World Breastfeeding Trends Initiative (WBT*i*)

AUSTRALIA

Second submission to the Australian Competition and Consumer Commission regarding Infant Nutrition Council Limited - application for revocation of authorization AA1000534 and substitution of AA1000665

Background and evidence

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1. About the World Breastfeeding Trends Initiative Australia (WBTiAUS)

The World Breastfeeding Trends initiative (WBTi) Assessment tool was launched by the International Baby Food Action Network (IBFAN) in 2004. It was devised as a simple way for nations to measure how effectively they are implementing the WHO Global Strategy for Infant and Young Child Feeding. As of April 2024, 99 countries have completed the WBTi report. In Australia, the WBTiAUS team consists of 10-15 academics, breastfeeding and infant and maternal health expert clinicians and advocates, without conflicts of interest, who have undertaken two assessments (in 2018 and 2023). The 2018 WBTi assessment is included in the Australian National Breastfeeding Strategy 2019.

Acknowledgements

WBTiAUS thanks the ACCC for public consultation on the Infant Nutrition Council Limited - application for revocation of authorisation AA1000534 and substitution of AA1000665, the Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement (MAIF Agreement) and its associated guidelines.

- This second submission provides background information and evidence to support our first submission (dated 6 June 2024) on the revocation and authorization of the MAIF Agreement.
- Given the importance of evidence to the ACCC's decision, we also address in detail the 2023 Review of the MAIF Agreement report, in the absence of the government's response to the report.

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2. Executive Summary

2.1 Response to authorisation of the MAIF Agreement

1. WBTiAUS does **not** support the reauthorisation of the Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement (1992) and strongly recommends that the ACCC **not** authorise the Infant Nutrition Council Limited's application (AA1000665-1) for any period (i.e. 0 years).

2. Instead, we strongly recommend that the government urgently mandate the World Health Organization International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly resolutions (the 'WHO Code') in full (World Health Organization, 1981), and human rights to breastfeeding based on United Nations Conventions, to which Australia is a signatory (United Nations, 1989, 2016).

2.2 Concerns about the marketing of cell-based human milk products

1. The emergence of novel commercial products challenges the viability of the MAIF Agreement. On 3 May 2024, the Food Ministers Meeting (Australian Government, 2024) agreed to "*ensure regulation of **cell-based human milk** products is consistent with 'traditional' infant formula products*" (Australian Government, 2024).
2. However, the issues paper associated with this advice is not yet available to inform the public about these products, their use, effects on breastfeeding, marketing and regulation. We note the following further concerns:
    - The ACCC's timeframe for submissions does not permit these issues to be addressed.
    - Key questions remain about whether these products are covered by the MAIF Agreement and if their manufacturers are members of the Infant Nutrition Council.

2.3 Response to the Review of the Marketing in Australia of Infant Formulas: Manufacturers and Importers (MAIF) Agreement Final Report (5 October 2023)

WBT*i*AUS has considerable concerns regarding the 2023 MAIF Report (Allen and Clarke Consulting, 2023b). Our comments on each recommendation of the 2023 MAIF Review Report are provided in Appendix 2, and summarised as follows:

1. **The recommendations are not consistent with the WHO Code.** Unlike the WHO Code, the report does not recommend the inclusion of toddler milks and retailers (supermarkets, pharmacies and manufacturers who sell directly to consumers, via stores and/or online) in the scope of regulating the marketing of commercial milk formulas. The failure to include toddler milks and retailers renders the remainder of the report's recommendations insubstantial and inadequate to protect breastfeeding from the modern marketing strategies and influence of the globalised commercial milk formula industries, of which Australia is a part. These strategies are documented in the following reports. The absence of this key evidence is a major deficiency of the report:

    - The Lancet Series on Breastfeeding 2023 (3 papers on formula marketing) (Baker et al., 2023; Pérez-Escamilla et al., 2023; Rollins et al., 2023)

- WHO -Scope and impact of digital marketing strategies for promoting breast-milk substitutes {World Health Organization, 2022 #150} https://www.who.int/publications/i/item/9789240046085
- WHO - How the marketing of formula milk influences our decisions on infant feeding (World Health Organization, 2022a). https://www.who.int/publications/i/item/9789240044609

We agree (with major qualification) to:

- The need for a stronger regulatory model (*Recommendation 1*). However, we seek more information to understand differences between a "prescribed mandatory code" under the Competition and Consumer Act 2010 and other legislative options, such as a separate Act, which were not investigated in the Review.
- Inclusion of explicit reference to electronic marketing and advertising (*Recommendation 4*)
- A stronger monitoring system (*Recommendation 5*).
- Improved efficiency, transparency and robustness of the complaints management mechanism (*Recommendation 6*). However, we note that this measure will be weak unless the scope of regulation includes toddler milks and retailers (see Recommendations 2 and 3).
- Changes to the committee to respond to complaints (*Recommendation 7*) but call for its membership to be independent of industry, and to include: (a) a community and consumer representative to advocate on behalf of breastfeeding families; (b) a legal expert and (c) an expert on marketing and communications who understands social media marketing to parents.
- Improved mechanisms for monitoring infant feeding, including breastfeeding (*Recommendation 8*), but call for data free from industry conflicts of interest and to include socioeconomic measures and links to short- and long-term health outcomes.
- Raised awareness among health care professionals and parents/consumers about the appropriate use of infant formula (*Recommendation 9*) but include awareness of its risks and require breastfeeding education for health care professionals and parents.

We reject:

- Retention of the current scope of regulated products (Recommendation 2). We call for the inclusion of toddler milks in the scope of regulated products.
- A failure to include retailers in its scope (Recommendation 3). We call for the inclusion in the scope of regulated parties: supermarkets, pharmacies and manufacturers who sell directly to the public, through stores and/or online.
- Establishment of policies and guidelines to enable donations of infant formula in emergency and disaster contexts through reputable charities (Recommendation 10). This recommendation is egregious. It has no foundation in the body of the report, its evidence or analysis. It is well accepted that donations of infant formula cause harm to non-breastfed and breastfed infants. It is a breach of World Health Assembly (WHA) Resolution 63.23 as well the WHA-endorsed Operational Guidance for Infant and Young Child Feeding in Emergencies (OG-IFE) for donations of infant formula to be made in emergencies. WHA 63.23 states that in emergencies 'any required breast-milk substitutes are purchased, distributed and used according to strict criteria.'
  There is ample and recent evidence, that infant formula manufacturers companies use charitable donations as a form of marketing, leveraging the vulnerability of populations affected by disasters and emergencies, food insecurity and cost of living crises:
  - Australian Breastfeeding Association work in this area, funded by the federal government: https://www.breastfeeding.asn.au/emergency-resources-babies-and-toddlers.

  - Emergency preparedness for infant and young child feeding in emergencies (IYCF-E): an Australian audit of emergency plans and guidance.
  - Infant Feeding in Emergencies Core Group – International Guidance
    (Baker, Zambrano, et al., 2021) (Fitsum Assefa & Hipgrave, 2008)

2. **There are several problems concerning the report's quality, methods and analysis.** These deficiencies include:
   - Narrow representation of infant feeding policy objectives and omission of health and social inequities.
   - Limited analysis of regulatory frameworks.
   - Inadequate knowledge of breastfeeding and simplistic analysis of causation.
   - Inadequate economic analysis, which fails to address the social and environmental costs of commercial milk formula, undervalues breastfeeding, and omits the costs to government and civil society of a regulatory model that requires repeated reviews, re-authorisation and submissions.

3. **The report neglects the policy, economic and social context, including:**
   - The structural causes of low rates of breastfeeding. These causes include policy neglect, specifically the lack of coordination, implementation and funding for the Australian National Breastfeeding Strategy (ANBS) 2019, and inadequate support of breastfeeding in hospitals, which are stretched after the COVID-19 pandemic.
   - The political economy of infant and young child feeding. The political and economic factors that underpin sales of commercial milk formula products include the influence of commercial milk formula industries on policy making, at national and international levels, which diminish or delay government investment in breastfeeding and its protection.
   - Discrepancies in power between commercial and civil society actors, that are ignored in ACCC models of self-regulation. Self-regulation of commercial milk formula marketing relies on overburdened mothers and public health and breastfeeding NGOs to resist, research, police and report these activities.
   - Potential conflicts of interest arising from:
     - The INC's CEO, Jonathan Chew, has worked previously for the alcohol industry, and his appointment undermines the credibility of the INC's evidence on public health issues, including infant and young child feeding.
     - The authors of the report, Allen and Clarke Consulting, provide secretariat support for the complaints process for the Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand, which undermines the independence of their recommendations on complaints processes for the MAIF Agreement (Allen and Clarke Consulting, 2024).

3. Introduction

3.1 Concerns with the ACCC re-authorisation time frame for proper scrutiny

We thank the ACCC for an extension for submissions (to 30 June 2024).
For the record, we note the restrictions on public information and debate necessary for good policy making as follows:

- In 2021, the ACCC reauthorised the MAIF Agreement for three years (Appendix 2), despite the INC's application for a reauthorisation period of 10 years and expressed concerns regarding the effectiveness of MAIF and that toddler milks could be advertised in similar packaging as infant formulas. The ACCC was also concerned about the transparency of the complaints reporting process and that MAIF was a voluntary agreement and therefore not all formula companies were signatories. The reauthorisation period of three years allowed time for the Department of Health and Aged Care (DHAC) to review the MAIF Agreement, which was also a commitment in the ANBS.

- In 2023 DHAC engaged consultancy firm, Allen and Clarke, to undertake a review of the MAIF Agreement. This report was complete in October 2023, but only released to the public on Friday 11th April 2024. This has left very little time for public health organisations and advocates to review the report and prepare a response. In addition, we have not been provided with the government's response to the report's recommendations. This makes it difficult to understand the policy agendas of DHAC and the ACCC, and whether reauthorisation of the MAIF Agreement is feasible. WBTiAUS has sent an email to the Minister for Health and Ageing requesting that the government's response to the report's ten recommendations be made available to the public. We are yet to receive this information.

- The ACCC notified interested parties of the INC's application for re-authorisation of the MAIF Agreement on 25 Mar 2024 with submissions due on 30 Apr 2024, yet, as noted above, the MAIF review report was not released until halfway through this period. This created a grossly unfair playing field – the INC had months/years to prepare their application, unlike public health organisations, clinicians and unpaid volunteers (with employment and carer responsibilities).

NB. At time of submission there remains no indication of the government's response to 10 recommendations.

