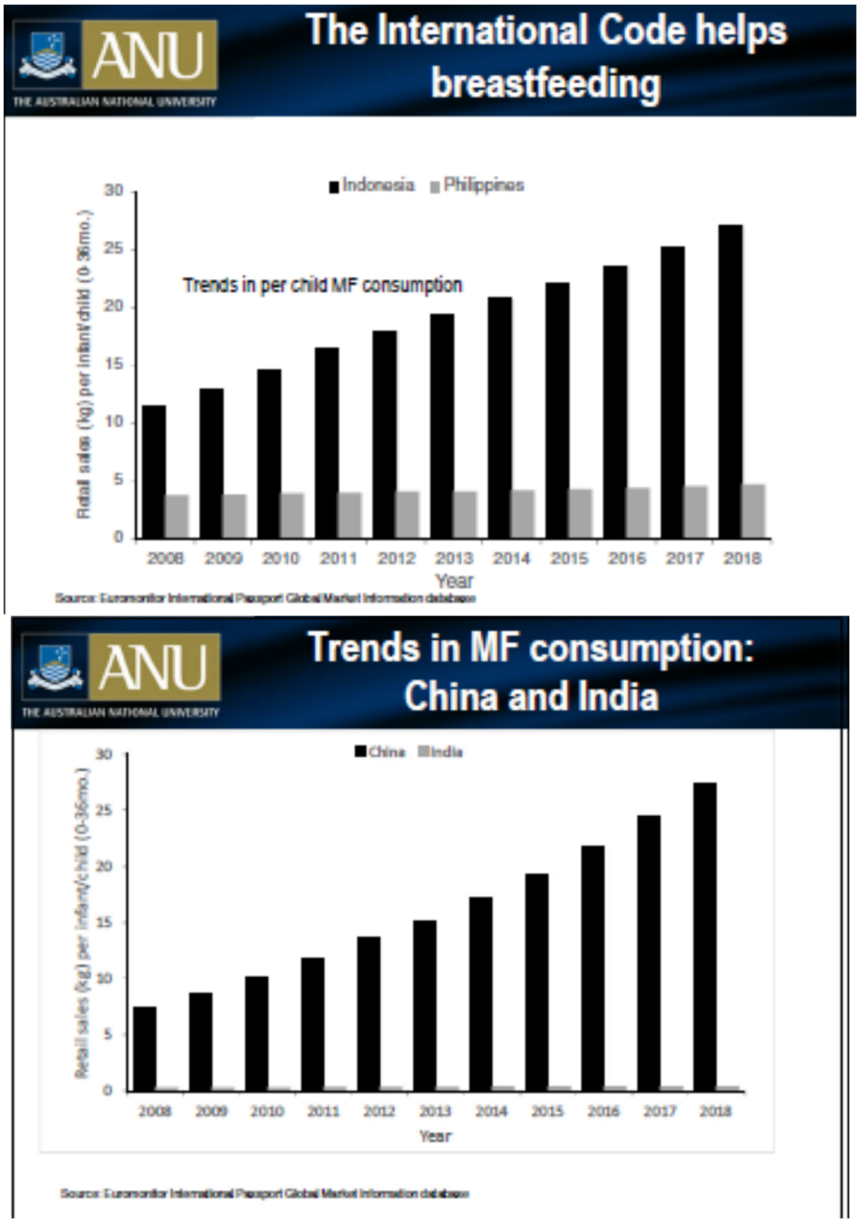


Figure 5: Comparison of per capita milk formula sales in countries with 'weak' vs 'strong' Code legislation

Source: (54)

BENEFITS TO INDUSTRY OF MAIF

10. The stated objectives of current policy as noted by the ANBS include to 'strengthen regulation of marketing so that inappropriate marketing of BMS ceases', and also for 'health professionals to receive education and training on breastfeeding that is not commercially influenced' (56). This is highly relevant to consideration of regulatory cost, and the contemporary counterfactual to current MAIF arrangements.

11. We appreciate ACCC acknowledging that INC member companies may restrain their advertising voluntarily to protect their public reputation. We note also that companies restrain their advertising voluntarily to avoid stricter regulation. Noting the structure of this industry and related evidence on food industry strategies noted in Section 1, it is possible that certain large INC member companies may have less need to market to the public than newcomers to the market because they already have a well established market share. INC member companies may have less need to market to the public that newcomers to the market because they already have crucial marketing access through health channels (see Section 3).

