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11 December 2020

David Hatfield

Director

Competition Exemptions Branch

Australian Competition and Consumer Commission

Dear Mr Hatfield,

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

Thank you for the invitation to make a submission on this INC application.

We are pleased to be able to contribute expertise and experience to inform your determination on these important questions.

To introduce myself, I am an economist and former senior officer in the Commonwealth Government, with research interests including public health, health services, and related public policy, particularly infant and young child feeding, and its trends, drivers, and effects on women's and children's health, chronic disease and health system and economic costs. My research since 2004 on economic aspects of breastfeeding has been funded by the Australian Research Council, and I currently am an ARC Future Fellow conducting research on markets in mothers' milk and economic valuation of breastfeeding. I am also a qualified Breastfeeding Counsellor with over 20 years' experience, and an Honorary Member and former Board Director for the Australian Breastfeeding Association. I currently hold an Honorary appointment in the Research School of Population Health and am a TTPI Fellow at the ANU Crawford School of Public Policy.

My colleagues Dr Phillip Baker (BSc., MHSc., PGDipHSc., PhD) and Dr Libby Salmon (B.Vet.Sci., M.Vet. Studies) are respectively a Research Fellow at Deakin University, and a Research Scholar at the ANU's Regulatory Institutions Network. Dr Baker currently leads a multi-country research project, funded by WHO, on the global regulatory and policy responses to protecting breastfeeding from harmful commercial practices. Dr Salmon is completing a PhD at the ANU on the social and legal regulation of human milk in Australia.

We would be pleased to elaborate on this and earlier submissions and attend any public hearings held by the ACCC during its deliberations.

Yours Sincerely

Honorary A/Professor Julie Smith

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Summary

Ten key facts about marketing of milk formula in Australia based on current evidence, and aligned with questions of public benefit and detriment and counterfactuals to authorising the Marketing in Australia of Infant Formula (MAIF) agreement

1. Breastfeeding is a human right of mothers and children which means governments should protect them from marketing of breastmilk substitutes.
2. The INC's MAIF Agreement has not protected breastfeeding, or proper feeding of substitutes where necessary. Breastfeeding has worsened, while sales and use of milk formula products have risen since 1992.
3. The World Health Organization (WHO) International Code recognises the particular vulnerability of mothers and newborns and is regularly updated for changes in marketing.
4. If authorised until 2030, the MAIF Agreement will be fifty years out of date, because it addresses only the 1981 World Health Assembly (WHA) resolution which established the WHO International Code but not the 19 subsequent resolutions of the WHA.
5. It is misleading to say that the MAIF Agreement is "Australia's official response to the WHO Code", and its governance continues to have a strong conflicts of interest including industry representation. This means it lacks legitimacy in the eyes of civil society groups and the public.
6. WHO and UNICEF do not consider Australia's MAIF Agreement as meeting the criteria for 'implementing' the WHO International Code. Hence, Australia is reported as not having implemented The Code in international monitoring reports.
7. The proposed MAIF Agreement still denies guidance from the WHO that toddler milk/formula is a breastmilk substitute, and that companies should not offer gifts, education or sponsorship to health care providers. Other countries are implementing this guidance, and Australia is once again, falling well behind international best practice.
8. There is compelling evidence of ongoing inappropriate baby food marketing and its harms to vulnerable consumers, but experience shows industry self-regulation is ineffective in a rapidly changing food environment for infant and young children
9. Australian governments' breastfeeding policy objectives are now to end inappropriate marketing and distribution of infant formula and breastmilk substitutes
10. The ACCC can and should do more to 'strengthen regulation of infant formula and breastmilk substitutes', including through its determination on the duration of MAIF Agreement and its associated Committee guidelines and INC publications.

Background and approach

The Australian Competition and Consumer Commission (ACCC) is seeking submissions on

- 'likely public benefits and effect on competition, or any other public detriment, from the proposed arrangements';
- '...general experience of the operation of the MAIF Agreement since 2016', and;
- 'public benefits and detriments ... from the MAIF Agreement during the previous authorisation period'.

This submission provides evidence relevant to the questions raised by the ACCC. It provides updated information relevant to our previous submissions on the 2015 INC application, and draws on work we have done jointly or as individual researchers since 2016 on issues around commercial marketing of foods for

infants and young children for the World Health Organization, and the Australian Department of Health. It also provides an overview of relevant research evidence since that time to illustrate how ineffectively the MAIF Agreement has operated since 2016, and its reduced effectiveness in the future. It is of particular concern that the multi-billion infant formula industry has been shown to be actively exploiting concerns about COVID-19 to increase sales, in violation of the WHO International Code of Marketing of Breast-milk Substitutes (the Code) and national law in many countries [1].

Firstly we summarise key arguments in our submission on the INC's 2015 application to the ACCC to reauthorise its MAIF Agreement.

We then draw attention to trends relevant to any public benefit of the Agreement and important changes in the context and regulatory environment since 2016. ANNEXES A, B AND C providing supporting information on infant feeding trends and the changing global policy context.

Drawing on our work for the World Health Organization and the Australian Department of Health, we present some important recent academic studies that are relevant to the experience with the INC self regulatory arrangements since 2016 and its likely public benefits and detriments, with links, references and a short annotated bibliography at ANNEX D.

Finally we make some recommendations on how the ACCC can contribute to strengthening current regulatory arrangements to ensure greater public benefit and reduced detriment from the MAIF Agreement in the Australian context for the WHO International Code.

Public benefit or detriment, and contemporary policy and regulatory context

In our three submissions on the INC reauthorisation application in 2015, we set out detailed arguments on the following that remain relevant to this current application.

- The relevant market for the purposes of the ACCC's determination should include the detrimental effects of authorising the MAIF Agreement on breastfeeding and on the financial viability of providing breastfeeding/lactation-related commercial products and health services such as donor human milk, commercial human milk products, or lactation consultants.
- Most infant and young child food marketing activity in Australia is not covered by the MAIF Agreement. Follow on and toddler formulas (targeting 6-36 months) are breastmilk substitutes and promote infant formula, but remain out of scope. Marketing of commercial complementary food products for infants and young children is not in scope. Many market participants are not members of INC. Marketing by retailers, and a range of other products covered by the WHO International Code is also considered out of scope.
- Potential public benefit of approving the MAIF Agreement is low as many milk formula products are considered out of scope, yet the Agreement helps INC members appear as good corporate citizens.
- Public detriment was likely as MAIF guidelines legitimise marketing of milk formula products through health channels by the major formula companies.
- Detriment was more likely and net public benefit lower the longer the period of the agreement.
- Governance arrangements do not meet Australia's commitments under the WHO International Code and subsequent WHA resolutions, and mislead the public about the industry-based nature of MAIF.
- The ACCC can increase public benefit by imposing conditions on reauthorisation of the MAIF Agreement.

In this submission we mainly update previous information to inform the ACCC's consideration of the same MAIF Agreement in a somewhat different global and national regulatory context and an increasingly online marketing environment.

Why did Australia adopt the MAIF Agreement and not the WHO Code into law? The political and economic power of the formula industry

The fact that Australia maintains the MAIF Agreement as a voluntary code rather than fully adopt the WHO Code into law, reflected the national and international power and influence of the baby food industry, and the conflicts of interest that this creates for policymaking [2]. In recent years there has been a growing awareness of the way that globalised food systems and transnational corporations influence food policy and population health.

The Infant Nutrition Council is one of many trade associations the food industry employs worldwide to lobby against implementation of the WHO Code of Marketing of Breastmilk Substitutes. This lobbying occurs in many countries, and also in international standard-setting bodies, including the World Health Assembly and Codex Alimentarius Commission [3].

The strategy of promoting self-regulation was developed by public relations experts working for the industry in the late-1970s. This was done to deflect and constrain criticism by activists groups, re-focus media attention, and to 'substitute' for regulation by government, while promoting a socially responsible image of the industry [4, 5].

The companies often claim that self-regulation and their own corporate policies on marketing demonstrates their support for the WHO Code, even though the scope of these corporate policies fall far short of compliance [5].

Furthermore, reports by Save the Children, the Access to Nutrition Index, and the International Baby Food Action Network, have long demonstrated frequent violations of both the WHO Code, and the companies own policies, across many countries [6-8]. Reports by the WHO on the implementation status of the Code amply evidence that many governments also do not meet their responsibilities under the Code.

Using Euromonitor data we have demonstrated an unprecedented global boom in milk formula sales, focussed in the Asia Pacific region, driven in part by marketing, and permitted by weak public regulation which companies themselves help devise [2, 9, 10]

Countries can and must regulate and protect public health under international law

Our previous submissions provided evidence of how international trade law has been invoked to discourage countries from legislating to regulate the marketing of the milk formula industry. Recent examples were Hong Kong, and The Philippines. Advocates for the industry in those countries sought to influence governments to accept self-regulation along the lines of the MAIF Agreement in Australia and New Zealand.

However, governments can and are obligated to regulate and protect public health under international law.

This counter-regulatory influence is an issue that is wider than the milk formula industry [11] and was recently dealt with at the World Trade Organization (WTO) in relation to Australia's plain packaging dispute with the tobacco industry [12].

As similar issues have arisen regarding regulation of marketing of milk formula, WHO recently responded to questions about international trade agreements and the International Code of Marketing of Breast-milk Substitutes.[13] It is intended for all those involved in Code-related policy and law-making, including legislators, policy-makers, regulators and other relevant officials.

The WHO document describes the right to regulate under WTO law, including core principles and relevant WTO covered agreements, noting that States have obligations to protect, respect and fulfil the right to health under international human rights law. This includes an obligation to protect and support breastfeeding under Article 24 of the Convention on the Rights of the Child (CRC).

Though determined case-by-case, WTO law protects the right to regulate to protect human health, and a WTO panel may consider international standards, such as the WHO Code. The WHO Code is a minimum standard, and each WTO Member has the right to determine its own appropriate level of protection with respect to a health risk.

Although WTO Members are required to ensure minimum standards of protection for intellectual property rights, including trademarks, there are exceptions, such as “marks that are misleading with respect to the health benefits of consuming a product, or misleading with respect to the relative health benefits of that product compared to breast feeding”.

Importantly, regarding trade marks and plain packaging, WHO’s advice is that;

WTO law does not guarantee a trademark owner the right to use that trademark, but only the right to exclude others from doing so. In any case, WTO Members may restrict the use of the trademark to where justified to protect public health.

This has crucial implications for preventing health or nutrition claims for milk formula products and for regulating marketing through health channels where consumer preferences for milk formula brands are established.

1. Breastfeeding is a human rights issue, and governments have accepted international obligations to protect, support and promote breastfeeding, and end inappropriate marketing of breast-milk substitutes

A [2016 statement](#) by experts from the United Nations Office of the High Commissioner for Human Rights articulated that breastfeeding is a human rights issue [14-16].

‘Breastfeeding is a human rights issue for babies and mothers and should be protected and promoted for the benefit of both’.