Adding to concerns to meet submission deadlines:

- On 3 May 2024, the Food Ministers Meeting (Australian Government, 2024) agreed to "*ensure regulation of **cell-based human milk** products is consistent with 'traditional' infant formula products*." However, the issues paper associated with this advice is not yet available to inform the public about the use, marketing and regulation of these products, which were not included in the 2023 MAIF Review Report. Our concerns are outlined in Section B. This has increased the time and work required to prepare submissions to the ACCC.
- This period (March-May) coincided with the delivery of the federal budget and action by advocates to lobby for funding and comprehensive implementation of the ANBS.

These comments on time are made in the interests of good public administration and to inform the ACCC in its decision on a model of regulation appropriate to the marketing of infant formula and toddler milk products. We note that the government does not monitor the marketing of these products: the burden of 'industry self-regulation' falls on civil society. The time and labour of monitoring marketing is shouldered by unpaid members of the public and NGOs, who are concerned with the inequitable state of breastfeeding in Australia and the rights of women, their children and grandchildren to health, not the protection of commercial interests in 'market share' of formula sales.

3.2 Policy context

Breastfeeding outcomes are the product of multiple, synergistic policies that remove barriers and create environments that enable breastfeeding (Rollins et al., 2016). The Australian National Breastfeeding Strategy: 2019 and beyond (ANBS) covers 10 areas for action, of which "prevent inappropriate marketing of breastmilk substitutes" is one. The WBTI assessment covers ten key policy domains necessary to achieve high rates of breastfeeding, through the promotion, protection, and support of breastfeeding in homes, health settings, workplaces and wider society, based on the 2003 WHO Global Strategy for Infant and Young Child Feeding(World Health Organization, 2003). Nations need to implement most of the ten policy domains to provide an environment that supports women to achieve their breastfeeding goals and improve health outcomes. This policy complexity has implications for types of evidence, and 'strength of evidence' relevant to policy making that are discussed in our response to the 2023 MAIF Review Report (Appendix 2).

3.2.1 Structural causes of inadequate rates of breastfeeding

WBTi reports for Australia (World Breastfeeding Trends Initiative, 2024) show deficiencies in multiple policy domains, for example, inadequate health professional breastfeeding education and institutional support (see WBTiAus Indicator 5 in Appendix 1). For Australian women, access to a Baby Friendly Health Initiative (BFHI) accredited hospital decreased from 26% to 21% (see Indicator 2 in Appendix 1). Importantly, the comprehensive WBTi assessment establishes the broader policy context for the regulation of marketing (see WBTiAus Indicator 3 in Appendix 1). These policy gaps are structural drivers of inadequate breastfeeding and make Australian families more vulnerable to marketing (World Health Organization, 2022a). These structural drivers make the effects of marketing on infant and maternal health more inequitable, and the effective regulation of marketing, imperative (Baker, Santos, et al., 2021).

The 2023 MAIF Review report ignores these structural drivers and perpetuates the fiction that individual women are primarily responsible for low rates of breastfeeding. This misleading paradigm frames the model of causation and evidence used in 2023 MAIF Review Report, and limits its recommendations for regulation of marketing, as discussed in Appendix 2 of our submission.

3.2.2 The political economy of infant and young child feeding

The policy context for the regulation of commercial milk formula marketing includes the political economy of infant and young child feeding. This political economy identifies the underlying interests and power of various stakeholders from government, industry and civil society ('actors')(Baker, Russ, et al., 2021; Baker et al., 2023). The ways that commercial interests exert power to influence infant feeding policies in their favour and shape under-investment in breastfeeding programs is well documented(Baker,

2020; Baker et al., 2023; Boatwright et al., 2022; Pérez-Escamilla et al., 2023; Rollins et al., 2023). This evidence is missing in the 2023 MAIF Review Report and provided in Appendix 2 of this submission.

The political economy of infant and young child feeding explains why we have seen four decades of pervasive, predatory marketing and piecemeal regulation erode the sociocultural base of breastfeeding(World Health Organization, 2022a). It explains why the current ineffective model of regulation persists, and how interests in trade and markets in commercial milk formula prevail at the cost of public health.

In a democracy, the government has a role to protect the vulnerable and implement their rights to health, yet women, infants and young children are abandoned to the market(United Nations, 1989, 2016). Decades of reviews (Knowles, 2001; Best Start Report, 2007; Nous Group, 2012; Nous Group, 2017; Allen and Clarke, 2023) show that the market wins every time, with no change to the scope and substance of the MAIF Agreement. This inaction exposes the deepest flaw in our regulatory system: its inability to reform our economic and health systems, in response to threats from corporations and climate change. It is time for Australian regulators to recognise the scale of these threats and work proactively to defend public health.

3.3 Climate, disasters, conflict and breastfeeding

In addition, the policy context for infant feeding includes the importance of breastfeeding to climate change adaptation and mitigation, and disaster and emergency planning and response(Infant Feeding in Emergencies Core Group, 2017). Infants and young children and their mothers are uniquely vulnerable in natural disasters and emergencies, including those driven by climate change, wars and civil unrest (Ratnayake Mudiyanselage et al., 2022; Summers & Bilukha, 2018). In these situations, disruption to supply chains and the risks of infection from bottle feeding make dependency on commercial milk formulas a national vulnerability, and not merely a matter of individual "informed choice" (Salmon, 2015). Breastfeeding is a pillar of national food security ('first food security'), as recognised in the 2022 Parliamentary Inquiry into Food Security in Australia, and the WBTiAUS-ABA submission to that inquiry(Commonwealth of Australia, 2023; WBTiAUS, 2022) (Appendix 3). Protecting breastfeeding includes emergency and disaster planning that incorporates measures to support breastfeeding and control the appropriate use, provision and distribution of commercial milk formula (Infant Feeding in Emergencies Core Group, 2017).

As our communities face climate change-driven threats to food systems, food security and health equity, we need to re-focus on breastfeeding's role in adapting to and mitigating these threats (Tomori, 2023) (Smith JP, 2024). Infant feeding is no longer a matter of "consumer choice." It needs a whole-of-government approach to put in place the institutional and societal structures that enable breastfeeding and protect our future.

National and global threats to food security raise the stakes on policy makers to protect breastfeeding from predatory marketing. The centrality of breastfeeding to national resilience to climate change challenges the remit of the ACCC and current policy objectives and policy-making criteria. Accordingly, we call for the Australian government protect its people, to abandon the MAIF Agreement as unfit for purpose, and commit to mandate the World Health Organization International Code of Marketing of Breast-milk Substitutes and subsequent World Health Assembly resolutions (the 'WHO Code') in full to genuinely protects breastfeeding.

4. Examples of marketing commercial milk formulas via toddler milks, retailers and health systems

The policy context includes the dynamic influence of marketing practices, which help normalise the use of commercial milk formulas in our communities and health systems, defuse outrage, reduce demand for policy makers to act, test the limits of regulation and enable more aggressive marketing. Exposure to products implies that they are safe and appropriate and endorsed by government health authorities. Two current examples are described here. Under the MAIF Agreement, the marketing of infant formula products is enabled and continues through toddler milks, retailers, electronic media and health professional associations in ways that undermine breastfeeding (Figs 1-4). This type of evidence has been presented in numerous previous submissions to the ACCC: in 2015 and 2020-21 (Appendix 4) and the four reviews of MAIF since the year 2000(Allen and Clarke Consulting, 2023b; Knowles, 2001; Nous Group, 2012; The Parliament of the Commonwealth of Australia, 2007). These reviews are no longer available to the public on the Department of Health and Aged Care website (Appendix 5). This evidence showed that the scope of products and activities covered by the MAIF Agreement is inadequate and that industry self-regulation is ineffective (Ching et al., 2021).

The first example shows endorsement by health professionals and toddler milks to sell commercial milk formula in supermarkets (Nutricia, Aptamil Gold, Figure 1), and the second example shows how commercial milk formula companies influence professional associations and health professionals through conference sponsorship and "education" (Nestle and DoHAD ANZPac, Figures 2-4).

These egregious examples illustrate how such marketing strategies worsen **health inequities** at local and global scales; the supermarket serves a disadvantaged community, and the conference serves a disadvantaged region.

Example 1: Marketing strategy to influence parents and carers by endorsement by health professionals and toddler milks in supermarkets (Nutricia Aptamil Gold)

Figure 1a shows a claim by a formula company (Nutricia) that paediatricians recommend a brand of commercial milk formula. Evidence shows that health professional endorsement of products is a powerful influence on parents and carers and their infant feeding decisions to start using commercial milk formula and to use a particular brand(Hastings et al., 2020; Pérez-Escamilla et al., 2023; Rollins et al., 2023; World Health Organization, 2022a). The image is from a prominent banner protruding into a supermarket aisle (Fig.1b) and is notable because this type of marketing contributes to health inequities. The supermarket in question serves areas with some of the greatest levels of socioeconomic disadvantage in the ACT (ACT Government, 2012).

Figure 1a. Marketing through retailers: using the authority of health professionals to market toddler milk on a banner in a supermarket aisle. (Woolworths, Charnwood ACT, 19 October 2023).

Figure 1b. Product placement and tactics to market infant formula (0-12 months) by marketing of toddler milks (12-36 months) through product placement, shelf position, label claims and banner. (Woolworths, Charnwood ACT, 19 October 2023).

This example shows the ineffectiveness of the MAIF Agreement to protect parents and carers from predatory marketing. The milk formula company is a member of the Infant Nutrition Council and a signatory to the MAIF Agreement. However, the MAIF Agreement does not apply to the marketing of toddler milks (the product shown on the banner). In addition, the banner and tins of toddler milk are placed adjacent to infant formula products on the shelf. Product placement and virtually identical label designs are recognized as “cross-marketing,” a strategy used to circumvent restrictions on marketing infant formula(Hastings et al., 2020).

Example 2: Marketing to influence professional associations and health professionals through conference sponsorship and "education" (Nestle and DoHAD ANZPac)

The Developmental Origins of Health and Disease Society of Australia and New Zealand and the Pacific (DoHAD ANZPac) is a 'society is made up of scientists, doctors, health workers and public health experts dedicated to studying how a healthy start to life can reduce the risk of developing many diseases, both now and in the future'(DOHaD, 2024). This example shows how DoHAD ANZPac is a vehicle for marketing by the globalized commercial milk formula industry to influence health professionals regionally (Figures 2-4). Through DoHAD ANZPac, commercial milk formula companies can influence health professionals in the richest and poorest communities in Australia and our region, which include some of the poorest in the world.