12. Importantly we draw the attention of the ACCC to the fact that like the tobacco industry (53), INC members may be motivated to maintain MAIF for strategic reasons related to WTO processes.

13. We have previously submitted that countries can and should regulate to protect public health, and that the WHO has recently offered guidance on this issue (16, 57). We have also identified that international trade treaties (World Trade Organization) and dispute processes have been used to intimidate governments such as in Hong Kong or the Philippines which have attempted to legislate the WHO International Code.

14. In June 2020, the World Trade Organization's (WTO's) Appellate Body decided in favour of Australia on the final remaining legal challenge to Australia's tobacco plain packaging laws. Finding that that tobacco plain packaging contributed to the objective of reducing tobacco use and exposure, the WTO also found it was not more trade-restrictive than necessary to achieve that public health objective, and that it did not infringe any intellectual property rights under the WTO Agreements.(58)

15. Just as tobacco companies challenged Australia's plain package tobacco control measures using trade treaties and WTO processes, milk formula companies have used international trade agreements to resist and prevent governments bringing in effective regulation of baby food marketing. Companies and their representatives argue in such fora that the industry self-regulatory arrangements in place in Australia and New Zealand are a sufficiently effective and more proportionate public health policy response, in order to prevent effective legislation or regulation in many countries around the world (59-63). This occurred in Hong Kong, and the Philippines and is now happening in an African country that has legislated the Code

16. Maintaining the fiction that the Australian and New Zealand MAIF arrangements are an effective public health response to the objective of promoting breastfeeding and ending inappropriate promotion of breastmilk substitutes is evidently important to the global counterregulatory strategy of the food industry. Hence INC members may threaten to leave the MAIF Agreement but are unlikely to do so as the industry will then no longer be able to use this example of industry self regulation in international trade fora to head off effective national regulation of marketing of breastmilk substitutes.

17. In the light of experience in other countries,(59-63) we urge the ACCC to investigate and account for any global strategic benefit to industry (and possible detriment to the Australian and global public) from INC members being able to display MAIF in litigation at the WTO as a 'poster boy' example in relation to legal tests on effective and proportional public health responses to the problem of milk formula marketing (64).
18. Also regarding the counterfactual MAIF, we already have what might be considered 'rampant' advertising in Australia including online. Based on past history, the MAIF simply shifts advertising to non regulated products such as toddler milk and other baby food products (19), supporting the argument that the counterfactual is little different from the MAIF status quo.

OUTSOURCING MONITORING COSTS OF REGULATION

19. We request that the ACCC should take into account and gather reliable data on the costs to the public of monitoring and attempting to enforce the Code in Australia under various self-regulatory or legislated regimes, as these costs to civil society appear to be considerable.
20. Evidence from research showing the benefits to industry from substituting self regulation for effective regulation should also be taken into account in determining the extent of detriment to the public from authorising MAIF.

SUMMARY

21. Lack of costs to government does not mean that the current arrangements are low costs because costs are incurred by others including NGOs and members of the public. The high costs of making a complaint via MAIF in return for zero results should be considered. The high costs to civil society of monitoring company marketing behaviour and responding to it in the public interest should also be considered.

RECOMMENDATIONS

1. We request that the ACCC collect and consider evidence of the cost to civil society organisations and individuals of monitoring and enforcing compliance of industry under 'self-regulation', and compare these with the regulatory cost of effective legislation to implement the Code in Australia, or with the cost of matching industry investment in marketing of breastmilk substitutes with promotion of breastfeeding from public budgets.

5. AUSTRALIAN EXPORT MARKETING ACTIVITIES SHOULD BE COVERED COMMENSURATE WITH AUSTRALIA'S HUMAN RIGHTS OBLIGATIONS AND TO PROTECT PUBLIC HEALTH FROM COMPANY STRATEGIES IN WTO PROCESSES

We urge that the ACCC's assessment of public benefit include marketing conduct of INC members in export markets, as required by Australia's trade practices law and human rights commitments.