The UN experts called for States to take urgent action to stop “misleading, aggressive and inappropriate” marketing of breast-milk substitutes, which “often negatively affect the choices women make on how to feed their infants in the best way possible, and can impede both babies and mothers from enjoying the many health benefits of breastfeeding”.

“We call on them to adopt such measures to protect babies and mothers from misleading marketing practices, and fully align with the recommendations contained in the International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly resolutions, and new guidance from the World Health Organization (WHO).”

The experts warned that also warned that,

‘there is a lack of corporate accountability for the adverse consequences of these abuses, noting that the global industry is currently worth \$44.8bn and is predicted to increase to more than \$70bn within three years. At the same time, breastfeeding rates remain stagnant, with only one in three of the world’s babies under six months old being exclusively breast-fed.’

The experts stressed the need for ‘stringent, comprehensive and enforceable legal measures’.

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Australia's poor performance in implementing such measures to protect breastfeeding was noted in the recent Report by the Australian Human Rights Commission to the UN Committee on the Convention on the Rights of the Child [17].

As we previously pointed out, Australia has also failed to act on its international obligations to protect babies and mothers in Australian export markets from misleading, aggressive or inappropriate marketing of breastmilk substitutes. This was a 2001 resolution of WHA (54.2) (see Annex B).

In 2018, UNICEF issued a report on children's human rights in relation to marketing. It called for a coordinated response across sectors to protect children from the effects of unhealthy food marketing, such as obesity. It noted that implementing the International Code of Marketing of Breastmilk Substitutes, relevant World Health Assembly resolutions, and recommendations in the 2016 WHO Guidance on ending inappropriate promotion of foods for infants and young children at a national level was essential to such a response [18].

2. The Australian formula industry's MAIF Agreement has not protected breastfeeding or proper infant feeding as in the WHO Code of Marketing of Breastmilk Substitutes ("WHO International Code"). Breastfeeding has declined and milk formula use has increased in Australia, and in our export markets.

Has self-regulation protected breastfeeding? No. Has it increased milk formula sales? Yes.

Trends in infant feeding show that the Infant Nutrition Council (INC)'sⁱ MAIF Agreement most likely protects dominant companies in the formula industry from effective regulation, rather than protecting breastfeeding, proper feeding of breastmilk substitutes, and mothers and their infants' nutrition and health as intended by the WHO International Code of Marketing of Breast-milk Substitutes ("WHO International Code").

Breastfeeding duration and exclusivity has barely improved or reduced in the thirty years since APMAIF was introduced in 1992. Full breastfeeding at hospital discharge and duration at 3 and 6 months has in fact declined in recent years, based on Victorian data (see Figure). Furthermore, in-hospital supplementation with milk formula products (special baby milk and infant formula) rose to around 30% in NSW and Victoria since 2011 and is likely similar in other jurisdictions and for Australia as a whole.[19]

Although evidence from Australia is lacking, reports from the UK suggest the industry-driven over-diagnosis of cows' milk protein allergy in particular, is a key determinant of the rise in specialised formula use [20].

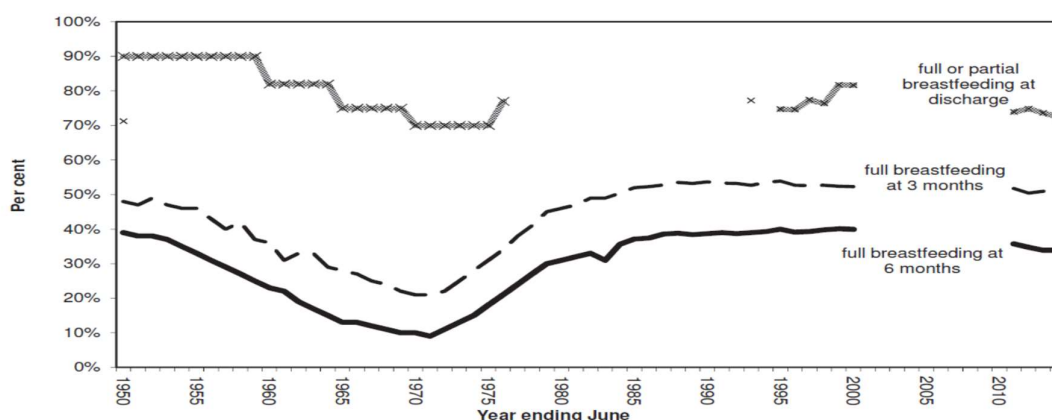
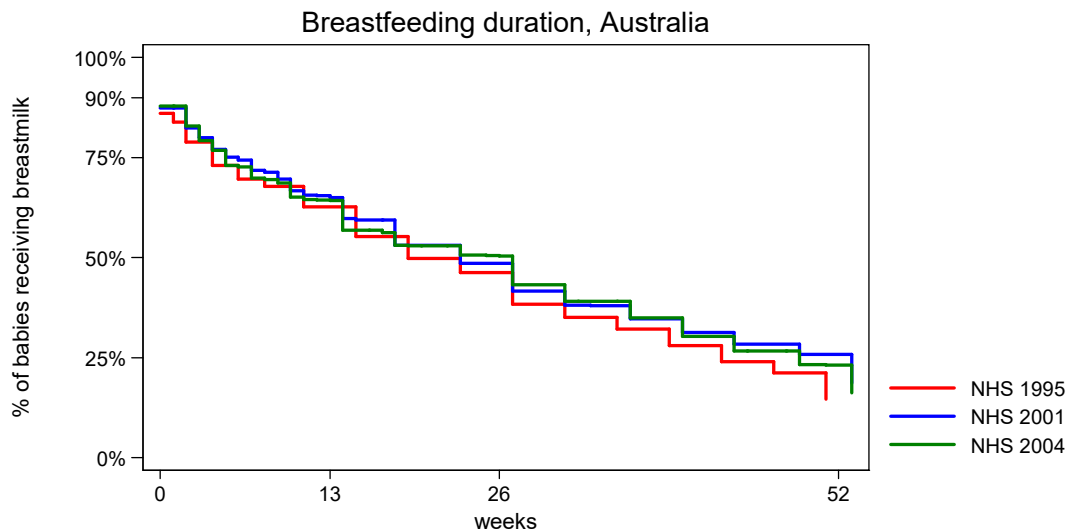


Figure 6 Long term breastfeeding trends in Australia. Source: Maternal & Child Health Services Annual Report, Victoria, 2013.

Source [21]

ⁱ Formerly the Infant Formula Manufacturers Association of Australia (IFMAA)
Australian National University



Source: [22]

Exclusive breastfeeding at 6 months remains low (25%), barely rising from 15% since the 1995 National Health Survey.[23]

Meanwhile, retail sales of milk formula products continue rising rapidly, despite a stable birth rate.[24, 25] Both the volume of sales, and the retail market have expanded massively since 2012, especially toddler formula sales but also other milk formula products (see ANNEX C). Clearly the MAIF Agreement has not protected breastfeeding or restrained sales of milk formula products.

The health and health cost as well as economic consequences of these ongoing trends in Australia are considerable [26-28].

Has MAIF Agreement produced public benefit by protecting consumers, or mothers and babies? No

Breastfeeding has declined and formula markets expanded in Australia since 1992. Experience in other comparable countries suggests breastfeeding rates have improved more and are higher than in Australia, associated with more effective constraints on marketing to the public, or to health facilities and health workers.

- Australia and New Zealand had comparable exclusive breastfeeding rates during the 1960s and 1970s and similar implementation of MAIF, but introducing BFHI in NZ reduced formula marketing and use in hospitals, and dramatically increased exclusive breastfeeding at hospital discharge between 2000 and 2011.[29]
- Norway had comparable breastfeeding trends to Australia historically but has legislated for comprehensive Code and BFHI implementation, as well as paid maternity leave. Breastfeeding initiation is now universal, and 80% of mothers breastfeed at 6 months.
- In Hong Kong, a change in hospital policy to not accepting free supplies and paying for formula greatly increased in-hospital exclusive breastfeeding and breastfeeding duration, by reducing medically unnecessary supplementation.[30, 31]
- In the US there is no WHO Code implementation or paid maternity leave, but breastfeeding has improved since 2011, partly reflecting US Surgeon-General Call to Action initiatives such as regular collection of breastfeeding data and BFHI which reduced formula marketing through hospitals.[32]

Has self-regulation protected consumers? No. It has enabled market segmentation and exploitation of consumers and protected the industry.

Most likely, the MAIF Agreement has enabled market segmentation and higher retail prices for formula, and kept effective legislation at bay while providing benefits for industry by enabling INC members to avoid its own infant formula marketing rules, and improve its public image.

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- Data provided in the most recent Euromonitor Report on the baby food market in Australia suggests that the value of sales of all infant formula products have risen much faster than the volume of sales. This suggests that prices for consumers have risen considerably.
- The apparent prices of ‘special baby milk’ products which target health and wellness anxieties of parents through health channel marketing have risen less than other milk formula categories. This suggests different pricing strategies in health channels to encourage supplementation in hospital and during the difficult early postnatal months when mothers and their infants are most in contact with the health system.
- Early supplementation reduces breastmilk supply, reduces breastfeeding duration, and makes caregivers of infants dependent on buying expensive commercial milk formula products.
- These market trends are significant as they may indicate the use of market power to the detriment of consumers purchasing these products from retailers in Australia or via informal (‘daigou’) export markets to China.
- While trade practices concerns about collusive behaviour are commonly focused on detriment to consumers arising from excessively high prices, in the case of infant feeding, low prices for milk formula products can cause detriment by inducing cessation of exclusive breastfeeding in vulnerable mothers and babies.

3. The WHO Code recognises that mothers and newborns are particularly vulnerable to marketing and that usual forms of marketing should not apply to breastmilk substitutes. WHA resolutions and updated WHO Guidance respond regularly to changing marketing environments and techniques.

Mothers and newborns are uniquely vulnerable to marketing

The WHO International Code is a ‘living document’ that is updated to respond to changing marketing environments and techniques through regular WHA resolutions, and periodic WHO reports and updates to its international guidance documents on the Code. In its 2017 update of ‘frequently asked questions’ on the Code, the WHO wrote,

The Code and subsequent relevant WHA resolutions must be considered together in the interpretation and translation into national measures.

Introducing the WHO Code in 1981, the Member States of WHO including Australia, emphasised their belief that products covered by the Code should not be marketed or distributed in ways that may interfere with the protection and promotion of breast-feeding.

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

Furthermore,

“the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products; mothers and their newborns are particularly vulnerable and usual forms of marketing should not apply”.

The Code also recognises “that the health of infants and young children cannot be isolated from the health and nutrition of women, their socioeconomic status and their roles as mothers”, and that breastfeeding was important for women as well as infants.