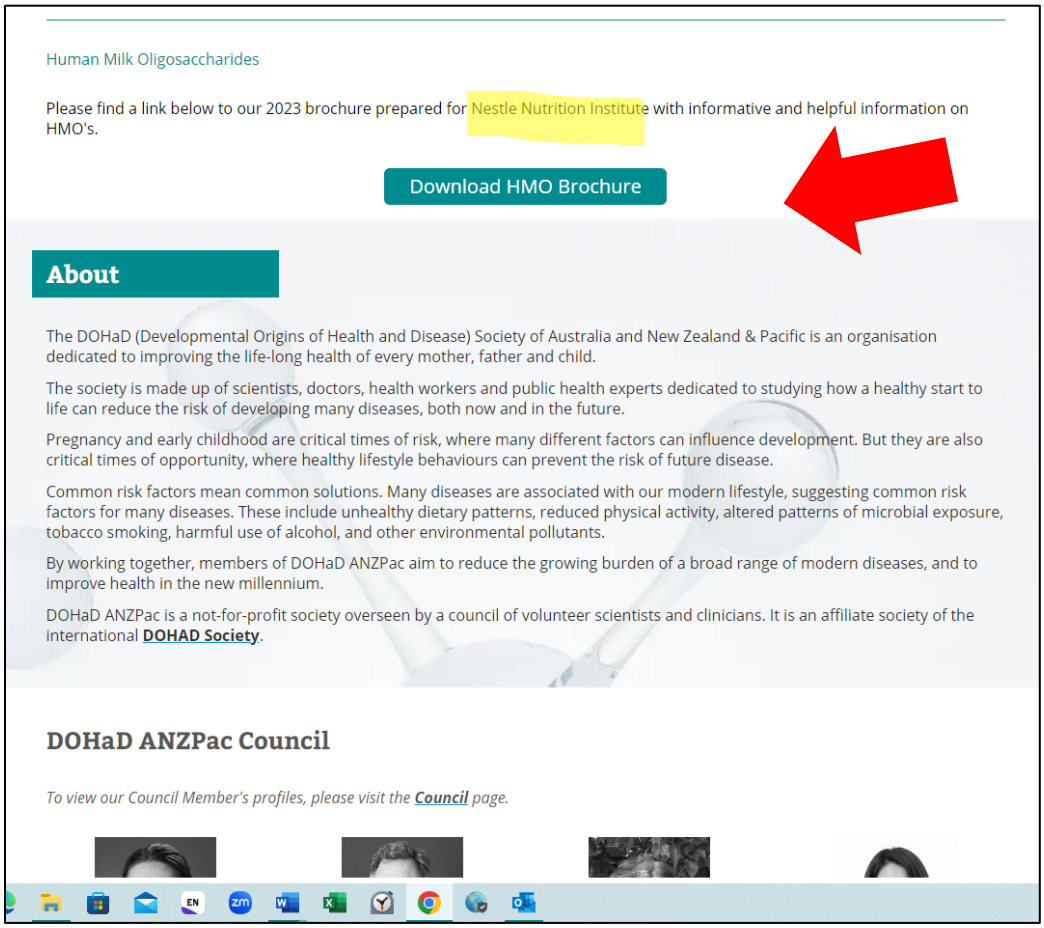
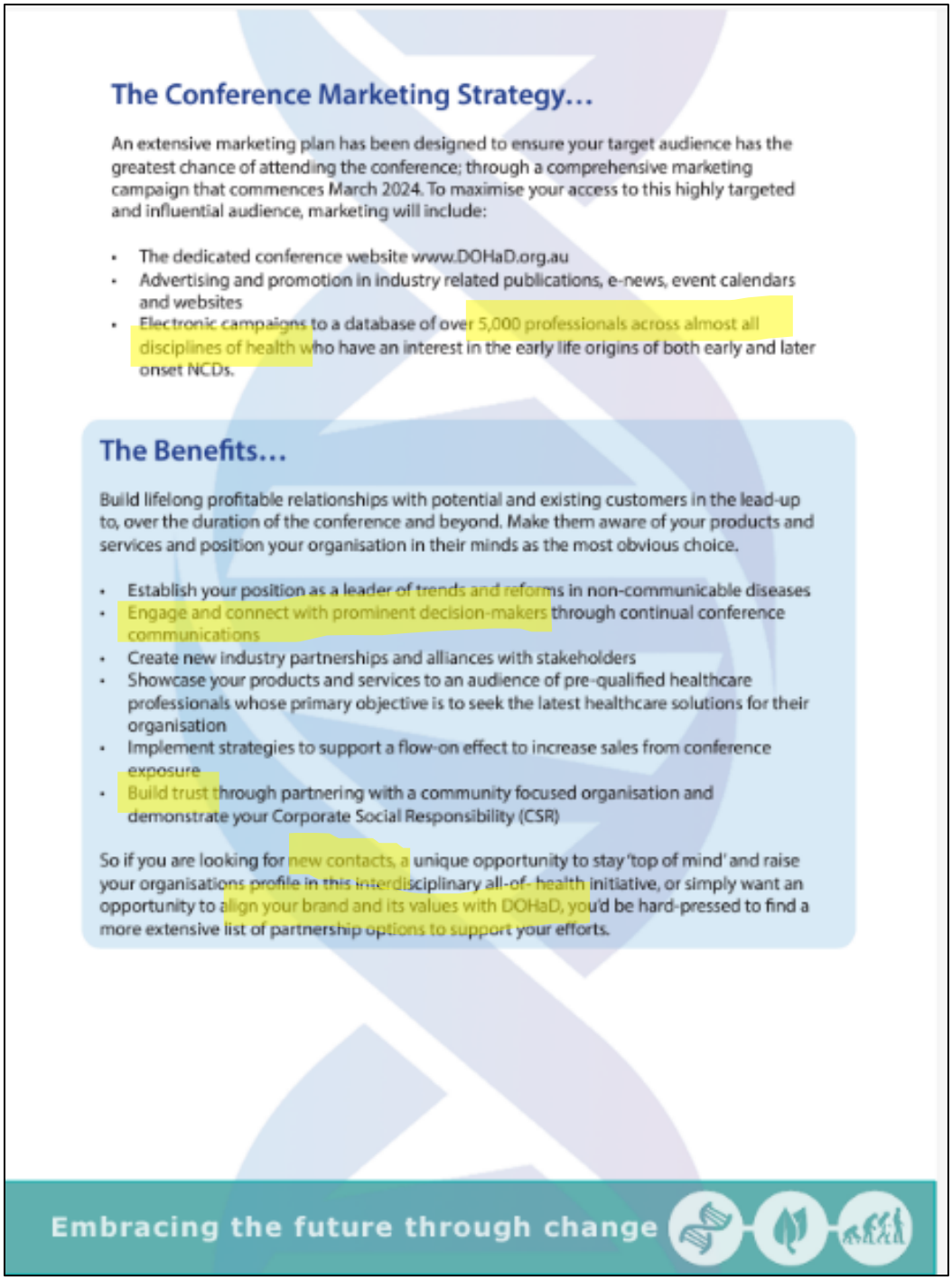


Figure 2. Marketing through health professional associations: branded information by Nestle Nutrition Institute about Human Milk Oligosaccharides, a novel ingredient of infant formula and toddler milks, on the main webpage of the DoHAD ANZPac Society, placed above the society's statement about the importance of 'dietary patterns' and other factors to disease risks(DOHaD, 2024).

Figure 3. Marketing through health professional education: branded information and talks by Nestle Nutrition Institute and use of industry-funded research for the 2024 DoHAD ANZPac conference. Flyer sent via email to potential attendees (DOHaD, 2024).



The Conference Marketing Strategy…

An extensive marketing plan has been designed to ensure your target audience has the greatest chance of attending the conference; through a comprehensive marketing campaign that commences March 2024. To maximise your access to this highly targeted and influential audience, marketing will include:

- The dedicated conference website www.DOHaD.org.au
- Advertising and promotion in industry related publications, e-news, event calendars and websites
- Electronic campaigns to a database of over 5,000 professionals across almost all disciplines of health who have an interest in the early life origins of both early and later onset NCDs.

The Benefits…

Build lifelong profitable relationships with potential and existing customers in the lead-up to, over the duration of the conference and beyond. Make them aware of your products and services and position your organisation in their minds as the most obvious choice.

- Establish your position as a leader of trends and reforms in non-communicable diseases
- Engage and connect with prominent decision-makers through continual conference communications
- Create new industry partnerships and alliances with stakeholders
- Showcase your products and services to an audience of pre-qualified healthcare professionals whose primary objective is to seek the latest healthcare solutions for their organisation
- Implement strategies to support a flow-on effect to increase sales from conference exposure
- Build trust through partnering with a community focused organisation and demonstrate your Corporate Social Responsibility (CSR)

So if you are looking for new contacts, a unique opportunity to stay 'top of mind' and raise your organisations profile in this interdisciplinary all-of- health initiative, or simply want an opportunity to align your brand and its values with DOHaD, you'd be hard-pressed to find a more extensive list of partnership options to support your efforts.

Embracing the future through change

Figure 4. The DoHAD ANZPac 2024 conference brochure on sponsorship. This marketing strategy is being used by commercial milk formula companies to influence health professionals in Australia and countries in the Asia-Pacific region and shows why the Australian government must act to implement the WHO Code in full as legislation and support similar action globally.

The DoHAD ANZPac 2024 conference brochure on sponsorship states that '*globalization has contributed to significant nutritional transitions in Pacific populations*' and promotes DoHAD as '*highly relevant as the Pacific region, as it has the highest rates of non-communicable disease risk and incidence globally'*. Yet, astonishingly, DoHAD enables commercial milk formula companies to promote products that contribute directly to infant and young child dietary transitions and non-communicable and communicable disease burdens in this region (DOHaD, 2024).

The DoHAD conference marketing strategy is explicit about the influence and reach of its event:

> '*To maximise your access to this highly targeted and influential audience, marketing will include:*
> *• The dedicated conference website www.DoHAD.org.au*
> *• Advertising and promotion in industry related publications, e-news, event calendars and websites*
> *• Electronic campaigns to a database of over 5,000 professionals across almost all disciplines of health who have an interest in the early life origins of both early and later onset NCDs*.'

DoHAD's dereliction of the WHO Code allows commercial milk formula companies to use DoHAD to boost their corporate image ("green washing" or "halo effect") and blatantly states:

> '*Build trust through partnering with a community focused organisation and demonstrate your Corporate Social Responsibility (CSR)'* (DoHAD ANZPac 2024 conference brochure on sponsorship (DOHaD, 2024))

This type of marketing shows why Australia's implementation of the WHO Code must be comprehensive in scope and cover exporters, in addition to manufacturers, importers and retailers.

These examples demonstrate why simplistic concepts of 'consumer choice' are inadequate to protect breastfeeding.