ACCC POWER TO REGULATE COMPANIES MAY EXTEND WIDELY AND TO COMPANIES' OVERSEAS CONDUCT

1. Some submitters on the INC application drew attention to the marketing practices of Australian companies in south-east Asia (65, 66). Representing mothers and babies in two of

the world's lowest income countries, they urged the ACCC to take action to restrain Australian companies from marketing milk formula products in breach of local laws, and contrary to the MAIF Agreement that companies have signed up to in Australia. Such milk formula export promotion undermines policies of protecting and promoting breastfeeding in these countries, and undermines the human rights of women and children (67-69).

2. However, at para 4.4 ACCC states that it is not within the scope of the ACCC's assessment of this authorisation application to 'consider conduct which occurs outside of Australia'.
3. We do not profess legal expertise in this area but understand that under section 51 of the Constitution, the Commonwealth may make laws relating to foreign corporations, and trading or financial corporations formed within the limits of the Commonwealth.
4. The ACCC has also taken the position that it has the power to regulate in this way, for example regarding technology companies. It is reported that the ACCC position on the jurisdiction of Australia law is that,

> *if you're accepting money from Australian consumers … if you're engaging in business in Australia, then you have to comply with Australian law.'22*

5. The public benefit test is also said to be interpreted broadly by the ACCC, such as encompassing growth of exports from Australia (70).
6. We therefore ask the ACCC to fully consider the extent of its powers to attached conditions to any reauthorisation of MAIF and have regard to public benefit associated with the MAIF applying equally to consumers in countries to which Australian companies export milk formula.

OBLIGATIONS OF AUSTRALIAN GOVERNMENT AGENCIES UNDER INTERNATIONAL HUMAN RIGHTS TREATIES

7. Furthermore Australia is signatory to several general and specific international human rights treaties which require it to regulate marketing of breastmilk substitutes and protect the rights of women and children to breastfeed, such as the Convention on the Rights of the Child, and the Convention on the Elimination of All Forms of Discrimination Against Women (71).
8. Countries which are signatories to such treaties have obligations to apply regulations extraterritorially where they have relevant legislation (72). This is the conclusion based on legal research conducted over a period of more than a decade by global legal experts on international human rights laws. Drawn from international law, the Maastricht principles aim to clarify the content of extraterritorial State obligations to realize economic, social and cultural rights with a view to advancing and giving full effect to the object of the Charter of the United Nations and international human rights.

This suggests that the ACCC has the obligation as an agency of the Australia government to extend its consideration to the effects of marketing by Australian companies in export markets. It also suggests that the ACCC also has the legal duty to do so.

9. In light of the above, we therefore urge the ACCC to fully investigate its authority and options for protecting breastfeeding from Australian milk formula exporters and Australian trade officials promoting milk formula exports to consumers in Cambodia, Myanmar and other countries, and consider making a condition of reauthorisation that the MAIF be extended to Australian export markets.

CONCLUSION

1. At para 4.80 the ACCC states that it

> *'considers that the assessment of the public benefit and detriment is finely balanced. This is because there is a substantial risk that much of the claimed public benefit will not be realised as a result of the marketing of toddler milk by infant formula companies effectively promoting infant formula.'*

2. At para 5.3 and elsewhere at para XXX, the ACCC states that

> *'Under subsections 90(7) and 90(8) of the Act, the ACCC must not grant authorisation unless it is satisfied in all the circumstances that the Conduct is likely to result in a benefit to the public and the benefit would outweigh the detriment to the public that would be likely to result from the Conduct.*

3. It is our submission that the ACCC must not grant this authorisation unless it ensures that the net public benefit is both certain and substantial. It is beyond power to grant the authorisation when the ACCC assessment is that the net benefit is both uncertain and finely balanced.
4. No evidence has been presented by INC or identified by ACCC that shows the MAIF actually provides significant and certain public benefit in terms of protecting and promoting breastfeeding. The evidence including since 2016 is to the contrary. Reauthorising MAIF delays effective regulation and public benefit, and detrimentally gives a highly concentrated and powerful industry the gift of an unwarranted 'social licence', reputational benefit, and strategic tools for resisting public health regulation globally. Furthermore, there is plausible evidence of detriment, and demonstrably high costs to civil society organisations and individual women of futile attempts to regulate industry behaviour when the Australia government itself fails in its responsibility to act to protect public health.
5. If the ACCC does grant this authorisation it must take steps to increase the certainty and the level of public benefit by imposing strong conditions, and ensuring outcomes are closely monitored over a short period of time, with ample room to move if an Australian government decides to implement the decisions of parliament over many decades.