There is regular reporting on the Code, and there have been 19 resolutions by the World Health Assembly since 1981 to keep up with changes in marketing environment and techniques (see ANNEX A). In its 2020 *Primer on the Inappropriate Promotion of Foods for Infants and Young Children*, WHO states that:

“Aggressive marketing of breast-milk substitutes and commercially produced complementary foods and beverages can undermine progress in optimal infant and young child feeding by misleading and confusing caregivers about the nutrition and health-related qualities, as well as the appropriate age and safe use of these foods. ...

Insufficient laws and lack of sanctions allow for continued systematic inappropriate marketing of breast-milk substitutes. However, new marketing techniques and strategies (for example, the use of social media) continue to create additional challenges. Furthermore, the infant and child food industry is continually expanding ways of promoting their products that circumvent the Code. Thus, there is a need for better protection of infants and children through clarification and inclusion of products and promotion techniques covered by the Code...

In response to a request by Member States in 2012, WHO prepared the Guidance on ending the inappropriate promotion of foods for infants and young children. Member States are urged to continue to implement the Code, and to take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children.”

The WHO Code aims to protect the safe and adequate nutrition of infants by protecting and promoting breastfeeding, along with proper use of breastmilk substitutes where necessary. ‘Proper use’ is based on adequate information and appropriate marketing and distribution.

Emphasis is added here, as the specific wording may not be used in industry description of MAIF despite the importance of these phrases.

Medical indications for ‘where necessary’ has been defined by WHO and other authorities including in [Australia](#). The sheer size of the milk formula market shows that this guidance is poorly adhered to by health workers in Australia and globally.[33]

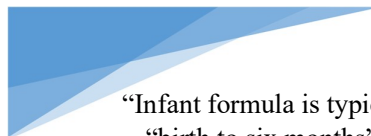
4. Reauthorising the MAIF Agreement until 2030 will leave Australia’s regulation of infant and young child food marketing half a century out of date.

In seeking an authorisation of the MAIF Agreement for ten years, INC celebrates that the document has changed little over time, and praises its stability. This misrepresents what is actually an unwelcome situation that with no significant changes 1992 and no further review planned for ten years, the MAIF Agreement will by 2030 be 50 years out of date with WHA and WHO responses to how marketing has evolved. That is, reauthorising the MAIF Agreement until 2030 as proposed by INC will purposefully embed Australia’s regulation of infant and young child food marketing in a framework that is half a century out of date.

Based on the 1981 WHA resolution that established the WHO International Code, the MAIF Agreement was already ten years out of step with global guidance by the time it was negotiated in 1992. The decade-long wait between the first WHA resolution establishing the WHO Code, and the negotiation of the MAIF Agreement in 1992 was no accident.

Rather, it was a delaying tactic allowing industry to devise and implement counter regulatory strategies. The decade-long delay allowed industry time to inventing and marketing Follow-Up Formulas (such as ‘toddler milk/formula’) to get around the MAIF Agreement on infant formula [34-36].

The counter-regulatory strategy behind infant formula product differentiation is openly acknowledged in industry expert commentary in New Zealand (see sidebar)



“Infant formula is typically defined as “birth to six months”; the product is then renamed for a range of reasons (primarily to avoid regulation and restrictions on advertising).”

Coriolis 2014, The Infant Formula Value Chain

Two years ago in the online [health journal Croakey](#), we summarised the evolution of Australia’s response to the 1981 WHO Code resolution, and it is reproduced below.

Regulating harmful marketing

In the 1980s, the Hawke-Keating Labor governments negotiated with formula importers and manufacturers on implementing the WHO International Code in Australia. The government eventually accepted a “Marketing Agreement on Infant Formula” (MAIF), a weak and limited voluntary agreement by formula industry leaders to restrain marketing to the public. Until 2014, this was loosely monitored by a panel of government and consumer representatives, with the Health Minister required to report to Parliament on how well the arrangement was working. Australian food laws were also amended over the decade to prohibit nutrition or health claims on infant formula products.

Notably, the MAIF did not apply to marketing in the form of company-provided ‘information and education’ or product samples to health workers, even though preventing conflicts of interest and commercial influence on infant and young child feeding is essential to avoid subtle product promotion within health services. However in 2003, the Australian government set out the professional ethical responsibilities of health workers to protect, promote and support breastfeeding in detailed Infant Feeding Guidelines whilst including breastfeeding in the first Australian [National Dietary Guideline](#).

Regulation and counter regulation

The ink had barely dried on the MAIF, but by 1992 the industry had already developed a [counter-strategy](#) – infant formula look-alike products known as ‘follow- on’ and ‘toddler’ formula (sometimes ‘growing up milks’). These in effect promoted infant formula and displaced breastfeeding, but were purported to not be covered by marketing restraints on breastmilk substitutes. A 2001 [industry review](#) as well as [additional research](#) exposed the tactic, but it soon spread globally. In Australia, and beyond, with rapidly rising female labour force participation from the 1980s, lack of paid maternity leave, and increasing time-pressed parents – just as anxious about feeding ‘picky

toddlers' as they were about feeding their infants – saw sales of these new milk formula products expand rapidly.

From the mid 2000s, a global '[white gold](#)' boom was underway as Chinese as well as Australian parents bought into the 'clean, green and clever' marketing lines. This was despite ongoing warnings from the World Health Assembly on the responsibility of industry to comply fully with the WHO International Code regarding breastmilk substitutes, and also the obligation on governments to apply appropriate measures to prevent their inappropriate promotion.

In 2013 WHO issued a statement that, as well as being unnecessary, these powdered milk products for older infants and young children are potentially harmful:

“...follow-up formula is unsuitable when used as a breast-milk replacement from six months of age onwards. Current formulations lead to higher protein intake and lower intake of essential fatty acids, iron, zinc and B vitamins than those recommended by WHO for adequate growth and development of infants and young children.”

The same was reaffirmed in 2018 when WHO issued [a clarification](#) on the classification of follow-up formulas for children 6 to 36 months as breast milk substitutes:

‘... the International Code aims to safeguard breastfeeding by ending inappropriate marketing and distribution of breast-milk substitutes. Because continued breastfeeding to two years and beyond saves lives and promotes the health of both the mother and baby, it is important that this protection include follow-up formula.

‘Convenience food’ marketing

Similar warnings were being sounded in Australia. A 2007 [parliamentary inquiry](#) noted the added costs to the public health system from marketing which discouraged breastfeeding, and recommended that the WHO International Code be ‘fully implemented’ in Australia. A 2011 [consultant’s report](#) commissioned by the Health Department recommended banning the misleading use of packaging and branding which conflated infant formula (for babies aged less than 12 months) with toddler formula, a marketing tactic known as ‘cross promotion’. This recommendation [fell on deaf ears](#) and formula [promotion](#) to busy, health-conscious families became more aggressive, and moved online.

By 2015, the Australian Competition and Consumer Commission (ACCC) was warning that such marketing of toddler formula was potentially a breach of consumer law.

In late 2017 at a Western Pacific Regional meeting of the WHA in Brisbane, Australia considered a [report](#) from WHO experts warning of the harmful effects of marketing on children, and noting that voluntary industry measures were proving ineffective.

‘Marketing activity’, as WHO documented, was pervasive and now included manipulating social and other mass media (paid ‘influencers’) to promote unhealthy commercial foods for children including breastmilk substitutes. Harmful food marketing activity identified by WHO in the region included behind-the-scenes industry political lobbying (‘stakeholder marketing’).

The impact of government policy was also to be seen in Australia when the Abbott Coalition government attempted to curtail maternity leave access, a move that baby food industry analysts predicted would result in decreased breastfeeding rates and Australian mothers turning to milk formula as a substitute. Finally, instead of strengthening Australia’s weak, narrow, and voluntary industry regulatory system, the Abbott

government abruptly ended public monitoring and oversight of the MAIF by abolishing the panel in 2014.

The large formula companies organised an alternative consumer complaints arrangement, similarly named 'MAIF', but there is no government monitoring role or accountability to Parliament. Many companies selling these products do not participate, or comply. Online marketing of milk formula products is now rife, globally as well as in Australia, breaching the WHO International Code and other public health guidance.

China is a major export market for Australasian baby food companies. Booming sales of toddler formula in China, alongside direct and sometimes corrupt marketing of milk formula products to doctors, saw breastfeeding rates halved there between 1999 and 2013, and milk formula sales escalating in Asia. Though this is purportedly in part due to fears of Chinese milk products following the melamine contamination over a decade ago, sophisticated marketing is driving product sales.

Regular coverage in the Australian media about empty supermarket shelves by Chinese buyers also promotes the misguided idea that toddler milk is a necessary and highly valued product. This is despite the WHO guidance and further WHA resolutions reinforcing that these products are unnecessary and possibly harmful and should not be inappropriately promoted."

By 2030, nearly half a century will have passed since the WHO International Code was established, during which the marketing environment has changed dramatically.

Member States of the WHO which include the Australian Government have committed to respond to such changes. As detailed below, the global and national policy context has changed substantially since 2016. Yet the MAIF Agreement proposed in 2020 to operate for a further decade is – to all intents and purposes, the same as that agreed to, after more than a decade's delay, in 1992.

5. MAIF is not how Australia applies the WHO Code, but a badly functioning industry self-regulatory agreement

INC's misleadingly asserts that the MAIF Agreement is 'Australia's official response' to the WHO Code, but this is far from the truth. Since the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) was abolished in 2014, the MAIF Agreement is not 'Australia's official policy applying the WHO Code', but rather is a voluntary industry code of practice. It is also just one part of Australia's implementation of the Code.

Australia's implementation of the WHO International Code

It is not widely understood that Australia's implementation of the WHO Code has occurred in at least three ways, only one of which was the APMAIF. Other official measures to implement the WHO Code included the National Health and Medical Research Council Dietary Guidelines and Infant Feeding Guidelines for Health Workers, and the mandatory packaging, labelling and composition provisions for infant formula, included in the Australia New Zealand Food Standards Code (Standard 2.9.1) [37]. The former sets out health workers' responsibilities under the WHO Code, which were most recently updated by WHO in 2020.[38]. The latter regulates marketing by prohibiting health and nutrition claims on all infant formula products (0-12 months).

The MAIF Agreement is not the same as the 1992 APMAIF

In 1992, the MAIF Agreement included most significant players in the milk formula market. This is no longer the case. There are many new entrants competing aggressively for a slice of the action, including the commercially invented but highly profitable follow on and toddler formula markets, and more recently the pregnancy/lactating mother formula market. Goats milk formula is an innovation which responds to cost

reduction pressures in the industry [24]. Supermarkets also now play a major role in formula distribution and marketing and exerting downward pressure on costs, sourcing milk formula products direct from manufacturers. The major Australian grocery retailers Woolworths, Coles and Aldi are not signatories to the MAIF Agreement, and hence highly-effective shop-front marketing strategies like price promotion, are beyond its scope.