The Australian government must act to implement the WHO Code in full as legislation that covers the scope of these activities, products and actors, and lead and support other countries to do so.

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5. WBT*i*AUS assessment of the regulation of commercial milk formula marketing in Australia

One of the ten indicators that the WBTi assesses is the protection of breastfeeding from inappropriate marketing (Indicator Number 3), according to the WHO Code and all the subsequent World Health Assembly (WHA) resolutions (World Health Organization, 1981).

The WHO Code exists:

1. to support the reproductive rights that women hold in relation to breastfeeding and the right of the child to health (Gribble & Gallagher, 2014) (Gribble et al., 2011).
2. because of the unique vulnerabilities of new mothers and infants, and the acceptance by governments that decisions about feeding of infants and young children should not be influenced by exploitative marketing.

As a member of the WHA, Australia is obliged to implement the WHO Code in its entirety, which includes 20 subsequent WHA Resolutions to address the harmful effects of marketing commercial milk formulas, foods, feeding bottles and teats for infants and young children aged 0-36 months. However, Australia has implemented very few of the provisions of the WHO Code nor enshrined them in legislation(World Health Organization, 2022b). This leaves substantial gaps in the regulation of the promotion, labelling and packaging of commercial breastmilk substitutes and foods for infants and young children in Australia(The Parliament of the Commonwealth of Australia, 2007).

Australia's current measures to implement the WHO Code consists of a voluntary, industry self-regulated Code of Practice, the MAIF Agreement, is claimed by the Australian government and the commercial milk formula and baby food industries to give effect to the WHO Code(COAG Health Council, 2019). However, as now acknowledged in five reviews, the MAIF Agreement is outdated, limited in scope, poorly governed and unenforceable(Allen and Clarke Consulting, 2023b; Knowles, 2001; Nous Group, 2012, 2017; The Parliament of the Commonwealth of Australia, 2007).

The MAIF Agreement only applies to infant and follow-on formula for children aged 0 to 12 months and excludes toddler milk drinks and commercial baby foods, as well as bottles and teats. Retailers are not included and not all manufacturers and importers are signatories(Allen and Clarke Consulting, 2023b). It does not prohibit samples or free or low-cost formula supplies to health or education facilities. Transparency around the interpretation and monitoring of the MAIF Agreement is minimal(Nous Group, 2017) and when a breach is found to have occurred there is no penalty imposed aside from being named on the Department of Health and Ageing website.

Despite many review recommendations to strengthen WHO Code implementation by widening its scope and improving monitoring and enforcement, the MAIF Agreement is substantially unchanged since first introduced. Provisions which implement the WHO Code in Australia are decades out of date. Implementation including Ministerial accountability has been weakened in the past decade.

Further to these reviews, the WBT*i*AUS assessments identified additional regulatory failures to protect breastfeeding from marketing:

- Australia has partly implemented the WHO Code recommendations for labelling infant and follow-on formula for children aged 0 to 12 months, in Australia and New Zealand Food Standards (FSANZ) Code – Standard 2.9.1- Infant formula products(Australian Government, 2022a). Unlike the MAIF Agreement, food standards are legislated, with penalties for breaches. Standard 2.9.1 includes labelling requirements for infant formula products and specifically prohibits some types of claims, images, and symbols on product labels.
  ANZ Food Standards Code – Standard 1.2.7 – Nutrition, health, and related claims(Australian Government, 2022c) states a nutrition content or health claim must not be made about infant formula.

However:

- Such labelling restrictions are limited to infant formula products from 0 to 12 months and do not include milk and other drinks and foods marketed for toddlers(Australian Government, 2022c) from 13 to 36 months.
- There is evidence that nutrition and health claims are being made about infant formula(Berry & Gribble, 2017), indicating a failure of monitoring and/or enforcement by FSANZ and State/Territory Food Authorities responsible for the enforcement of the ANZ Food Standards.
- There is also evidence of inappropriate claims being used to market infant and toddler foods other than infant formula (Simmonds et al., 2021).

Of great concern, is the fact that Australia New Zealand Food Standards Code – Standard 2.9.2 – Food for infants(Australian Government, 2022b) continues to permit labelling of commercial baby foods as suitable for children from 4 months of age. Many infants are introduced to commercial baby foods between 4 and 6 months(Australian Institute of Health and Welfare, 2011), reducing exclusive breastfeeding.

The WHO Code places responsibilities on governments to monitor and enforce WHO Code measures which the Australian government has not met. The WBT*i*AUS assessment of Australia's status is based on the absence of publicly available evidence of monitoring or sanctions for WHO Code violations under the Food Act or other relevant law in Australia. The lack of comprehensive and effective government monitoring and enforcement of the WHO Code measures reduces government costs but places an additional unpaid work burden on women and breastfeeding Non-Government Organisations (NGOs) (mostly staffed by women, many of whom volunteer or are employed in underpaid feminised occupations in the health and care sectors, in addition to their unpaid caring roles) (Smith, Baker, Iellamo, Hull, et al., 2021; Smith, Baker, Iellamo, & Hull, 2021). Reducing the costs of monitoring and enforcement for government regulators such as FSANZ and the ACCC is a strategy that shifts the costs away from government and mostly onto women[1] and NGOs.

Additionally, there are no effective measures addressing WHO Code provisions regarding the use of health care facilities for promotion, giving gifts or incentives to health workers, sponsoring health professional meetings, or providing free or low-cost formula supplies through the health system or in emergency response. The National Health and Medical Research Council (NHMRC) *Infant Feeding*

[1] The need to address gender inequities in labour in Australia are recognized in the Sex Discrimination Act 1984 and the Secure Jobs, Better Pay Act 2022.

Guidelines(National Health and Medical Research Council, 2012) draw attention to the need for health workers to be aware of their responsibilities under the WHO Code but these guidelines and are not systematically or regularly communicated to health workers or their professional associations and are not enforced.

6. WBT*i*AUS detailed recommendations

A law is needed urgently that recognises breastfeeding as important to population health, food security and climate change resilience.

6.1 Immediate action

After decades of ineffective self-regulation, it is now time for action. The Australian Federal Government should amend its implementation of the *WHO International Code of Marketing of Breastmilk Substitutes* to **reflect all subsequent WHA resolutions.** This requires the MAIF Agreement to be abolished and replaced with legislation that applies to a wider scope of products and actors, and with mandatory measures and penalties that are enforced and overseen by a government body independent of commercial influence.

6.2 Recommendations for a new legal model

WBTiAUS recommends that the Australian Government enacts legislation in the form of a new **law** that includes:

1. **The objective to protect breastfeeding from inappropriate marketing.**

2. **Scope that covers emerging products, actors and marketing media.**
    a. The **products** covered by the law include:
        i. infant formulas and toddler milks 0-36 months
        ii. cell-based human milk products
        iii. commercial foods for infants and young children 0-36 months
        iv. feeding implements such as bottles, teats, and dummies.
    b. The **parties** to comply with the law include:
        i. Manufacturers, importers and distributors
            1. Retailers, including supermarkets, pharmacies and online retail platforms, including direct selling by manufacturers.
                a. Including retailers addresses the blurring of distinctions between online retailing and marketing and the use of social media as conduits for news, information and advertising. Unless marketing by retailers is controlled, the regulation of digital marketing is likely to be unworkable and much less effective.
                b. Regulating marketing by retailers will not affect availability but will restrict practices that include price premiums, discounting, product placement and the use of illegal claims (Fig. 1).
        ii. Social media influencers.

iii. Exporters and marketing in overseas destinations of commercial milk formula products manufactured in Australia

1. As a signatory, Australia has an obligation to uphold the WHO Code internationally, including in countries with limited regulatory capacity and weak implementation of the WHO Code.
2. To counter globalized corporate marketing strategies, and protect breastfeeding at home and abroad, Australia should lead and support the international governance by developing and adopting "a framework convention on the commercial marketing of foods for infants and young children." (Baker et al., 2023)

c. The marketing **media** covered by the law should cover:
   i. Digital media, including social media platforms.

3. Governance of the new legislation by the Department of Health and Aged Care, advised by an independent committee of experts in breastfeeding, health and human rights,[2] not consumer lawyers and industry.

The committee would:

a. Provide advice to the Australian Government Minister for Health and Aged Care, including on any further or updated measures to protect breastfeeding and safe infant feeding and the aims of the WHO Code.
b. Receive regular reports of the Department's handling of complaints and enforcement regarding the marketing in Australia of products within the scope of the new law.
c. Oversee the Department's regular monitoring of the extent of commercial milk formulas and IYC food marketing in Australia using the WHO Net Code protocol (World Health Organization, 2017) for periodic monitoring of compliance.
d. The advisory committee of experts in breastfeeding, public health, human rights and breastfeeding NGO representatives should be free of industry representatives, free from commercial influence, and supported by a secretariat which is adequately funded.

6.3 Additional measures to protect breastfeeding

Separate to the ACCC's implementation of the prescribed mandatory code, WBTiAUS recommends that the Australian Government implement the following additional measures to protect breastfeeding:

1. The **ANZ Food Ministers' Meeting** authorises the Food Regulation Standing Committee (FRSC) to
   a. Develop a Policy Guideline that prohibits any health or nutrition claims on toddler milk or infant or toddler foods.
   b. Develop a Policy Guideline that labelling of baby food products under *Standard 2.9.2* of the Food Standards Code should align with WHO and NHMRC recommendations for 6 months of exclusive breastfeeding over any fair-trade considerations, and that:
      i. Labels do not refer to any earlier infant age than 6 months,

[2] The protection of breastfeeding is a health issue that requires knowledge of breastfeeding as a biocultural practice, in addition to its nutritional, immunological and developmental importance to infants.
The marketing of infant formula and toddler milks is a violation of the human rights of women and children to health, food and economic security.
Marketing practices that obtain and use information about a woman's pregnancy and birth status diminish her autonomy, reproductive rights and rights to privacy.

   ii. Packages carry a warning that any use before 6 months is likely to displace superior nutrition from breastfeeding,
   iii. Labels of all baby food products for infants aged < 12 months indicate serving sizes which are demonstrated to be consistent with continued breastfeeding duration to at least 12 months.
2. **Funding to FSANZ** to establish a dedicated unit to ensure **compliance** with the relevant Food Standards on labelling infant and young child (IYC) food products.
3. Require FSANZ to collate and report annually on the performance of FSANZ and State/Territory Food Authority functions and powers in relation to IYC food products for children 0 to 36 months.
4. **All health professional organizations** should include WHO Code compliance as part of their professional ethical standards, and sponsorship/partnership polices, and compliance with the WHO Code and related guidance for health workers should be enforced as a mandatory standard for registration and accreditation by the Australian Health Practitioner Regulation Agency (AHPRA).
5. NHMRC Infant Feeding Guidelines are updated to fully incorporate recent guidance published by WHO for health workers (World Health Organization (WHO), 2020) and these be regularly communicated to health workers via their health professional associations and health facility.