This requires at least the following:

DETAILED RECOMMENDATIONS

1. That the ACCC impose a condition on any authorisation which extends the limitations on advertising set out in Clause 5(a) of the MAIF Agreement to apply to all breastmilk substitutes, including toddler milks. Clause 5(a) Manufacturers and importers of infant formulas should not advertise or in any other way promote formulas to the general public. (WHO Code Article 5.1) We further recommend that for any future authorisation of MAIF, the ACCC require INC to provide robust evidence on the extent to which MAIF has prevented or reduced promotion or sales of breast milk substitutes, or had positive effects on breastfeeding practices, as well as public detriment.
2. That the reauthorisation period should be for 2 years. As in our 2015 submission we further recommend that the ACCC publicly indicate its intention to place this market under formal market review during 2021-22.

3. That the ACCC require as a condition of authorisation that INC revise its guidance documents covering interactions in health channels and with health professionals to achieve full compliance with the WHO International Code guidance for health workers within 2 years. These guidelines should be a formal element of MAIF. We further urge that the ACCC encourage all health professional organisations seeking ACCC authorisations to similarly add all aspects and full Code compliance into their ethical and professional codes of practice.
4. That the ACCC account for and gather evidence of the regulatory cost to civil society organisations and individuals, and compare these with the regulatory costs and net fiscal benefit of effective legislation to implement the Code and thereby increase breastfeeding in Australia.
5. That the ACCC's assessment of public benefit include marketing conduct of INC members in export markets, as required by Australia's trade practices law and human rights commitments.

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APPENDIX A: TRENDS IN BABY FOOD SALES: EXTRACT FROM EUROMONITOR REPORT ON THE AUSTRALIAN BABY FOOD MARKET, 2020

Table 1 Sales of Baby Food by Category: Volume 2015-2020

'000 tonnes

	2015	2016	2017	2018	2019	2020
Dried Baby Food	1.0	0.9	0.6	0.6	0.5	0.5
Prepared Baby Food	12.1	12.2	12.4	12.7	12.8	12.9
Other Baby Food	2.9	3.1	3.2	3.4	3.7	4.0
Milk Formula	25.6	31.7	33.4	37.1	38.2	41.4
- Standard Milk Formula	6.9	8.4	8.8	9.7	10.1	10.9
-- Liquid Standard Milk Formula	-	-	-	-	-	-
-- Powder Standard Milk Formula	6.9	8.4	8.8	9.7	10.1	10.9
- Follow-on Milk Formula	5.5	7.0	7.4	8.4	8.5	9.3
-- Liquid Follow-on Milk Formula	-	-	-	-	-	-
-- Powder Follow-on Milk Formula	5.5	7.0	7.4	8.4	8.5	9.3
- Growing-Up Milk Formula	8.6	11.5	12.2	13.8	14.2	15.6
-- Liquid Growing-Up Milk Formula	-	-	-	-	-	-
-- Powder Growing-Up Milk Formula	8.6	11.5	12.2	13.8	14.2	15.6
- Special Baby Milk Formula	4.5	4.8	5.0	5.2	5.4	5.6
-- Liquid Special Baby Milk Formula	-	-	-	-	-	-
-- Powder Special Baby Milk Formula	4.5	4.8	5.0	5.2	5.4	5.6
Baby Food	41.5	47.9	49.7	53.8	55.2	58.9

Source: Euromonitor International from official statistics, trade associations, trade press, company research, store checks, trade interviews, trade sources

Table 3 Sales of Baby Food by Category: % Volume Growth 2015-2020

% volume growth

	2019/20	2015-20 CAGR	2015/20 Total
Dried Baby Food	-1.9	-11.0	-44.2
Prepared Baby Food	1.3	1.4	7.4
Other Baby Food	7.8	6.2	35.3
Milk Formula	8.4	10.1	61.9
- Standard Milk Formula	7.6	9.4	56.7
-- Liquid Standard Milk Formula	-	-	-
-- Powder Standard Milk Formula	7.6	9.4	56.7
- Follow-on Milk Formula	9.5	11.2	69.7
-- Liquid Follow-on Milk Formula	-	-	-
-- Powder Follow-on Milk Formula	9.5	11.2	69.7
- Growing-Up Milk Formula	9.5	12.5	80.5
-- Liquid Growing-Up Milk Formula	-	-	-
-- Powder Growing-Up Milk Formula	9.5	12.5	80.5
- Special Baby Milk Formula	5.0	4.5	24.9
-- Liquid Special Baby Milk Formula	-	-	-
-- Powder Special Baby Milk Formula	5.0	4.5	24.9
Baby Food	6.6	7.2	41.8