Also, importantly, at the time of the *MAIF Agreement 1992*, compliance with the agreement was monitored by the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF), a non-statutory panel appointed by the Commonwealth Government. The APMAIF was required to report annually to Parliament. That is, the MAIF Agreement could be described as part of Australia's official response to the WHO Code. Monitoring of compliance with the MAIF Agreement by the APMAIF and its annual reports to Parliament met to a degree the government's obligations which it accepted by endorsing the 1981 WHA Resolution.

After the breakdown of the APMAIF arrangement from the mid-2000s and especially since its abolition in 2014 by the Abbott Government, the MAIF Agreement can no longer be said to represent Australia's official response to the WHO Code. For INC to describe it this way is false and misleads the public about the self-regulation arrangements organised by INC members.

WHO provides technical advice on request to its Member Countries on meeting their WHO Code obligations, and we urge the ACCC to seek such advice with a view to constraining the industry's use of current self regulatory arrangements to 'whitewash' their marketing activities as 'official'.

Governance of the MAIF Agreement

The operation of the MAIF Agreement has been severely criticised in several government-commissioned reviews over the past two decades [39-42]. Our previous submissions in 2015-16 commented on the weak governance arrangements for INC's MAIF Agreement, even compared to the unsatisfactory post-1992 APMAIF arrangements. Below we provide updated comment on recent MAIF Agreement governance, in the light of ongoing instability in the nature of this industry agreement and with regard to INC's statement that ACCC 'provides guidelines for voluntary industry codes of conduct' (3.2).

Several taxpayer funded reviews now provide evidence that the governance of the MAIF Agreement has been ineffective and/or dysfunctional, and is inherently unstable (Knowles 2001, NOUS 2012, 2017). In 2001, a review by former Victorian Health Minister Rob Knowles urged that 'a legislated statutory framework' be brought in if changes to the 'dysfunctional' APMAIF arrangements were not implemented, 'to honor Australia's commitment to the Code'. At that time, criticisms of APMAIF's effectiveness were wide ranging. but the issue of free samples to health professionals was a key controversy. By 2012, cross marketing of infant formula via similar packaging of toddler formulas was central to NOUS's criticism of the MAIF Agreement. Fast forward to the review by NOUS in 2017, which once again confirms that industry self-regulation centred on the MAIF Agreement remains unfit for purpose as a model for effective implementation of global and national policies to end inappropriate promotion of breastmilk substitutes. Similar issues were evident in 2001. NOUS 2017 also notes that the terms of reference for the MAIF Tribunal had been under revision since 2014, highlighting the intrinsic difficulties of reconciling the diverse commercial interests of INC members in a stable self-regulatory arrangement.

In our 2015 submissions to the ACCC, we showed that self-regulation does not operate effectively when there is industry "churn" in ownership of BMS and the entry of new players, incomplete coverage of industry, retailers are omitted, the lines between manufacturing and retailing are blurred by internet marketing and when supermarkets and other retailers develop private brands and technological developments in digital marketing circumvent scrutiny.

The NOUS 2017 review also points out that oversight of BMS marketing in the health system requires implementation of BFHI. However, unlike NZ, Australia has very low rates of BFHI accreditation of hospitals. In addition, Australia lacks awareness and inclusion of BMS marketing in planning and management for emergencies and disasters (WBTi 2018 report). Therefore these "arms" of regulation are missing in the Australian system, leaving parents and health professionals even more vulnerable to inappropriate marketing and conflicts of interest.

As stated in NOUS 2017, current regulation of BMS marketing is fragmented between the ACCC, the Department of Health, the INC and The Ethics Centre, with poor continuity of knowledge and expertise in the WHO Code and its subsequent resolutions, the MAIF complaints process and a lack of expertise in breastfeeding and representation of consumers.

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These arrangements do not enable the public to 'police' marketing of BMS effectively, and it is not reasonable to expect them to do so, given the disparities between industry and breastfeeding mothers in power, influence and resources.

The NOUS 2017 review considered four alternative models of managing MAIF complaints, and recommended that the Department of Health "resume the role of determining complaints, as per the previous APMAIF arrangements" (p. 30). While this recommendation is welcomed as a move towards some official accountability for monitoring and enforcement, in reality it amounts to tinkering at the margins, and MAIF Committee credibility is severely undermined by strong conflict of interests.

Furthermore, the operation of INC's self-regulatory arrangements now also imposes significant costs on taxpayers. NOUS recommended industry funding of these costs of managing complaints about industry marketing practices, but the INC's cost sharing arrangements with the Department of Health are not presently evident, or its processes transparent. It would be reasonable to consider an industry-wide levy to meet the costs of managing consumer complaints about all inappropriate marketing of foods for infants and young children. Such a model is in place for example for the telecommunications industry and could be considered as a fairer, and more stable, efficient and effective financing basis for the MAIF Agreement's governance. Alternatively this could be considered as an element of reforming GST exemptions for processed food products [43].

The ACCC is an expert body in regulation and has a key role in demanding best practice governance and ensuring effectiveness of industry arrangements for self-regulation. We commented extensively on the potential relevance ACCC's guidance for the MAIF Agreement in previous submissions.

In evaluating the effectiveness of self-regulation, it needs to be recognised that consumers no longer bother making complaints about breaches of the MAIF Agreement. Many complaints have been by formula companies themselves against their competitors, and most complaints are ruled out of scope. Complaints are rarely upheld, and when they are, there are no consequences for the company. Reporting is not timely, and there is no transparency or accountability either for companies or for the publicly funded 'regulators'. Decision-making is opaque and does not comply with good administrative practices.

The primary means of implementing the WHO Code is now the efforts of interested individuals, volunteer groups and interested health workers who monitor and enforce the Code by exposing the marketing practices of companies to various Australian consumer regulatory bodies, and ensuring that the companies weak motivations to avoid reputational damage constraints their marketing to at least a minimal degree.

It is evident that other countries are taking legislative action to protect infant and young child feeding through restrictions on marketing highly processed high salt high fat foods to children (UK) and taxes on sugary beverages. To provide consistent protection of nutrition of children across the continuum of 0-5 years, legislation is required to prevent inappropriate marketing of BMS for 0-36 months.

It is time to draw a line under the MAIF Agreement, and internalise the externalities from inappropriate marketing practices. We call for the ACCC itself to show regulatory leadership in this crucial area of public health, by requiring INC to provide evidence of an adequate public benefit from reauthorising the MAIF Agreement.

It is also timely to for the ACCC to recommend that in the light of the unhappy experience with the MAIF Agreement over the decade since the Best Start Parliamentary Inquiry, the WHO Code and subsequent WCA resolutions should be implemented through legislation to the extent necessary to achieve Australian policy objectives of strengthening regulatory arrangements so that 'inappropriate marketing and distribution ceases' [44].

Arguments about the changing international and national policy context for regulation of marketing of infant and young child foods and breastmilk substitutes are elaborated below.

6. WHO/UNICEF do not count the MAIF Agreement as implementing the WHO International Code.

It is important to note at the outset that in 2020 the WHO's regular report on country implementation of the Code counted Australia as one of the few countries worldwide that has failed to implement the WHO Code [45]. Australia's Code status is described in WHO reporting one of the 58 countries as having 'no legal

measures at all'. By contrast 70% of 194 WHO Member States had enacted legal measures with provisions to substantially or partly align with the Code.

Many Australian trading partners such as China, Indonesia, South Korea, Cambodia, and Vietnam and high income countries such as the United Kingdom and Norway are reported as partially implementing the Code. India and Philippines 'substantially' implement the Code. Countries like the Japan, USA, Canada, Malaysia and a range of low income countries such as North Korea have 'no legal measures'.

The urgent call by WHO during the COVID 19 pandemic emphasises that Australia is not only failing to keep pace with global progress towards implementing WHO Guidance on the Code, but is going backwards by further entrenching INC's long outdated, narrowly scoped and demonstrably ineffective industry Agreement.

7a. Updated WHO guidance in 2018 states clearly that toddler formulas are breastmilk substitutes which displace breastfeeding and should not be promoted

The 2016 WHA Resolution A69/7 and WHO *Guidance on Ending the inappropriate promotion of foods for infants and young children* [46] makes clear that toddler formulas are breastmilk substitutes which promote infant formula indirectly, displace breastfeeding, and should not be promoted.

WHO advises health workers [38] that;

...companies increasingly promote breast-milk substitutes for older infants and young children, from 6 months to 3 years of age. These products undermine sustained breastfeeding up to two years or beyond.

The packaging and marketing of these products indirectly promotes infant formula.

The WHO Frequently Asked Questions about the Code in 2017 noted the following:

The Code advocates that babies be breastfed. If babies are not breastfed, for whatever reason, the Code also advocates that they be fed safely on the best available nutritional alternative. Breast-milk substitutes should be available when needed, but not be promoted...

Exclusive breastfeeding from birth is possible for most women who choose to do so. It is recommended for all children except for a few medical conditions, such as maternal medication with radioactive substances. Exclusive breastfeeding as often and as long as the baby wants results in ample milk production

The 2016 resolution on ending inappropriate promotion of foods for infants and young children (WHA 69.9) urges Member States, manufacturers and distributors, health care professionals and the media to implement new WHO Guidance recommendations that contain a number of implications for the Code. These are:

Clarification that "follow-up formula" and "growing-up milks" fall under the scope of the Code and should not be promoted.

Recommendation that messages on complementary foods should always include a statement on the need for breastfeeding to continue through 2 years and that complementary foods should not be fed before 6 months.

Recommendation that the labels and designs on products other than breast milk substitutes need to be distinct from those used on breast-milk substitutes to avoid cross-promotion.

Regarding arguments that the MAIF Agreement provides information to parents for their infant feeding choices, WHO 2017 guidance is that:

"Appropriate information for families should be accurate and unbiased. The information from baby food companies serves the interests of selling products, and thus cannot be independent and unbiased.

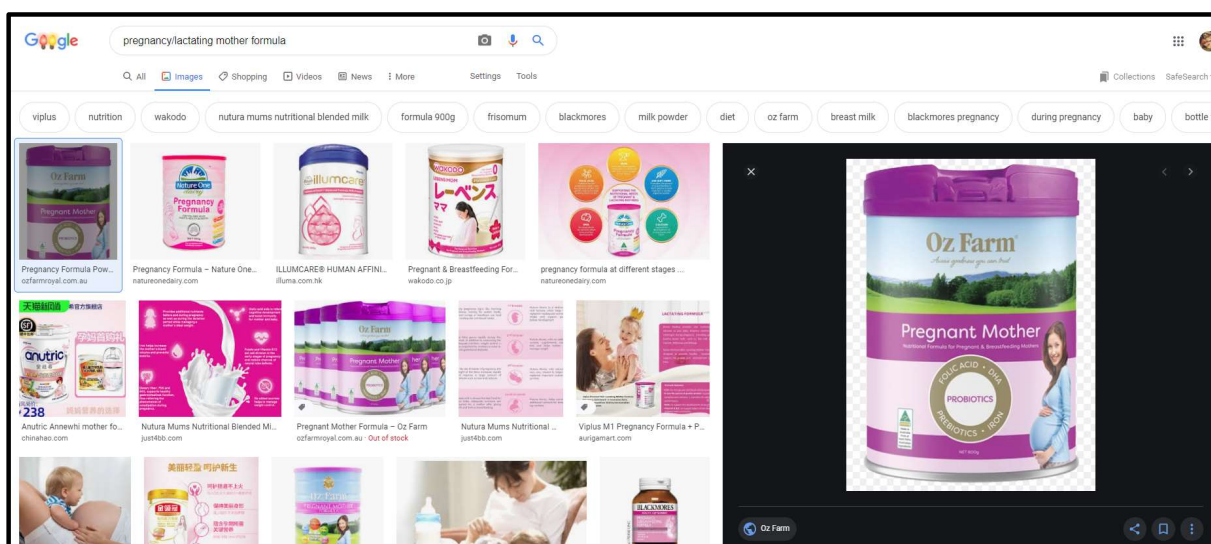
Moreover, the primary responsibility for providing such information to mother and other caregivers lies with the government, NGOs and healthcare providers."