7. Conclusion

We consider that the MAIF Review report recommendations are weak and inappropriate, if used to inform the government and the ACCC's response to the INC application for the reauthorisation of the MAIF Agreement.

We urge the ACCC to consider the wider policy context and challenges for breastfeeding in Australia, and not to authorise the MAIF Agreement. The MAIF Agreement fails to protect breastfeeding from marketing strategies for commercial milk formulas and emerging, novel infant feeding products. Australia urgently needs a new and unique law that enshrines the WHO Code in full to protect the rights of mothers, infants and young children to breastfeed from the commercial power of the globalised milk formula industry, the growing complexity of products and the imminent threats of climate change.

8. Appendices

Appendix 1: WBTi Australia report 2023

WBTi-Australia-report 2023

Appendix 2: WBT*i*AUS response to the MAIF Review report 2023

This section provides WBTi Australia's detailed comments on the *Review of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement Final Report 05 October 2023,* conducted by Allen and Clarke Consulting, published by the Department of Health and Aged Care 11 April 2024 (the report) (Allen and Clarke Consulting, 2023b).

The report concludes that the MAIF Agreement is ineffective but recommends reforms that are unlikely to protect breastfeeding adequately. The report recommends strengthening regulation by adopting a "Prescribed Mandatory Code" for manufacturers and importers that is governed, monitored and enforced by the ACCC, rather than by the Department of Health, industry or third parties. This proposed regulation includes marketing via electronic media but not retailers, and instead recommends that government "review the scale and impact of inappropriate marketing of infant formula by supermarkets and pharmacies" (p.7), and "raise awareness among healthcare professionals and parents/consumers about the appropriate use of infant formula."

However, the proposed regulation does not include the marketing of toddler milks, or marketing by retailers (supermarkets and pharmacies). The report advises that the marketing of toddler milks will be addressed by requirements to change regulations for the labelling infant formula in FSANZ Review of ANZ Food Standard 2.9.1 -Infant Formula Products (P1028). However, the FSANZ proposal has not been announced or debated publicly, nor is there evidence of its likely effectiveness or indication of a time frame for the implementation of such a measure.

Our criticisms of the report affect every section of the report and cast doubt on its value to good policy making. These criticisms centre on four themes (Fig 1):

1. Policy principles
2. Regulatory framework
3. Models of causation
4. Quality of evidence

1 Policy principles

The report adopts policy principles that do not serve breastfeeding.

1.1. The report does not critique the fact that the MAIF Agreement omits the WHO Code principle to **protect breastfeeding**. The principles of the WHO Code recognize that breastfeeding mothers and infants and young children are uniquely vulnerable, and that breastfeeding requires protection (World Health Organization, 1981). Unless the protection of breastfeeding is foremost in policy to regulate marketing, these policies drift to economic rationalism, which emphasises an individual consumer's choice between products rather than the structural factors that influence decisions. In this framework, infant feeding is treated in the MAIF Agreement as a choice between commercial milk formulas, ignoring the consequences of their use on a woman's breastmilk supply, and the effort required to regain her supply once lost. This path dependency,

where a choice to use formula reduces a woman's capacity to breastfeeding in the future, must be foremost principle in policy to regulate marketing.

1.2. The report downplays the human rights principles that underpin the WHO Code and the absence of these principles in the MAIF Agreement. These omissions perpetuate the instrumentalisation of women as vehicles for infant health, or their treatment as mere consumers, subject to the overarching market-based principles of competition law rather than principles of human dignity and worth (MAIF Review report section 2.2, p. 62(Allen and Clarke Consulting, 2023b)).
1.3. The report promulgates policies that prioritise profit and economic values, rather than public health and wellbeing, as demonstrated in the report's limited policy options and benefit-cost analysis.
1.4. The report does not call out the repeated misrepresentation in Australian policy of the MAIF Agreement as implementation of the WHO Code, despite acknowledging that the scope of the WHO Code includes toddler milks and retailers.
    1.4.1. The terms of objectives of the Review were limited and did not assess the MAIF Agreement against the WHO Code and subsequent WHA resolutions.
    1.4.2. WBTiAUS considers it a fallacy to say that the MAIF agreement aligns with the WHO Code. The MAIF agreement was written in 1992 and fails to take into account the many WHA resolutions that have been added to the Code since then and omits the key phrase "protection and promotion of breastfeeding".
    1.4.3. MAIF ignores that WHO Code, in full, is the minimum requirement, not the maximum i.e. MAIF paints itself as better than other counties with even weaker implementation of the WHO Code e.g. NZ, USA.
1.5. The report adopts principles of policymaking that are incremental and marginal rather than comprehensive and effective, despite urgent threats to breastfeeding outlined in the policy context above.
    1.5.1. The report makes no mention of this context, as if marketing occurs in a social and political vacuum. Breastfeeding is being killed off by delays to policy reform: more than a decade has elapsed since FSANZ commenced its review of infant formula products (P1028); five years have drifted by without an implementation plan and targets for the 2019 Australian National Breastfeeding Strategy; thirty years and five reviews have brought no change to the MAIF Agreement, other than erosion of its oversight. These delays align with an industry playbook of strategies to avoid reform and ensure "business as usual" to protect profits (Baker et al., 2023). The ACCC risks being another institutional stooge to industry interests at the expense of public health.
    1.5.2. Transformative change in rates of breastfeeding protection requires a shift in paradigms, for example laws that recognize human rights to breastfeed and the value of breastfeeding to food security, rather than minor reforms and adjustments to the current system (Lawrence et al., 2015; Malhi et al., 2009; McIsaac et al., 2019).

2 Regulatory frameworks

The report's regulatory framework (anti-trust law) reflects the flawed policy principles outlined above. The ACCC is not an appropriate authority to determine this important aspect of health policy. As an authority, it lacks the public health expertise and specialist knowledge of infant feeding and its complexity.

This complexity includes the range of infant feeding methods and products that compete with breastfeeding and their regulation under frameworks for food, human tissue, and potentially therapeutic goods, and various combinations of these (Salmon, 2023) (Fig. 5). These products compete with breastfeeding at individual and system levels. At the individual level, feeding these products reduces

demand for breastmilk by infants and decreases the production of breastmilk by mothers in accordance with the physiological feedback mechanisms of lactation, unless the mother is supported to express milk, for example by using a breast pump. At the system level, the use of these products may devalue breastfeeding, and discourage investment by health professionals and institutions in the education, resources and skills required to support and encourage women and their infants to overcome breastfeeding problems. These issues also apply at the societal level, in families, communities and workplaces. Marketing these products amplifies this displacement of breastfeeding.[3]

2.1 Which regulatory frameworks address human rights to breastfeed?

The regulatory frameworks available under the Competition and Consumer Act do not address human rights to breastfeed. These rights are derived from United Human Rights Conventions to which Australia is a signatory (United Nations, 1989, 2016).

The objectives of the 2023 MAIF Review included consideration of "alternative regulatory models" and did not restrict the review to competition and consumer (anti-trust) law (p.9, 2023 MAIF Review Report}(Allen and Clarke Consulting, 2023b).

The limitations of competition and consumer law to protect breastfeeding is that it frames people as "consumers" and their decisions as "choice" between "products," and ignores the complex breastfeeding environment outlined in our submission. In addition, the effective protection of breastfeeding extends beyond this narrow, instrumentalist framing.

An alternative regulatory framework is human rights. The right of women to breastfeed and for infants and young children to be breastfed is enshrined in the Sex Discrimination Act 1984 (Cth) and 2011 amendments. However, this legislation doesn't hold to account the corporations which distort beliefs of politicians, governments, health professionals and parents and carers through marketing strategies for commercial milk formula.

The clear advantage of a new law is that when a bill is developed, it is drafted in accordance with Australia's human rights obligations, which are set out and assessed in the Explanatory Memorandum that accompanies the bill. This Explanatory Memorandum is effectively part of the legislation, and legislative process, which must be considered when the bill is introduced and voted upon in parliament, and when any subsequent amendments are made. An example is the Explanatory Memorandum for amendments to the Fair Work Act (Parliament of Australia, 2022). The Explanatory Memorandum set out how the amendments enacted human rights in the labour sector, including specific rights to breastfeed and express milk in workplaces, consistent with the Sex Discrimination Act 1984, and provisions to request flexible work to breastfeed and meet family and caring roles.

In assessing regulatory options, the ACCC is restricted in the regulatory models that it can consider (various Codes), and which do not refer to human rights. The MAIF Review and report reflect these limitations. Consequently, a new legal framework is required, administered by a different government agency, for example the Department of Health and Ageing.

[3] In the 2023 Federal budget, the government committed $6 million dollars to milk banking. Department of Health and Aged Care. Budget overview 2023-24. Canberra: Australian Government; 2023. 6 p. Available from: https://www.health.gov.au/sites/default/files/2023-05/overview-budget-2023-24_1.docx

Recognizing human rights to breastfeed does not negate the need to protect consumers from inappropriate marketing. The protection of breastfeeding needs to be enshrined in a law that includes multiple measures to enable breastfeeding and prevent it from being undermined or displaced. This overarching law, based on human rights principles, would address the complex ecology of breastfeeding and include measures based on appropriate models of causation, as discussed in the next section.

2.2 Other problems with the models of regulation considered in the MAIF Review

The regulatory model to protect breastfeeding from inappropriate marketing needs to address the expanding range of products that compete with breastfeeding (Fig. 5), and their associated regulatory frameworks.

By definition, anti-trust laws address market failures that arise from anti-competitive behaviours concerning monopolies, information asymmetries, inefficiencies in production and negative externalities(Biggar, 2022). In this framework, negative effects on the health of consumers are a negative externality and included in the ACCC's assessment of the costs and benefits of regulatory options. However, harms exist beyond consumers, for example the harms of environmental degradation from the dairy industry and commercial milk formula production, manufacture, distribution and waste.

Regulatory frameworks to protect breastfeeding from marketing need to include a wide range of products and actors that enable this marketing. The products and actors missing from the report include cell-based human milk products and how the regulatory model omits retailers and sidesteps their responsibilities by recommending that busy parents and carers are made more "aware" of the appropriate use of products, thereby placing a regulatory burden on the least powerful.