Source: Euromonitor International from official statistics, trade associations, trade press, company research, store checks, trade interviews, trade sources

Table 4 Sales of Baby Food by Category: % Value Growth 2015-2020

% current value growth

	2019/20	2015-20 CAGR	2015/20 Total
Dried Baby Food	-1.2	-10.6	-42.8
Prepared Baby Food	2.3	2.2	11.6
Other Baby Food	11.0	10.3	63.6
Milk Formula	11.7	14.6	98.0
- Standard Milk Formula	10.4	13.9	91.9
-- Liquid Standard Milk Formula	-	-	-
-- Powder Standard Milk Formula	10.4	13.9	91.9
- Follow-on Milk Formula	14.2	17.5	123.8
-- Liquid Follow-on Milk Formula	-	-	-
-- Powder Follow-on Milk Formula	14.2	17.5	123.8
- Growing-Up Milk Formula	11.8	16.5	114.7
-- Liquid Growing-Up Milk Formula	-	-	-
-- Powder Growing-Up Milk Formula	11.8	16.5	114.7
- Special Baby Milk Formula	9.8	8.9	53.4
-- Liquid Special Baby Milk Formula	-	-	-
-- Powder Special Baby Milk Formula	9.8	8.9	53.4
Baby Food	10.2	11.7	74.1

Source: Euromonitor International from official statistics, trade associations, trade press, company research, store checks, trade interviews, trade sources

APPENDIX B: BABY FOOD MARKET SHARES: EXTRACT FROM EUROMONITOR REPORT ON THE AUSTRALIAN BABY FOOD MARKET, 2020

Table 5 NBO Company Shares of Baby Food: % Value 2016-2020

% retail value rsp Company	2016	2017	2018	2019	2020
Nutricia Australia Pty Ltd	26.4	28.2	28.2	29.6	29.6
Bellamy's Australia Ltd	17.8	14.7	18.0	13.8	13.8
Aspen Pharmacare Australia Pty Ltd	10.9	11.4	11.2	12.0	12.2
A2 Dairy Products Australia Pty Ltd	5.6	7.2	7.7	9.8	10.7
PZ Cussons Australia Pty Ltd	7.0	7.0	6.4	6.2	5.9
Nestlé Australia Ltd	4.6	4.6	4.4	4.5	4.4
Aldi Stores Supermarkets Pty Ltd	3.9	4.1	3.9	4.0	3.9
Heinz Co Australia Ltd, HJ	8.3	7.1	4.9	4.1	3.4
McCallum Industries Pty Ltd	3.0	3.1	2.9	2.9	2.9
Bubs Australia Ltd	0.1	0.1	0.5	1.1	1.7
Woolworths Ltd (Australia)	1.6	1.6	1.4	1.4	1.4
Every Bite Counts Pty Ltd	0.3	0.5	0.7	1.0	1.2
Amyson Pty Ltd	0.5	0.6	0.6	0.6	0.6
Kids Food Co Ltd, The	0.2	0.3	0.4	0.4	0.5
Organic Baby Food Co Pty Ltd, The	0.4	0.3	0.2	0.2	0.2
Bioliving Pty Ltd	0.1	0.1	0.1	0.0	-
Annabel Karmel Group Holdings Ltd	0.1	-	-	-	-
Golden Circle Ltd	-	-	-	-	-
Wyeth Australia Pty Ltd	-	-	-	-	-
Hain Celestial Group Inc, The	-	-	-	-	-
Rafferty's Garden Ltd	-	-	-	-	-
Ella's Kitchen Ltd	-	-	-	-	-
Bellamy's Organic Pty Ltd	-	-	-	-	-
Hampden Trading Pty Ltd	-	-	-	-	-
Others	9.1	9.3	8.5	8.2	7.7
Total	100.0	100.0	100.0	100.0	100.0

Source: Euromonitor International from official statistics, trade associations, trade press, company research, store checks, trade interviews, trade sources