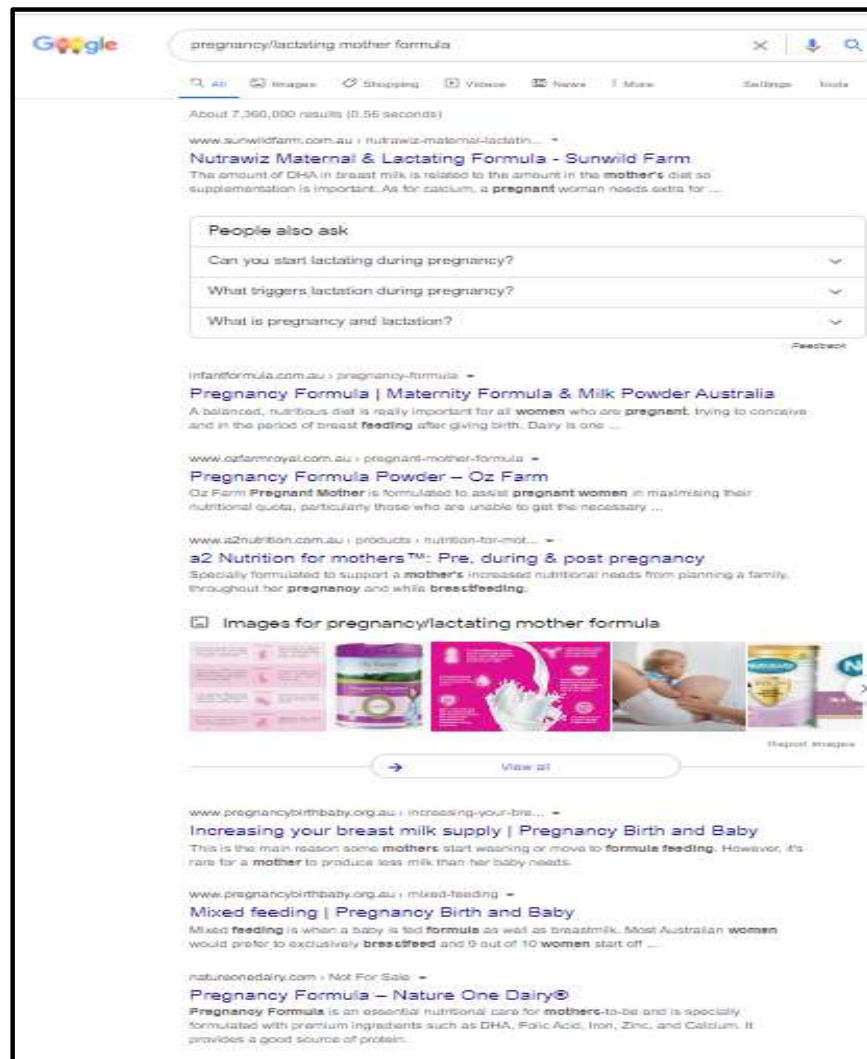
Far from giving parents appropriate information ensuring proper feeding of breastmilk substitutes ‘where necessary’, the MAIF Agreement has normalised irresponsible marketing through cross promotion and line extensions, euphemistically called ‘staging’.

This has risked the safety and proper nutrition of infants and young children in Australia.

For example, twin toddlers died of starvation after their mentally ill mother mistakenly fed them nothing but toddler formula in 2015, while more recently a newborn infant was found by a health worker to have been fed for its first 48 hours at home with a ‘mothers’ formula’ product.

Such look-alike brand products (see pictures below) are placed in supermarkets alongside infant and toddler formulas in what is known as ‘womb to tomb’ marketing to extend customer’s to lifelong engagement with brands.





Online promotion of 'pregnancy/lactating mothers formula', December 2020

7b 2018 WHO guidance states that companies manufacturing or distributing breastmilk substitutes must not create conflicts of interest (COI) for health facilities and health workers, and health facilities and health workers are obligated to avoid COI

In 2020, the WHO warned in its report on Code implementation that while 44 countries had strengthened their regulation of marketing over the past two years, countries were failing to protect parents from misleading information:

Of the 194 countries analysed in the report, 136 have in place some form of legal measure related to the International Code of Marketing of Breast-milk Substitutes and subsequent resolutions adopted by the World Health Assembly (the Code). Attention to the Code is growing, as 44 countries have strengthened their regulations on marketing over the past two years.

However, the legal restrictions in most countries do not fully cover marketing that occurs in health facilities. Only 79 countries prohibit the promotion of breast-milk substitutes in health facilities, and only 51 have provisions that prohibit the distribution of free or low-cost supplies within the health care system.

Only 19 countries have prohibited the sponsorship of scientific and health professional association meetings by manufacturers of breast-milk substitutes, which include infant formula, follow-up formula, and growing up milks marketed for use by infants and children up to 36-months old.

Dr Francesco Branca, Director of WHO's Department of Nutrition and Food Safety also stated that the aggressive marketing of breastmilk substitutes, especially through health professionals that parents trust for nutrition and health advice, is a major barrier to improving newborn and child health worldwide:

Health care systems must act to boost parent's confident in breastfeeding without industry influence so that children don't miss out on its lifesaving benefits

As elaborated below, the 2016 WHA resolution reaffirmed that maternity care facilities should not have conflicts of interest or accept free or low cost supplies of IYC food products [47-50] Importantly, it emphasised that companies had obligations not to create conflicts of interest through their marketing to health facilities or health workers. It implied:

Recognition that any donations to the health care system (including health workers and professional associations) from companies selling foods for infants and young children represent a conflict of interest and should not be allowed.

Recommendation that sponsorship of meetings of health professionals and scientific meetings by companies selling foods for infants and young children should not be allowed."

WHO's 2020 reporting on the Status of Code implementation particularly focussed on health facilities and health workers. Noting that industry was already exploiting the COVID 19 to undermine breastfeeding, WHO called on governments to urgently strengthen legislation on the Code.

The Code bans all forms of promotion of breast-milk substitutes, including advertising, gifts to health workers and distribution of free samples. Labels cannot make nutritional and health claims or include images that idealize infant formula. Instead, labels must carry messages about the superiority of breastfeeding over formula and the risks of not breastfeeding.

WHO and UNICEF call on governments to urgently strengthen legislation on the Code during the COVID-19 pandemic. Governments and civil society organizations should also not seek or accept donations of breast-milk substitutes in emergency situations.

Health care services aimed at supporting mothers to breastfeed, including counselling and skilled lactation support are strained as a result of the COVID-19 crisis. Infection prevention measures, such as physical distancing make it difficult for community counselling and mother-to-mother support services to continue, leaving an opening for the breast-milk substitute industry to capitalize on the crisis, and diminish confidence in breastfeeding.

Likewise the most recent guidance in WHO's 2020 *Frequently Asked Questions about the WHO Code Responsibilities of Health Workers* restates the unacceptable conflicts of interest that are still being created by companies [38] and allowed by health care providers, undermining the provision of ethical and consistent quality maternal and newborn care such as through the Baby Friendly Hospital Initiative [48, 51].

Firstly, is not the role of companies to 'promote breastfeeding'.

14. Is it ok to distribute brochures promoting breastfeeding that come from manufacturers of baby foods as long as there are no advertisements for their products?

No. The Code does not allow baby food companies to directly or indirectly provide education to parents and other caregivers on infant and young child feeding in health facilities. Brochures would be one way of providing education. Besides that, brochures from baby food companies often have pictures or implicit messages that favour commercial products over breastfeeding.

The Code includes a number of provisions about the role of health workers and health systems and points out that health workers should make themselves familiar with their responsibilities under the Code.

As a health worker, part of your job is to inform and educate mothers and other caregivers about appropriate and optimal infant and young child feeding. Mothers should be supported to make informed and unbiased decisions free from any commercial influences by baby food companies.

The Code prohibits any type of promotion of breast-milk substitutes in health services. It also has specific recommendations for health workers on how to avoid being influenced by baby food companies.

The WHO explains that baby food companies promote breast-milk substitutes using health workers by

Promotional practices include donating free or subsidized supplies of breast-milk substitutes, providing free samples of formula, offering education for families, giving gifts to health workers and their families, and sponsoring conferences and meetings.

Baby food companies often target health workers and health facilities to help promote their products. They build relationships and offer subtle incentives that lead to direct or indirect endorsement of the company's products. These relationships threaten health workers' independence, integrity and public credibility.

All of these practices are prohibited by the International Code of Marketing of Breast-milk Substitutes.

The document also explains why it is so wrong to accept free formula to be used by mothers who can't breastfeed, even in a poor area and with the need to cut hospital costs everywhere. This also applies to free samples for patients who can't afford milk products.

Experience has shown that unregulated and unlimited free supplies of formula lead to its overuse and undermines breastfeeding. Companies donate formula knowing that free distribution creates brand loyalty among mothers after they leave the hospital.

Therefore, donations of free or subsidized supplies of breast-milk substitutes or other products are not allowed in any part of the health care system. Any infant formula needed for infants with medical reasons for its use should be obtained through normal procurement channels.

The Code clearly states that health workers should not give samples of any breast-milk substitute to pregnant women, mothers of infants and young children, or members of their families.

WHO reiterates that most women are physically able to breastfeed their babies and don't need to use breastmilk substitutes;

Their use interferes with the production of the mother's own milk. Even in the rare occasions when infants have a metabolic disorder where breastfeeding is contraindicated, or a specialized formula is needed, health workers should not give out samples.

If a mother is given a free sample in the hospital, she will tend to use it even if it isn't needed. Samples encourage families to purchase the products when the samples run out, even if they can't really afford the product. Families may be persuaded to formula feed because the sample is implicitly endorsed by you.

For example WHO rules out many practices which continue to be legitimated by the MAIF Agreement, such as small gifts or equipment donations.