2.2.1 Products

2.2.1.1. Toddler Milks

The MAIF Review report does not recommend the inclusion of toddler milks in the scope of regulating the marketing of commercial milk formulas. It is difficult to understand why the marketing of toddler milks is not included in the scope of regulation when these products:

a. Reduce breastfeeding duration (World Health Organization, 2022a).
b. Are not recommended in the NHMRC Infant Feeding Guidelines (National Health and Medical Research Council, 2012).
c. Condemned as unnecessary, probably harmful and a waste of money (Fuchs et al., 2023; Harris & Pomeranz, 2020; McCann et al., 2022).
d. Are not under review by FSANZ, because they are covered by Food Standards Code 2.9.3- (Formulated meal replacements and formulated supplementary foods) and are outside the scope of P1028 (the FSANZ review of Food Standard 2.9.1 - infant formula products).
e. Are the subject of FSANZ approvals for novel ingredients, for example Human Milk Oligosaccharides (HMOs), which are used to market toddler milks. Under Standard 2.9.3, HMOs are not subject to the labelling restrictions for HMOs that apply to infant formula in Standard 2.9.1.

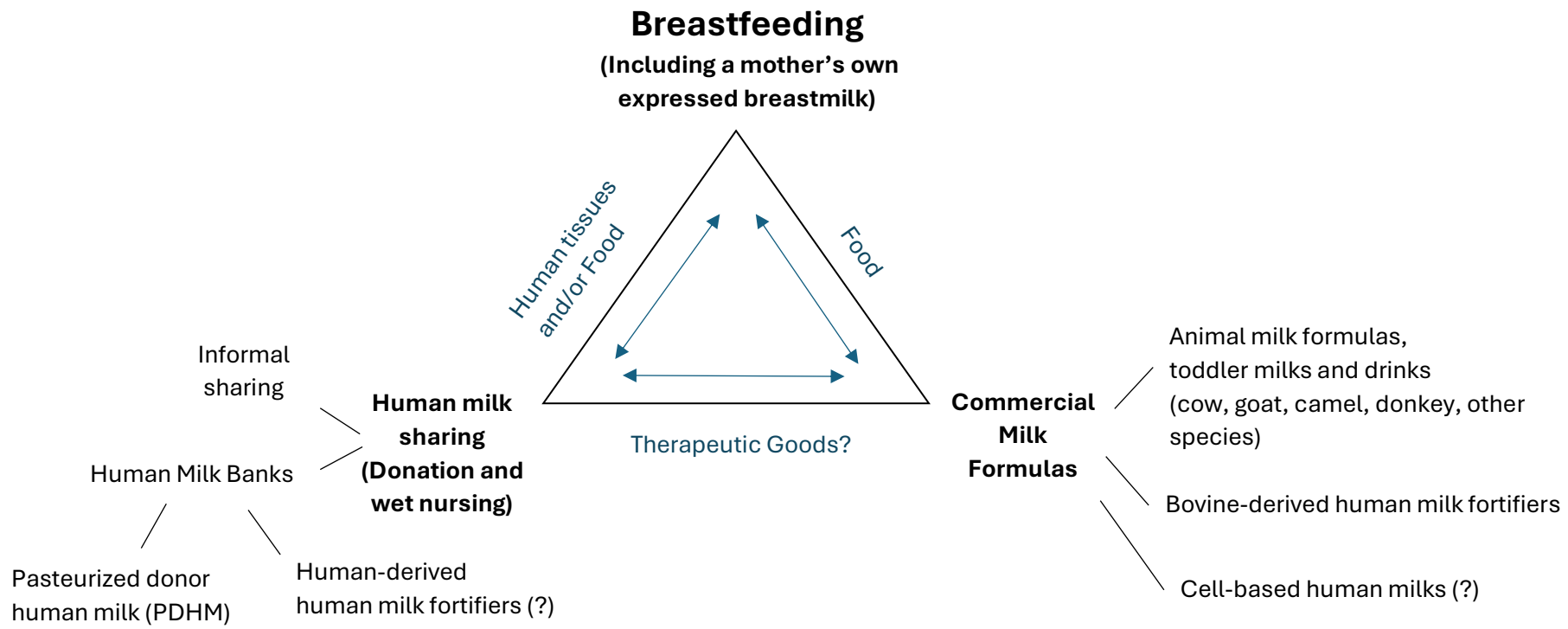

Figure 5. The three-way competition in infant feeding between breastfeeding, commercial milk formulas and human milk sharing, and associated products. The blue text indicates regulatory frameworks for food, human tissue and therapeutic goods and their approximate alignment with various infant feeding methods and products. Question marks indicate uncertainty (Salmon, 2023).

2.2.1.2. Cell-Based Human Milk Products

Cell-Based Human Milk Products have their implications for the MAIF Agreement and regulatory frameworks to protect breastfeeding. They show that, to protect breastfeeding, the regulation of marketing needs to address the complexity of a wide range of commercial milks and formula products.

On 3 May 2024, the Food Ministers Meeting agreed to "ensure regulation of **cell-based human milk** products is consistent with 'traditional' infant formula products." Cell-based human milk products add to the growing list of infant and young child feeding products of animal,[4] human, cell-based and synthetic origin.[5] We are concerned that:

- The 2023 MAIF Review report did not consider these cell-based human milk products.
- The MAIF Agreement does not address the regulatory complexity of an increasing range of commercial animal- and human-derived and synthetic products and ingredients to feed infants and young children, how this complexity affects their use in marketing and their implications for breastfeeding.
- The notice from the Food Ministers' Meeting about the regulation of cell-based human milk products, and its uncertainty increased the time and work required to prepare submissions to the ACCC, which includes the delayed publication of the 2023 MAIF Review report until 11 April 2024, after the submission period had commenced on 25 March 2024. The guidance of the Food Ministers is vague.
- It is unclear how the marketing of cell-based human milk products would be regulated for children older than 12 months, given that the regulation of infant formula, by definition, applies to products for infants under 12 months. There are very few restrictions on marketing products under Standard 2.9.3 applied to toddler milks.
- These products are so diverse in their origin, composition, manufacture and use that their representation by a single industry body (INC) is questionable, which makes the application of the MAIF Agreement to cell-based human milks uncertain and industry self-regulation an inappropriate model to regulate their marketing.
- If the MAIF agreement did not apply to cell-based human milk products, the regulation of marketing of these products would be limited to provisions under ANZ Food Standards Code- Standard 2.9.1 on product labelling. These provisions amount to restrictions on label images and names, warning statements and health and nutrition claims. No other aspects of the WHO Code would apply to cell milks.
- There are large differences in the way these products can be used, promoted and priced with the potential to increase competition and aggressive marketing strategies between them, which threaten breastfeeding in new ways, as outlined below.

[4] bovine, caprine, camelid, asinine (donkey) milks

[5] Commercial milk formula products include milk or components produced synthetically (cell culture, fermentation technology) or by genetically modified or selected genotypes of cows (e.g. modified proteins, human milk oligosaccharides and lactoferrin).
Other infant feeding products include:
• fortifiers for breastmilk (human-derived or bovine-derived) that are used for hospitalized premature infants under medical supervision.
• donor breastmilk in various forms (fresh, frozen, freeze-dried, heat or pressure treated, including pasteurized) and from various sources (families and informal social networks, non-profit and for-profit milk banks, companies)

The implications of these products to the protection of breastfeeding stems from the complex competition between breastfeeding, donor human milk and commercial milk formulas - a three-way contest (Figure 5). Breastfeeding must compete with all other forms of infant feeding. This competition is recognized in the 2003 WHO Global Strategy for Infant and Young Child Feeding, which sets out a hierarchy of feeding options that prioritize breastfeeding and expressed breastmilk over infant formula products:

> "*For those few health situations where infants cannot, or should not, be breastfed, the choice of the best alternative – expressed breast milk from an infant's own mother, breast milk from a healthy wet-nurse or a human-milk bank, or a breast-milk substitute fed with a cup, which is a safer method than a feeding bottle and teat – depends on individual circumstances*."

This hierarchy is emphasized for vulnerable hospitalized infants, especially those requiring intensive care, for example extremely premature and very low birthweight infants (World Health Organization, 2020). These infants constitute one of the largest market segments for commercial milk formulas, 'special' formulas for premature infants. These products compete with pasteurized donor human milk, supplied by human milk banks, which require considerable community, philanthropic and government investment Marketing aims to give specific products a competitive advantage. However, this competition is constrained in complex ways through the different regulatory frameworks applied to these products and the interactions of these frameworks (Fig. 5). Regulatory complexity arises because:

1. Products of human origin are regulated by a range of legal frameworks, which include food, human tissue (or a combination of both), and, potentially, biologicals or therapeutic goods.
    a. The legal classification of human milk varies between Australian jurisdictions, which apply legal frameworks for human tissue or food (or a combination of both). This uncertainty creates a regulatory burden (in legal advice and administrative costs) for human milk products, which affects their price and accessibility.
    b. There is no international agreement on the legal classification of human milk products, which may affect trade, although international trade of commercial human milk occurs.
    c. In contrast, in all Australian jurisdictions, infant formula products are regulated consistently as a food, and in accordance with international food standards that facilitate safe trade (Codex Alimentarius).
2. Different legal frameworks applied to products constrain advertising and remuneration.in different ways and create a competitive advantage for some products over others.
    a. Constraints on advertising human tissues prevent human milk donors and milk banks from advertising and places them at a disadvantage relative to commercial milk formulas. While the advertising of infant formula is constrained by the WHO Code and the Food Standards, these products are still marketed through their labelling, pricing and placement on retailer shelves and internet sites, and other ways described in this submission.
    b. Cell-based human milk products present new marketing opportunities through the potential to make novel health and nutrition claims and closer comparisons with breastmilk (implied or overt). On the other hand, animal milk formula companies may compete with these products by manipulating social disgust at bodily fluids or fear of breastfeeding women as vectors of disease. All of these marketing strategies compete with breastfeeding in practice and create a confusing decision-making environment for parents and carers that may devalue breastfeeding.
    c. Constraints on remuneration affect who profits from these products. For example, human tissues legislation applied to donor human milk in some states and territories prohibits payment or compensation to donors, but do not prevent others from being paid e.g. milk

banks or companies that make commercial human milk products. Companies that manufacture and sell commercial milk formula have no constraints placed on their profitability.