APPENDIX C: HEALTH PROFESSIONAL ETHICS AND CODES OF PRACTICE, AUSTRALIA 2020

No	Category	Name of the organization	Link	Title	Year	COI	Sponsorships	CME	Research	Funding for Travel and Leisure	Gifts or other donations	With tools
1	Nurses	Maternal Child and Family Health Nurses Australia		Advertising and Publication position Statement	2017	Yes	Yes		Yes		Yes	
2	Nurses	Australian College of Children & Young People's Nurses		Position Statement Industry Sponsorship and Advertising	2015	Yes	Yes		Yes		Yes	Yes
3	Nurses/Midwives	Australian Nursing and Midwifery Association	https://anmf.org.au/	none found								
4	Pediatricians	The Royal Australasian College of Physicians		Breastfeeding	2007	Yes			Yes			Yes
5	Pediatricians	The Royal Australasian College of Physicians		Guidelines for the Funding of Paediatric Research by Formula Companies	2007	Yes	Yes		Yes			Yes
6	Others	Public Health Association of Australia		Policy-at-a-glance – Breastfeeding Policy	2019	Yes	Yes		Yes			Yes
7	Others	Pharmaceutical Society of Australia		Position Statement Infant Feeding	2004	Yes						Yes
8	Others	Public Health Association of Australia		Marketing of food and beverages to children	2018	Yes						
9	Nurses	Australian College of Children and Young People's Nurses		POSITION STATEMENT Industry Sponsorship and Advertising	2020	Yes	Yes					
10	Nurses	Australian College of Nurse Practitioners	no statements or policies on this website									
11	Nurses	Australian Confederation of Paediatric and Child Health Nurses	no statements or policies on this website									
12	Nurses	Australian Nurse Teachers Society (ANTS)	no statements or policies on this website									
13	Nurses	Australian Practice Nurses' Association	no statements or policies on this website									
14	Nurses	Australian Primary Health Care Nurses Association	no statements or policies on this website									
15	Nurses	Australian Women's Health Nurse Association	no statements or policies on this website									
16	Nurses	Council of Children's Nurses	couldn't find them on internet									
17	Nurses	Congress of Aboriginal and Torres Strait Islander Nurses	Constitution	Constitution	2018	Yes						
18	Nurses	National Enrolled Nurse Association	No statements or policies on this website									
19	Nurses	Enrolled Nurse Profession Association NSW	No clear policy/statement									
20	Nurses	Gastroenterological Nurses College of Australia	No clear policy/statement									
21	Nurses	Maternal, Child and Family Health Nurses Australia		Advertising and Publication Position Statement	2014	Yes	Yes	Yes			Yes	
22	Midwives	NSW Midwives Association	Home - NSW Nurses and Midwives' Asso	No statement								
23	Nurses	School Nurses Association of NSW	Standards of Practice	NATIONAL SCHOOL NURSING STANDARDS for PRACTICE: REGISTERED NURSE	2019							
24	Midwives	Australian College of Midwives	https://www.midwives.org.au/	Use of Pacifiers for the Healthy Term Breastfed Baby (ACM) Position Statement	2018							
			https://www.midwives.org.au/	Use of Human Donor Milk (ACM) Position Statement - 2014	2014							
				Code of professional standards for midwives	2018	Yes						
25	Midwives	Midwives Australia	https://www.midwivesaustralia.com.au/about-us/	Constitution	2012							
26	Physicians	Australian College of Rural and Remote Medicine		DEFINING THE SPECIALTY OF GENERAL PRACTICE	2007							
				Constitution	2001	Yes						
27	Physicians	Australian Medical Association		Position Statement on Advertising and Public Endorsement 2020	2020	Yes						
				Doctors relationship with the Industry	2018	Yes						
				AMA Guidelines for Doctors on Managing Conflicts of Interest in Medicine 2018	2018	Yes						
				Position statement on breastfeeding	2007							
28	OB-GYN	Royal Australian and New Zealand College of Obstetricians and Gynaecologists		Advertising and Sponsorship Policy	2016							
	Physicians	Perinatal Society Australia and New Zealand (PSANZ)		Policy on Formula		Yes	Yes					
29	General Practitioners	Royal Australian College of General Practitioners		Maternity care in general practice	2021							
				General Practitioners and Commercial Sponsorship	2006	Yes	Yes	Yes	Yes	Yes	Yes	