7. In my facility, can I display posters/calendars/information materials given by a baby food company that has pictures of babies breastfeeding?

No. Any gifts to health facilities from baby food companies are not allowed. Gifts, even small ones such as calendars or pens, create a sense of obligation and continuously remind the person who received them about the "generosity" of the giver.

In addition, the Code says that health care facilities should not be used for the display of products within the scope of the Code, or for placards or posters concerning such

products. Usually, posters or information materials from baby food companies contain subtle messages that undermine breastfeeding even if they show pictures of breastfeeding babies.

Just as much as free samples could 'hook' a mother to a particular brand of breast-milk substitute, so could attractive displays of materials by a baby food company.

8. Our formula representatives bring us chocolate when they come to tell us about their products. Can I give that chocolate to my kids? While the offering of chocolate by your formula representative may seem innocent, even small gifts, including chocolate, may make you feel that the company means well and that you owe the company loyalty or gratitude. Companies know that this sense of loyalty or gratitude often leads to endorsing and promoting the company's products. This is one of the reasons why the Code does not allow gifts to health facilities and health workers.

9. Sometimes I receive stationery, pens and other useful items from a company. Is accepting such items against the Code?

Yes. These are gifts from the company, and the Code makes it clear that gifts from baby food companies are not allowed. In addition, these items often have logos or slogans from the company that can imply an endorsement of their products.

10. A company is hosting an event in my facility for mothers and babies, and they're giving away prizes to the winners. That's ok, right?

No, it is not ok. If health facilities allow baby food companies to access families directly, the facility will implicitly be promoting products rather than promoting health. The Code makes it absolutely clear that marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.

11. Can we accept donations of laptop computers from baby food companies to be used in our clinics as long as they don't have any logos of the company?

Donations of equipment, including laptops, will positively influence the attitudes of health workers and management of the facility towards the company and its products. This sense of obligation or influence can interfere with institutional policy and decision-making and the responsibility of the health professional to give trustworthy advice. Such practices potentially undermine optimal infant and young child health and development.

Even when there is no company logo, the donation itself will create a sense of obligation and loyalty.

WHO considers that displaying branded posters or branded milk formula products in health facilities is unacceptable promotion and undermines breastfeeding.

12. Is it acceptable for baby food companies to advertise in our waiting room?

No, the Code says that health care facilities should not be used for the display of products within the scope of the Code, or for placards or posters concerning such products.

13. We have shelves of infant formula in our hospital for babies that can't breastfeed. Should we put up a curtain to cover it up?

Yes. Any breast-milk substitute stored in hospitals, including in maternity wards, should be stored out of sight. A closed cupboard or generic bags could also be used to prevent promotion to patients or staff members.

14. Is it ok to distribute brochures promoting breastfeeding that come from manufacturers of baby foods as long as there are no advertisements for their products?

No. The Code does not allow baby food companies to directly or indirectly provide education to parents and other caregivers on infant and young child feeding in health facilities. Brochures would be one way of providing education. Besides that, brochures from baby food companies often have pictures or implicit messages that favour commercial products over breastfeeding.

Finally, WHO is clear that industry involvement in health worker education or training should not be allowed. For example;

16. I need to improve my professional knowledge. Why can't I accept funding from a baby food company for travel or attendance at professional conferences or meetings?

Funding provided by baby food companies for travel or attendance at professional conferences or meetings is another way the company tries to influence you and create a relationship in which you feel indebted to them. It is a form of financial inducement and is prohibited by the Code.

The MAIF Agreement, its 'committee guidelines' and 'INC publications' fail to reflect current and authoritative interpretations of the WHO International Code, and misrepresents the MAIF Agreement as applying it or implementing it in Australia. Indeed, these documents directly contradict the WHO International Code on numerous aspects of marketing to health workers or health facilities.

Furthermore, as argued in our previous submissions, it is likely that the MAIF Agreement facilitates collusive and aggressive marketing of milk formula products by the major companies through health channels, creates dependence on formula in newborns, and disincentivises quality care.

Also as previously argued, marketing through health channels creates caregiver dependency on purchasing milk formula in the retail market. With around a third of mothers introducing formula within the first postnatal weeks, it can be estimated that a substantial part of the Australian market for milk formula products, perhaps 10-20%, is created by marketing through health channels. Creating dependency on expensive commercial milk formulas by making such branded products freely and easily available in hospitals, and endorsed and/or promoted by health workers, is unconscionable.

The current INC proposal presents updated 'MAIF guidelines' on marketing via health institutions. It also provides 'INC publications'. It should be noted that these are far out of line with WHO Guidance, and have no legitimacy as information on implementing the Code.

Moreover, the ‘committee’ guidelines are explicitly not part of the INC’s MAIF Agreement. If they were part of the Agreement, it is possible they might be enforced on INC members, who may perceive disadvantage compared to the many participants in the industry who are not INC member industry.

The above demonstrates how far the MAIF Agreement is from current international standards of accountability and integrity in the marketing of milk formula through health channels.

For the MAIF Agreement to reflect global best practice implementation of the WHO International Code it would include guidelines that incorporate the above WHO guidance into the MAIF Agreement itself. ACCC could require for example, that MAIF incorporate guidelines that require for formula supplied to health facilities to be in unbranded packaging.

1. Breastfeeding is a human right of mothers and children which means governments should protect them from marketing of breastmilk substitutes.
2. The INC’s MAIF Agreement has not protected breastfeeding, or proper feeding of substitutes where necessary. Breastfeeding has worsened, while sales and use of milk formula products have risen since 1992.
3. The WHO International Code recognises the particular vulnerability of mothers and newborns, and is regularly updated for changes in marketing.
4. If authorised until 2030, the MAIF Agreement will be fifty years out of date, because it addresses only the 1981 World Health Assembly (WHA) resolution establishing the WHO International Code but not the 19 subsequent resolutions of the WHA.
5. It is misleading to say that the MAIF Agreement is “Australia’s official response to the WHO Code”, and its governance continues to have a strong conflicts of interest including industry representation. This means it lacks legitimacy in the eyes of civil society groups and the public.
6. WHO and UNICEF do not consider Australia’s MAIF Agreement as meeting the criteria for ‘implementing’ the WHO International Code. Hence, Australia is reported as not having implemented The Code in international monitoring reports.
7. The proposed MAIF Agreement still denies guidance from the WHO that toddler milk/formula is a breastmilk substitute, and that companies should not offer gifts, education or sponsorship to health care providers. Other countries are implementing this guidance, and Australia is once again, falling well behind international best practice.

8. There is compelling evidence of ongoing inappropriate baby food marketing and its harms to vulnerable consumers, but that industry self-regulation is ineffective in this area. In a rapidly changing environment for infant and young child feeding that includes expansion of human milk banking and trade in human milk, companies use sophisticated new techniques which are non-compliant but circumvent regulations.

In the past five recent years, there is compelling evidence that inappropriate marketing of baby food products including breastmilk substitutes continues via line extension, digitally and through health channels, globally and in Australia. This evidence includes documentation of illegitimate health and nutrition claims, untoward industry influence, and clear conflicts of interest created for health professional organisations and health workers. It is beyond question that this situation harms the health of vulnerable consumers, mothers and their infants and young children. It is also clear that industry self-regulation is ineffective [52], This is because infant and young child feeding is an important area for companies to build lifetime brand loyalty, resulting in strong disincentives for companies to comply voluntarily with marketing restrictions. Research on marketing infant and young child food products shows that companies in Australia and in global markets are using sophisticated new digital marketing techniques, which are often non-compliant with The Code, as well as marketing intensively and aggressively through traditional health channels. The technique of ‘cross-promotion’ across the entire branded product range, is used to circumvent regulations applying to products for the first six months only. It is unacceptable to quarantine regulation of commercial food marketing

activity, which harms mothers and their children well beyond the age of 0-12 months, to the INC's MAIF Agreement.

ANNEX D provides a brief sample of the literature by providing an annotated bibliography of key studies.

- Increasing intensity and sophistication of baby food industry marketing and globalised supply chains is driving booming milk formula sales, with inadequate policy and regulatory frameworks supporting industry expansion over child and maternal health [9].
- The milk formula industry uses comparable marketing tactics to the tobacco industry [53] including 'stakeholder marketing'.
- Political influence by the milk formula industry disrupts regulation for public health benefit [54].
- Packaging and labelling on milk formula products misleads and confuses consumers [55-57].
- There is evidence of health and nutrition claims in Australia via online advertising [58].
- Health claims on specialised formula products,[59] and allergy formulas lack scientific support, with evidence of bias due to industry research funding [60].
- Baby Friendly Hospital Initiative (BFHI) policies which limit free formula or require paying for formula, dramatically reduce in hospital supplementation and increase exclusive breastfeeding [61-63].
- The expansion of human milk banking and international exchange of human milk adds to the complexity of the regulatory environment, and creates scope for companies to exploit gaps in regulation and social protection [64, 65].

9. Australian breastfeeding policy was revised in 2019 with the objective of ending inappropriate marketing of infant formula and breastmilk substitutes, but reauthorising MAIF will not achieve this.

Consistent with Australia's international obligations on human rights, and the AHRC Report in 2019 [17], Australian breastfeeding policy was revised in 2019 with the objective of ending inappropriate marketing of food products for infants and young children. Reauthorising the MAIF Agreement will not meet this objective given the basic design of this self-regulatory arrangement.

The *Australian National Strategy 2019 and Beyond* included in its six key objectives at least two which are about inappropriate marketing:[44]

"Strengthen the regulatory arrangements for marketing of infant formula and breastmilk substitutes so that inappropriate marketing and distribution ceases".

"Increase the proportion of health professionals who receive adequate, evidence-based breastfeeding education and training that is free from commercial influence".

Forced to give formula

"She told me if I don't sign the consent form to give her formula, I will starve her and something bad would happen."

"I was also given a nipple shield to use and the brand name of the formula the hospital used as my baby would have been used to it by now."

Forced to give formula top-ups:

"When I say forced I mean the hospital refused to let me take my son home unless I gave him formula. ... I found out from a midwife at the hospital that they have a special arrangement with S26Gold to promote their products to all mums and babies. So they don't care about what's right for the babies, only about their special deal with a formula company for rewards!"

"It was appalling they would only let me leave if I promised to use formula."

Formula offered or recommended:

"Formula offered regularly from XXX Hospital. Formula and a teat brought in placed on my table, without me asking for it. Nurse gave my friend (taking me home) 3 bottles of XXX Formula to take with us for the trip.

"Basically Doctors told me every time to use formula.

The ANBS was agreed by all Australian governments through COAG processes after extensive consultation [66] and on the basis of an Evidence Check prepared by us and brokered by the Sax Institute for the federal Department of Health [52].

Our Evidence Check confirmed the effectiveness of voluntary codes of practice as a basis for implementing the WHO International Code.