3. Overall, this regulatory complexity sets up unfair and inconsistent competition between cell milk, breastfeeding, donor human milk and infant formula (Fig 5), which may not give effect to the prioritisation of infant feeding options according to the 2003 WHO Global Strategy (World Health Organization, 2003).
    a. Cell-based human milk products regulated as a food under Food Standard 2.9.1 only covers labelling and, by definition, will represent the product as close to breastmilk.
        i. The less stringent regulation of these products under food regulation frameworks may promotes co-investment and ownership of cell milk by commercial milk formula companies.
        ii. In contrast, donor human milk that is regulated as a human tissue prevents marketing, giving it a competitive disadvantage.
    b. Alternative regulatory frameworks may apply to cell-based human milks. For example, the regulation of "biologicals" under the Therapeutic Goods Act, which allows selling but imposes more stringent requirements, for product efficacy and therapeutic claims.
    c. Cell-based human milk products are a new industry, and a group of manufacturers who may be unfamiliar with the principles of protecting breastfeeding and the requirements of the WHO Code.
        i. Has the Department of Health and Aged Care considered whether manufacturers, distributors and retailers of cell-based human milk products will be educated in the WHO Code and bound by its principles?

2.2.2 Actors

Key actors covered by the WHO Code and subsequent WHA resolutions are missing in the MAIF Agreement (retailers, exporters and the owners and users of digital media). These omissions determine how the burden of regulation is distributed in society.

2.2.2.1 The scope of actors to be regulated

The MAIF Review report recommends that government takes a more active role in monitoring and enforcing the regulation of marketing infant formula products. However, the report does not recommend that retailers are covered in any regulatory model under consideration and calls for further evidence through a review of "the scale and impact of inappropriate marketing of infant formula by supermarkets and pharmacies." This recommendation is misleading, because the products considered in such a review would be limited to infant formula and omit toddler milks, which are the vehicle for cross-product marketing of infant formula, as illustrated by example 1 in this submission (p.10), copious data in previous submissions to the ACCC and the published literature (Breastfeeding Advocacy Australia, 2020; Smith, Baker, Iellamo, Hull, et al., 2021).

We welcome the MAIF Review Reports' recommendation that digital media are included in the scope of any regulation of infant formula. Digital media clearly extend the reach of marketing messages to parents, carers and health professionals. However, unless toddler milks are included in the scope of products covered by regulation, the proposed restrictions on marketing through digital media will be ineffective.

As shown in example 2 (p.12), the marketing of commercial milk formulas through health professional associations and education needs to include exporters, because these associations, conferences and

education events are transnational and influence health professionals in destination markets for Australian commercial milk formula products. Australia has a duty of care, as a nation that relies on revenue from higher education and a good international citizen, to ensure that infant feeding education provided to health professionals upholds the principles of the WHO Code in full, as a minimum standard of integrity and good governance in the education sector. These health professionals work in Australia and overseas, including in our poorest neighbours, and have great influence on health systems, policies and public health outcomes at home and abroad.

2.2.2.2 How the burden of regulation is distributed among actors

The MAIF Review report omission of key actors in marketing commercial milk formulas effectively re-distributes much of the burden of regulation to civil society, parents and carers.

The model of regulation in the 2023 MAIF Review report places a regulatory burden on parents and carers. Rather than providing parents and carers with environments that support breastfeeding and unbiased decision making in infant feeding, the report recommends that some unspecified entity (government, industry, the ACCC?) should "raise awareness among healthcare professionals and parents/consumers about the appropriate use of infant formula." This recommendation, though important, privileges the market over preventive health. It does not address the marketing strategies shown in examples 1 and 2 in Section 1of this submission, and places an unfair burden on parents and carers, especially those with the least resources, including education, to make appropriate decisions. Furthermore, this recommendation is unbalanced, in that it does not bring attention to, or address the gaps, in education about breastfeeding for healthcare professionals and parents/carers Appendix 2.

3. Models of causation needed for breastfeeding as a complex system

There is no silver bullet or policy that will increase breastfeeding. Breastfeeding is a complex sociocultural behavior that requires community, workplace and institutional knowledge and support, especially in the health system This complexity is recognized in the literature through the application of socioecological models and complex systems approaches to breastfeeding (Baker et al., 2023; Pérez-Escamilla et al., 2023).

By definition, complex systems have complex interactions and causal pathways, and often require multiple, concurrent interventions to produce desired outcomes (Galea, 2010). A prime example of this is the 2003 WHO Global Strategy for Infant and Young Child Feeding, which addresses ten policy areas that need to be implemented and coordinated to increase rates of breastfeeding (World Health Organization, 2003). In complex systems, policy coordination and coherence (a policy "gear model") is crucial for success and recognized in the public health policy literature (Pérez-Escamilla, 2012; Pérez-Escamilla & Hall Moran, 2016). Policy coordination creates synergies in effectiveness greater than the sum of the parts, or individual policy areas. In contrast, single interventions or picking 'best bets' or responding to simplistic agendas pursued by narrow interests are unlikely to have much effect.

Consequently, it is invalid to assume that a single intervention in a complex system will cause a substantial change in outcome. Yet this mistaken assumption is made in the MAIF Review report (Section 4.5.2, page 60), which assesses the effectiveness of WHO Code implementation as a single measure, in isolation of its context, including the implementation and coordination of other breastfeeding policies, for example the Baby Friendly Hospital Initiative (World Health Organization, 2020). As shown in the WBTiAUS assessment, Australia has major deficits in breastfeeding policy implementation across almost

all ten key policy areas and no recognizable coordination (no breastfeeding functioning central committee and no implementation plan). An appropriate response to this dire situation should be to 'pull all the stops out' and recommend the implementation of multiple policies, including the WHO Code. Instead, the MAIF Review report rejects the full implementation of the WHO Code (i.e. do nothing or tinker with minor details).

Other implications for policy making arise from the report's simplistic and misleading model of causation. The report implies that low rates of breastfeeding are the fault of individual women. For example, Appendix D (p.78) lists the reasons or "factors" that women give for stopping breastfeeding. A more informed analysis suggests that many of these factors are symptomatic of breastfeeding problems that were not prevented or treated with timely, skilled knowledge and care. They are also symptomatic of women's beliefs and capacity to blame themselves rather than hold governments to account for failing to protect and support breastfeeding. It serves the commercial interests of milk formula companies to perpetuate women's erroneous beliefs and self-blame for breastfeeding problems and present their parent helplines and products as solutions. This is shown in the marketing of milk formula products that make spurious, unregulated claims, "tailored" to address a range of infant behaviors (crying, wakefulness, colic).

These beliefs and simplistic models of causation influence how evidence is framed in the MAIF Review report, as discussed in the next section.

4. Quality of evidence in MAIF Review Report

The MAIF Review report lacks reference to recent, high-quality reviews of evidence and articles in the published literature of the harms of marketing commercial milk formulas, including toddler milks, to parents and carers and health professionals, through health systems and influence on policy makers and politicians. We know the consultants that undertook the review were made aware of this evidence.

4.1. The onus of proof: where is industry evidence that marketing doesn't work and doesn't need regulation?

Given the amount that the commercial milk formula industry spends on marketing (estimated to be about 10% of the value of global sales, or about US$5 billion) (World Health Organization, 2022a) , and the growth in the sales of commercial milk formulas, including toddler milks, in Australia and globally (Baker, Russ, et al., 2021), where is the evidence that:

1. marketing doesn't work?
2. retailers are not involved in this marketing and direct beneficiaries of it?

Yet in reviews of the MAIF Agreement, including the latest, the onus of proof is always on public health and breastfeeding advocates and NGOs to show that marketing does affect breastfeeding.

4.2. Missing evidence on marketing and the political economic systems that support it

The MAIF Review report summarises the findings and sentiments of participants interviewed and surveyed (Allen and Clarke Consulting, 2023a) but does not analyse the results using in a meaningful way. The report sets out the divergent positions of industry and health (public health and breastfeeding advocates) but does not provide an independent analysis of those positions and the quality of the evidence that supports them. This evidence incudes a model of how breastfeeding works as a complex system and its political economic drivers, as outlined earlier in this submission. The published political economic literature on infant feeding describes various actors or players with interests in infant feeding and how

they influence policy making and breastfeeding environments (Baker, 2020; Baker, Zambrano, et al., 2021). This power and influence are exercised at political, institutional and societal levels, and these "causes of causes" ultimately dictate the flow of public and private resources to various types of infant feeding. These analyses highlight the vast disparity in power and resources between corporate actors with commercial interests and actors with interests in human rights and public health.

A political economic framework is crucial to the interpretation of actor positions on the marketing of commercial milk formulas, but sorely missing from the 2023 MAIF Review report. Consequently, the MAIF Review objectives and findings are distorted: an "even playing field among industry" (Recommendation 1, p22) does not amount to an even playing field for mothers, or public health. Similarly, without a political economic framework and a complex systems model of breastfeeding, it is not surprising that the MAIF Review report found lack of "sufficient justification for expanding the scope of products (Recommendation 2, p. 23). This evidence is presented below.

Without a political economic understanding of infant feeding, the quality of evidence cannot be assessed accurately for potential conflicts of interest and bias. There is a reliance on biased and inaccurate infant and young child feeding (IYCF) practices data in the report (Section 4.5.2, page 60). The OzFITS study (Netting, 2022) used to intimate that breastfeeding rates have been increasing in Australia, is funded by industry and criticized by the public health community due to a potential conflict of interest.

Data from the latest National Health Survey (NHS) 2022 survey found 37.7% of babies were exclusively breastfed to 6 months (Australian Bureau of Statistics, 2022). However, the Australian Bureau of Statistics (ABS) warns about the quality of breastfeeding data in NHS surveys and their consistency across years. ABS NHS breastfeeding data is weak, inconsistent with other infant feeding surveys, and not sufficient to make the claim that Australian breastfeeding rates are increasing. The WBTi AUS team do not consider these statistics as valid and therefore do not report on them.

It is a disappointing omission that interview and survey participants in the MAIF Review referred to, and provided the consultants with, the Lancet Breastfeeding Series 2023 and key WHO publications, but that the findings of these papers are not mentioned in the Final Report.

The key findings of the three papers in this series are highlighted here:

- Paper 1: Unpredictable and irritable behavior by newborns is common but sadly this is often confused by mums, their partners, other family members and health professionals as a milk supply issue. Concern about low milk supply is a frequent reason for mums to be worried about their breastfeeding and for introducing commercial milk formulas. The authors of this paper found that the formula industry works on a global level to exploit these concerns and the vulnerabilities of parents with claims and messaging that are not backed by evidence (Pérez-Escamilla et al., 2023).

- Paper 2: Less than half the world's babies are not exclusively breastfed to six months of age as per the WHI Infant feeding Guidelines. And at the same time the commercial milk formula industry is a $55billion business globally. Their marketing playbook infers that their products can solve the problems of new parents with little evidence to back them up. Digital platforms have substantially elevated their reach in the last decade undermining the International Code of Marketing of Breast-milk Substitutes. A policy environment that removes commercial influence

on how babies and young children are fed is needed but will require political commitment, adequate financing, and transparency (Rollins et al., 2023).

- Paper 3: The authors of this paper highlighted the power that the commercial milk formula industry has to change the direction of policy at a national and international level, and they explain the social political and economic reasons for this. They demonstrate that breastfeeding is undermined by the systems and policies that ignore 'women's work' and by the lack of adequate protection, promotion and support of breastfeeding. They make evidence backed suggestions of how these problems can be overcome (Baker et al., 2023).

- WHO Report 2022 *How the marketing of formula milk influences our decisions on infant feeding.*
- "This report summarizes the findings of a multicounty study examining the impact of formula milk marketing on infant feeding decisions and practices, which was commissioned by WHO and UNICEF" (World Health Organization, 2022a).

There is clear evidence of industry strategies to influence infant feeding policy in Australia, in accordance with the globalized corporate "playbook" of strategies used by commercial milk formula companies (Baker et al., 2023; Rollins et al., 2023).

- For example, in June 2021, within months of the ACCC re-authorization of the MAIF Agreement and concerns that the marketing of toddler milks was a problem, the formula industry held a conference at Parliament House to promote "networking" and "market access" (ironically titled "Safeguarding the Future"). The Sydney Morning Herald reported that 'The Infant Nutrition Council sold tickets to a cocktail event at Parliament House …promising access to "government officials" and seeking between $5000 and $10,000 from sponsors" (Daniel, 2022).

4.3. Evidence of the pervasiveness and harms of digital marketing

The marketing strategies used by commercial milk formula companies is similar in high and low income countries (World Health Organization, 2022a, 2022c), and their effect on formula sales is globalised, through international trade (Baker, 2020; Baker, Russ, et al., 2021; Baker, 2016). The WHO 2022 report showed that digital landscape is becoming the predominant method for promotion of breastmilk substitutes. These marketing strategies have the power to reach parents and carers, and as well as health professionals, amplifying the reach. The strategies utilised in the digital space are constantly evolving (World Health Organization, 2023b) and therefore require intentional monitoring.

Recently FHI Solution's Innovation Incubator, in collaboration with the Corporate Accountability Tool and Communications Hub (CATCH) have developed artificial intelligence that detect marketing violations of the commercial milk formula industry. This is called the Virtual Violations Detector (VIVID) (Appendix 7). Australia was included as a pilot country for the testing phase of this tool given it has some of the lowest breastfeeding rates in the world and only voluntary self-regulation of marketing of commercial milk formulas (FHI Solutions, 2023). In the first eight months nearly 4000 items were captured by the tool. For more details see Appendix No.9.

4.4. Evidence and policy on the effects of donations of infant formula in emergencies

Disasters and emergencies are increasing in frequency and intensity under climate change. It is therefore concerning that the report makes a recommendation (number 10) regarding policy for facilitating industry

donations of infant formula in emergencies. Donations of infant formula in emergencies undermine child health (Infant Feeding in Emergencies Core Group, 2017). It is often donated well in amounts in excess of what is required, the wrong type, or close to/ past expiry date. There is often no certainty of continuity of supply and can cause significant logistical problems. Because it comes without cost, donated infant formula is not distributed as carefully as it should be. It is often given without proper assessment of need, without ensuring that caregivers have all the other resources they require (list them), and often distributed to breastfeeding women. These result in reduction of breastfeeding, unsafe formula feeding practices and places infants at risk, and more prone to food insecurity (Gribble, 2023).

4.5. The economic evidence – benefits of regulating to health, food security and antimicrobial resistance

In its economic analysis of regulating marketing, the MAIF Review report claims that stronger (mandatory) regulation is costly and that the benefits of such regulation are low. However, the report underestimates the costs of weak (voluntary) regulation and the benefits of breastfeeding from savings to health system costs, increased food security and potential resilience to antimicrobials.

4.5.1 Breastfeeding and Health System Costs

The MAIF Review's Cost Effectiveness Analysis (Appendix E), claims that stronger mandatory regulation is costly and health cost savings (benefits) of regulation are low. This claim is not substantiated by evidence. The economic analysis used in the report is minimalist, inadequate and based on flawed data from the Australian Bureau of Statistics (ABS) National Health Survey (NHS) estimates of breastfeeding rates.

- The report's economic analysis estimates that a 7% increase in breastfeeding rates would be needed to justify the strongest mandatory regulation approach. However, this takes no account of the costs to the public, including NGOs, like the Australian Breastfeeding Association (ABA) and the Public Health Association of Australia (PHAA) and their unpaid, volunteers, of 'regulating' the industry.
- The data on breastfeeding used in the report cast doubt on the credibility of the analysis (Amir, 2020). The report uses NHS data which the ABS has warned could not be relied on due to COVID and new online data collection (Australian Bureau of Statistics, 2020-21).
    - The report uses rates of exclusive breastfeeding rates at 6 months of 73.8%, which are extremely high (p. 95). Such a figure is the rate of "any" breastfeeding at six months reported in Appendix C (p. 77) and double the rate of exclusive breastfeeding at that age.
    - In contrast, reliable data from the Australian Institute of Health and Welfare (AIHW) collected in 2010 showed breastfeeding rates that were less than half the rates reported by the ABS surveys (about 15% of infants were breastfed exclusively for at least **5 months**) (Australian Institute of Health and Welfare, 2011). In addition, recent perinatal statistics show that in NSW and Victoria, about one third of infants are fed infant formula before discharge from hospital (Centre for Epidemiology and Evidence, 2023; Yuen et al., 2022).
- The analysis is also based on extremely narrow cost estimates of the benefits from increasing breastfeeding rates (in savings to health costs). These cost issues have been extensively researched and applied in the Cost of Not Breastfeeding Tool (Ahsan et al., 2022), which shows

the actual costs/value of lost milk for a full range of conditions (Walters et al., 2019) (Smith et al., 2002) (Ip S, 2009; Smith et al., 2023).

- In addition, the report fails to count the costs to organisations and individuals of *not* regulating [REF].
    - The real cost of not regulating also includes the household costs to families of having sick children (in lost time, income, leave and productivity), and not just a narrow costing of the additional burden on the health system.

Overall, it would take much smaller increases in breastfeeding to justify the regulatory costs calculated in the report (which are also overstated).

- In high income countries, women and communities with low levels of education and access to breastfeeding support are more vulnerable to marketing (Conway R, 2023). The report does not take into account the social gradient of breastfeeding, with lower rates of breastfeeding associated with socioeconomic disadvantage (Amir & Donath, 2008; Ogbo FA, 2017; Ogbo FA, 2019). For these groups, investment in the regulation of commercial milk formula marketing is likely to be more effective and return greater savings to health systems than estimated in the report.
- In addition, poorer households bear a greater burden of communicable and non-communicable disease. Consequently, the burden of not breastfeeding on the health and budgets of poorer households is relatively greater. Commercial milk formula adds to the cost-of-living pressures on these households and may contribute to one supermarket reporting that 'Baby formula was the most prized item among Australian thieves' (Staff writer, 2023).

4.5.2 Breastfeeding and food security

The value of breastfeeding to infant and young child food security in everyday and emergency situations was outlined in the WBTiAUS-ABA joint submission to the Inquiry into Food Insecurity in Australia 2022 (Appendix 3). The food security benefits of high rates of exclusive and extended breastfeeding accrue to individuals, communities and nationally. Breastfeeding is a highly localized, safe way to feed infants in emergencies and disasters, when infrastructure and supply chains fail. In these situations, the costs of not breastfeeding may be catastrophic. Breastfeeding is also cost-effective to address food insecurity in households facing cost of living pressures, but only if governments invest in breastfeeding protection, promotion and support. Government investment in breastfeeding through the WHO Code is one such protection.

The report's omission of the health, social and economic benefits of breastfeeding in emergencies and disasters contributes to the report's underestimate of the benefits of breastfeeding, The failure of the report to consider these factors represents the limited, outdated models used to assess regulatory options, and does not address the urgency and threats of climate change to the Australian population, as noted in the government's Health and Climate Strategy (Department of Health and Aged Care, 2023). The MAIF Review and its report are simply not fit for purpose in terms of their conceptual models, evidence and methods of assessment.

4.5.3 Breastfeeding and addressing the risk of antimicrobial resistance

Breastfeeding has a potential role in addressing the increasing prevalence of resistance to antibacterial drugs (antibiotics) (Nadimpalli et al., 2020). Globally, antimicrobial resistance contributed to about 5 million deaths in 2019 (World Health Organization, 2023a) and is of major concern to the Australian government (Australian Government). Breastfeeding has a unique, and complex role in the development

of the immune system of infants and young children and resistance to infection (Ballard & Morrow, 2013). This is shown by reduced rates of gastrointestinal, pulmonary and ear infections in infants and young children who are breastfed, with rates about half those fed commercial milk formula in high income countries (Victora, 2016). Further research is required on exposure and resistance to antibiotics by comparative studies of different methods of infant and young child feeding

Appendix 3: WBTiAUS-ABA joint submission to Inquiry into Food Security in Australia 2022

House Standing Committee on Agriculture. Inquiry into food security in Australia. Submission #164. World Breastfeeding Trends Initiative Australia and Australian Breastfeeding Association and others

Appendix 4: ANU Submissions to ACCC, 2015 and 2020-21

(a) Honorary A/Professor Julie Smith, Dr Libby Salmon -14 August 2015

(b) Honorary A/Professor Julie Smith, Dr Phillip Baker, Dr Libby Salmon -11 December 2020

(c) Honorary A/Professor Julie Smith, Dr Phil Baker, Mr Alessandro Iellamo, Ms Naomi Hull-7 April 2021

(d) Honorary A/Professor Julie Smith, Dr Phil Baker, Mr Alessandro Iellamo, Ms Naomi Hull, Dr Libby Salmon -27 April 2021

Appendix 5: Reports of previous reviews of the MAIF Agreement

We provide pdfs of the following reports that are no longer available on the Department of Health and Aged Care website here - https://wbtiaus.com/2024/05/19/is-time-up-for-the-maif-agreement/

(a) Knowles 2001

(b) Best Start Report 2007

- Chapter 8: The impact of breast milk substitutes -Section 8.27: Review of MAIF and APMAIF

(c) Nous Group 2012. MAIF Review

(d) Nous Group 2017. Complaints Handling Process Review.

Appendix 6: Virtual Violations Detector (VIVID)

Virtual Violations Detector (VIVID) and Findings: Findings Brief. September 2023

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