A key theme from extensive public consultations on the draft Australian National Breastfeeding Strategy in 2018 was the need to *‘strengthen Australia’s response to the WHO Code and regulate marketing of infant formula/fully implement the WHO Code and subsequent resolutions’*.

The ANBS Consultation Report also documented many examples of *‘inaccurate advice from health professionals and lack of support from hospitals’* on breastfeeding issues (see sidebars). These included health professionals promoting formula and brands to mothers.

WHO/UNICEF BMS Call to Action

In recent months, there have been further policy developments internationally which are relevant to ACCC’s consideration of the industry’s proposal. In particular, a WHO/UNICEF BMS Call to Action was included in the rules of engagement for the [Nutrition For Growth](#) Congress in Japan in late 2021 [67].

The Call to Action involved inviting all manufacturers of breastmilk substitutes (BMS) to take all the following steps to achieve Code compliance:

“1. Publicly commit your company to full compliance with the International Code of Marketing of Breastmilk Substitutes and subsequent resolutions (the Code) globally (including coverage of breastmilk substitutes up to 36 months of age), and disclose a concrete plan for achieving this goal by 2030 at the latest, with delineation of clear incremental steps.

2. As a first step toward full Code compliance, by the end of 2020:

For companies that do not currently have a BMS marketing policy, adopt a Code-aligned BMS marketing policy for all countries for products marketed as suitable for infants between birth and 12 months of age, and commit to upholding your policy including in all jurisdictions where regulations are absent or less stringent than your policy. In countries where national law is more stringent than your policy, adherence to national law always takes precedence.

For companies that have a BMS marketing policy in place, ensure that your current policy and practices (including promotion to consumers and healthcare providers) are Code-aligned and for products marketed as suitable for infants between birth and 12 months of age, extend them to all countries, and commit to upholding your policy in all jurisdictions even where regulations are absent or less stringent than your policy. In countries where national law is more stringent than your policy, adherence to national law always takes precedence.

3. Commit to support the adoption and implementation of national legislation fully aligned with the Code in order to create a level playing field for all companies.

4. Agree to provide information on your company’s policies and practices to the Access to Nutrition Initiative (ATNI) as requested, recognizing ATNI as an independent actor responsible for monitoring companies’ progress toward their plans for achieving Code compliance.”

To date few companies [have responded](#), but there is the opportunity for the ACCC to encourage INC members to develop plans and commitments in line with the Call to Action by the end of 2020, and assess responses as part of its consideration of the INC proposal for reauthorising the MAIF Agreement.

10. The ACCC can do more to protect and promote breastfeeding and ensure proper infant feeding by strengthening regulation of infant formula and breastmilk substitutes.

The ACCC has the power to ‘strengthen regulation of infant formula and breastmilk substitutes, and can also provide policy advice to support this new Australian policy objective.’ It can do this through shortening the *Australian National University*

duration of the MAIF Agreement, and by imposing conditions related to associated documents on toddler formulas, marketing in health channels and digital marketing. Such actions would improve the effectiveness of the MAIF Agreement, and align with broader concerns about harmful marketing to children including addressing important chronic disease risk factors in the Australian population such as child obesity [68].

Ensuring public benefit from the MAIF Agreement and relevant counterfactuals to INC's reauthorisation application

As noted previously, industry reputation and marketing strategy options benefit from the MAIF Agreement, though this is not its public policy purpose. The existence of MAIF Agreement protects the reputation of the industry, and in its absence, it is possible even likely that companies would act individually to restrain marketing within socially acceptable bounds [69] as was evident during the 1980s in Australia before the APMAIF was introduced [34]. As noted earlier, INC members can potentially benefit from the MAIF Agreement endorsement of strategies for marketing in health channels including segmentation to facilitate indirect promotion of infant formula products such as special infant formulas.

There is more than one counterfactual to reauthorising the *MAIF Agreement* as submitted by INC. One is for the ACCC to not reauthorise it.

Another is authorising it for a much shorter duration.

A further alternative is for the ACCC to strengthen the potential for MAIF Agreement to provide public benefit by shortening its duration to two years. We also argued previously that ACCC could place conditions on its determination to authorise the agreement. We refer you to our previous submissions on this.

Here we propose that the ACCC fully explore the opportunity to more fully use its regulatory powers, by placing conditions on any reauthorisation. Reauthorisation should be conditional on INC of bringing the MAIF Agreement's informal 'Committee guidelines' formally into the Agreement within two years. Appropriate revisions of these guidelines would mean fully incorporating WHA resolutions and WHO guidance on the Code since 1981 as detailed above.

In this regard, it is worth noting that a *WHO-UNICEF-Lancet* Commission on Child Health and Wellbeing recently proposed adding an Optional Protocol to the UN Convention on the Rights of the Child on commercial marketing of harmful products [70]. This was an intended first step in protecting children from harm by marketing. Importantly, the Commission identified a hierarchy of harm among products and deliberately focussed on those that 'directly threatened children's physical and mental health', including foods for infants and young children [71].

Hence our focus on tobacco, alcohol, unhealthy foods, sugar-sweetened beverages, breastmilk substitutes, and gambling applications.

The Commission's proposal also targets the predatory data practices of large companies like Facebook and Google, which, without regulation, harvest and use children's data for profit. An important example is Digital Marketing of Infant Formulas. Using digital marketing to market infant formulas raises important issues of consumer privacy, and breaches the human rights of children and their caregivers [72].

It has been proposed that in line with online prohibitions of tobacco and food advertising to children, digital platforms should also prohibit infant formula advertising [73]. The ACCC could progress such an approach in Australia in discussion with Facebook, Google and other providers.

We propose that the ACCC require a revised MAIF Agreement be finalised by 2023 which incorporates INC's 'Committee guidelines' into the Agreement. MAIF guidelines also purport to cover digital and aspects of health channel marketing as well as general guidelines for interpreting the MAIF Agreement, and must be revised to fully reflect the Code and subsequent resolutions of the WHA and WHO's authoritative guidance such as in 2017 on 'ending inappropriate promotion of foods for infant and young children', and other most recent BFHI and Code related guidance documents for maternal and newborn care facilities, including for health workers.

Furthermore, the ACCC draft determination on the INC application could be informed by INC member responses to the WHO/UNICEF 'Call to Action on Code Compliance', noted earlier. This also provides a convenient mechanism for the ACCC to continuing monitor progress on the Call to Action by companies operating in Australia.

8. There is compelling evidence of ongoing inappropriate baby food marketing and its harms to vulnerable consumers, but experiences shows industry self-regulation is ineffective in a rapidly changing food environment for infant and young children
9. Australian breastfeeding policy was revised in 2019 with the objective that inappropriate promotion of infant formula and breastmilk substitutes ceases', but reauthorising MAIF will not achieve this.
10. More could be done by the ACCC on toddler formulas, marketing in health channels and digital marketing that would be effective in Australia and align with broader concerns about harmful marketing to children and help address child obesity.

Recommendations to ACCC

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

In our previous submissions we pointed to options for the ACCC based in its regulatory history of placing conditions on authorisations.

We make the following recommendations to ACCC to increase the net public benefit of existing self-regulation by better aligning MAIF with contemporary marketing environments, techniques and strategies, and with the aims of the WHO International Code and Resolutions of the World Health Assembly to which the Australian Government is committed.

1. ACCC announce publicly that the market for infant and young child foods (0-36 months) is an *ACCC Compliance and Enforcement Priority* for 2021 and 2022, and provide a public report evaluating the industry response.
2. Include cross promotion through 'mothers formulas' targeting pregnant and breastfeeding mothers in the above surveillance.
3. ACCC to monitor and assess companies' 2020 response to the WHO/UNICEF 'Call to Action on Code Compliance'.
4. ACCC authorise the current Agreement for no longer than 2 years
5. ACCC make such authorisation conditional on all milk formula supplies and samples to institutions or health workers not displaying company brands by the commencement of the reauthorised MAIF Agreement.
6. ACCC to monitor trends in sales of milk formula products in Australia between 2020 and 2023, and require INC to provide evidence that a) rates of in-hospital supplementation, and b) per capita sales volumes of all milk formula product categories targeting infants and young children (0-36 months) are stable or declining in any future application to reauthorise MAIF.
7. ACCC determination to include that any future authorisation is conditional on MAIF including agreed Guidelines that a) comprehensively and fully implement the 1981 WHO Code and all WHA Resolutions and related WHO Guidance from 1981, and b) such guidelines to include specific provisions on i) digital marketing and ii) marketing of toddler milk formula products and iii) marketing to health workers and health facilities.

We also recommend that ACCC

1. Advise Australian federal and state governments on how to legislate the WHO Code and subsequent WHA resolutions the extent necessary to fully implement the Code

2. Advise Australian governments to introduce legislation enabling a requirement for all milk formula manufacturers and distributors including home brands and new entrants to comply with any reauthorised MAIF Agreement.
3. Advise the federal government on the merits of fully incorporating WHO guidance on the Code responsibilities of health workers and health facilities into an urgent update of the NHMRC Infant Feeding Guidelines.
4. Encourage Australian governments to fully reflect WHA/WHO guidance on the Code in an urgent update of the Infant Feeding Guidelines and NHMRC Dietary Guidelines.
5. Consider whether INC is misleading the public and thereby breaching Australian competition and consumer law by referring to current arrangements as 'Australia's official response to the Code' when it clearly falls short of this standard.
6. Take active steps to confirm whether Australian governments are meeting their international obligations, by seeking technical advice from WHO on current self-regulatory arrangements for infant formula and breastmilk substitutes.
7. Advise the federal government on the merits of using its export powers to require Australia's standards of protection for consumers (FSANZ, NHRMC IFG and MAIF) to apply to baby food product exports to other countries, in line with WHA resolutions.
8. Consider whether the governance reform recommendations by NOUS in 2017 should be more fully explored as an alternative to reauthorising MAIF Agreement in 2023, including funding monitoring and compliance arrangements through a baby food industry levy to internalise the high cost of dealing with out of scope consumer complaints.

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ANNEX A Breastfeeding data

Comprehensive national data on infant feeding in Australia has not been collected since 2010.[74] The Australian National Breastfeeding Strategy provides information on indicators of breastfeeding practices in Australia.[44] The National Health Survey provided information for 1995, 2001 and 2005 but only limited data in 2014 and 2018. Victoria and NSW publish annual information on breastfeeding for those states. Full breastfeeding at hospital discharge has declined.

APPENDIX D BREASTFEEDING DATA COLLECTED, BY JURISDICTION— SNAPSHOT OF CURRENT INDICATORS

2011 AIHW workshop indicators	National health surveys			State-based data collection							
	Australian National Infant Feeding survey 2010	National Health Survey 2011–12	National Health Survey 2014–15	ACT Regular monitoring	NSW Regular monitoring	NT Collected but not reported	Qld Point-in-time infant feeding surveys	SA Regular monitoring	Tas Regular monitoring	Vic Regular monitoring	WA Regular monitoring
Proportion of children ever breastfed	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Proportion of children breastfed at each month of age, 0–24 months	✓	4 months 6 months 9 months 12 months 24 months	6 months 12 months 24 months	Discharge Each month to 6 months 12 months	Discharge—overall rates per year		Each month to 6 months		Discharge 2 months ² 4 months	Discharge 2 weeks 3 months 6 months	Discharge 0–14 days 8 weeks 4 months 12 months 24 months
Proportion of children exclusively breastfed to each month of age, 0–6 months	✓	2 months 4 months 6 months	2 months 4 months 6 months	Discharge Each month to 6 months	Discharge—overall rates per year		✓		4 months ³	Discharge 2 weeks 3 months 6 months	Discharge 0–14 days 8 weeks 4 months

² Data limitation: State-based, administrative, non-representative data based on the proportion of infants who attend scheduled child health visits. The four-month data is collected retrospectively, relying on maternal recall, at the six-month scheduled child health visit.

³ Data limitation: State-based, administrative, non-representative data based on the proportion of infants who attend scheduled child health visits. The four-month data is collected retrospectively, relying on maternal recall, at the six-month scheduled child health visit.

2011 AIHW workshop indicators	National health surveys			State-based data collection							
	Australian National Infant Feeding survey 2010	National Health Survey 2011–12	National Health Survey 2014–15	ACT Regular monitoring	NSW Regular monitoring	NT Collected but not reported	Qld Point-in-time infant feeding surveys	SA Regular monitoring	Tas Regular monitoring	Vic Regular monitoring	WA Regular monitoring
Proportion of children predominantly breastfed to each month of age, 0–6 months	✓						Each month to 6 months				Discharge 0–14 days 8 weeks 4 months
Proportion of children receiving soft/semi-solid/solid food at each month of age, 0–12 months	✓	4 months 6 months	4 months 6 months				Each month to 6 months				Each month to 4 years
Proportion of children receiving non-human milk or formula at each month of age, 0–12 months	✓				Discharge—overall rates per year		Each month to 6 months				Each month, to 4 years

Sources

National Health Survey 2011–12: <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/6664B939E49FD9C1CA257B39000F2E4B>

National Health Survey 2014–15: <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/4364.0.55.002~2014-15~Main%20Features~Breastfeeding~10000>

Australian National Infant Feeding Survey 2010: <https://www.aihw.gov.au/about-our-data/our-data-collections/australian-national-infant-feeding-survey-2010>

ACT: <https://www.children.act.gov.au/indicators/breastfeeding>

Vic: <https://www.data.vic.gov.au/data/dataset/vcams-breastfeeding-rates>

NSW: http://www.healthstats.nsw.gov.au/Indicator/mab_feed_cat/mab_feed_cat_lhd_trend

Qld: https://www.health.qld.gov.au/~data/assets/pdf_file/0033/465099/qld-infant-feeding-2014survey.pdf

WA: <http://ww2.health.wa.gov.au/~media/Files/Corporate/Reports%20and%20publications/Population%20surveys/Health-and-Wellbeing-of-Children-in-Western-Australia-2016-Overview-and-Trends.pdf>

Tas: http://www.breastfeedingtas.org/breastfeeding_rates

ANNEX B World Health Assembly Resolutions, 1974-2018

The following is a list of World Health Assembly Resolutions related to the marketing of BMS, the International Code of Marketing of Breast-milk Substitutes and the Inappropriate Promotion of Foods for Infants and Young Children.

No	Year	Title	Recommendations to Member Countries/States
1	1974	WHA 27.43 Infant nutrition and breast feeding	<p>URGES Member Countries to:</p> <ul style="list-style-type: none"> - review sales promotion activities on baby foods and - to introduce appropriate remedial measures, including advertisement codes and legislation where necessary
2	1978	WHA 31.47 The role of the health sector in the development of national and international food and nutrition policies and plans, with special reference to combating malnutrition	<p>RECOMMENDS Member States to:</p> <ul style="list-style-type: none"> - support and promote breast-feeding by educational activities among the general public; - legislative and social action to facilitate breast-feeding by working mothers; - implementing the necessary promotional and facilitating measures in the health services; and regulating inappropriate sales promotion of infant foods that can be used to replace breast milk;
3	1980	WHA 33.32 The role of the health sector in the development of national and international food and nutrition policies and plans, with special reference to combating malnutrition	<p>URGES countries which have not already done so to review and implement resolutions WHA27.43 and WHA32.42</p>
4	1981	WHA 34.22 Infant nutrition and breast feeding	<p>URGES all Member States to:</p> <ol style="list-style-type: none"> 1. give full and unanimous support to the implementation of the provisions of the International Code in its entirety as an expression of the collective will of the membership of the World Health Organization; 2. translate the International Code into national legislation, regulations or other suitable measures; 3. involve all concerned social and economic sectors and all other concerned parties in the implementation of the International Code and in the observance of the provisions thereof; 4. monitor the compliance with the Code;

No	Year	Title	Recommendations to Member Countries/States
5	1982	WHA 35.26 International Code of Marketing of Breast-milk Substitutes	URGES Member States to give renewed attention to the need to adopt national legislation, regulations or other suitable measures to give effect to the International Code.
6	1984	WHA 37.30 Infant and young child nutrition	URGES continued action by Member States, WHO, nongovernmental organizations and all other interested parties to put into effect measures to improve infant and young child feeding, with particular emphasis on the use of foods of local origin;
7	1986	WHA 39.28 Infant and young child feeding	<p>URGES Member States to:</p> <ol style="list-style-type: none"> 1. implement the Code if they have not yet done so; 2. ensure that the practices and procedures of their health care systems are consistent with the principles and aim of the International Code; 3. make the fullest use of all concerned parties – health professional bodies, nongovernmental organizations, consumer organizations, manufacturers and distributors -generally, in protecting and promoting breast-feeding and, specifically, in implementing the Code and monitoring its implementation and compliance with Its provisions; 4. ensure that the small amounts of breast-milk substitutes needed for the minority of infants who require them in maternity wards and hospitals are made available through the normal procurement channels and not through free or subsidized supplies
8	1988	WHA 41.11 Infant and young child nutrition	URGES Member States: to ensure practices and procedures that are consistent with the aim and principles of the International Code of Marketing of Breast-milk Substitutes, if they have not already done so
9	1990	WHA 43.3 Protecting promoting and supporting breast-feeding	<p>URGES Member States to:</p> <ol style="list-style-type: none"> 1. to protect and promote breast-feeding, as an essential component of their overall food and nutrition policies and programmes on behalf of women and children, so as to enable all infants to be exclusively breast-fed during the first four to six months of life; 2. enforce existing, or adopt new, maternity protection legislation or other suitable measures that will promote and facilitate breast-feeding among working women; 3. ensure that the principles and aim of the International Code of Marketing of Breast-milk Substitutes and the recommendations contained in resolution <u>WHA39.28</u> are given full expression in national health and nutrition policy and action, in cooperation with professional associations, women's organizations, consumer and other nongovernmental groups, and the food industry

No	Year	Title	Recommendations to Member Countries/States
10	1992	WHA 45.34 Infant and young child nutrition and status of implementation of the International Code of Marketing of Breast-milk Substitutes	<p>URGES Member States to:</p> <ol style="list-style-type: none"> 1. give full expression at national level to the operational targets contained in the Innocenti Declaration; 2. encourage and support all public and private health facilities providing maternity services so that they become “baby-friendly” 3 take measures appropriate to national circumstances aimed at ending the donation or low- priced sale of supplies of breast-milk substitutes to health care facilities providing maternity services; 4. draw upon the experiences of other Member States in giving effect to the International Code
11	1994	WHA 47.5 Infant and young child nutrition	<p>Urges Member States take the following measures to:</p> <p>(1) to promote sound infant and young child nutrition, in keeping with their commitment to the World Declaration and Plan of Action for Nutrition,2(2) through coherent effective intersectoral action, including:</p> <p>(a) increasing awareness among health personnel, nongovernmental organizations, communities and the general public of the importance of breast-feeding and its superiority to any other infant feeding method;</p> <p>(b) supporting mothers in their choice to breast-feed by removing obstacles and preventing interference that they may face in health services, the workplace, or the community;</p> <ol style="list-style-type: none"> 2. promote sound infant and young child nutrition, including fostering appropriate complementary feeding practices from the age of about six months, emphasizing continued breast-feeding and frequent feeding with safe and adequate amounts of local foods; 3. ensure that there are no donations of free or subsidized supplies of breast-milk substitutes and other products covered by the International Code of Marketing of Breast-milk Substitutes in any part of the health care system; 4. exercise extreme caution when planning, implementing or supporting emergency relief operations, by protecting, promoting and supporting breast-feeding for infants, and ensuring that donated supplies of breast-milk substitutes or other products covered by the scope of the International Code are given only if all required conditions are followed.
12	1996	WHA 49.15 Infant and young child nutrition	<p>URGES Member States to ensure:</p>

No	Year	Title	Recommendations to Member Countries/States
			<p>1. that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding;</p> <p>2. that the financial support for professionals working in infant and young child health does not create conflicts of interest, especially with regard to the WHO/UNICEF Baby Friendly Hospital Initiative</p> <p>3. to ensure that monitoring the application of the International Code and subsequent relevant resolutions is carried out in a transparent, independent manner, free from commercial influence;</p> <p>4. to ensure that the practices and procedures of their health care systems are consistent with the principles and aim of the International Code;</p> <p>5. to provide the Director-General with complete and detailed information on the implementation of the Code;</p>
13	2001	WHA 54.2 Infant and young child nutrition	<p>URGES Member States to:</p> <ol style="list-style-type: none"> 1. Take necessary measures as States Parties effectively to implement the Convention on the Rights of the Child, in order to ensure every child's right to the highest attainable standard of health and health care; 2. Strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation, taking into account the findings of the WHO expert consultation on optimal duration of exclusive WHA54.2 3 breastfeeding,1 and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years of age or beyond, emphasizing channels of social dissemination of these concepts in order to lead communities to adhere to these practices; 3. Support the Baby-friendly Hospital Initiative and to create mechanisms, including regulations, legislation or other measures, designed, directly and indirectly, to support periodic reassessment of hospitals, and to ensure maintenance of standards and the Initiative's long-term sustainability and credibility; 4. Improve complementary foods and feeding practices by ensuring sound and culture specific nutrition counselling to mothers of young children, recommending the widest possible use of indigenous nutrient-rich foodstuffs; 5. Develop, implement or strengthen sustainable measures including, where appropriate, legislative measures, aimed at reducing all forms of malnutrition in young children and women of reproductive age... 6. Strengthen national mechanisms to ensure global compliance with the International Code of

No	Year	Title	Recommendations to Member Countries/States
			Marketing of Breastmilk Substitutes and subsequent relevant Health Assembly resolutions, with regard to labelling as well as all forms of advertising, and commercial promotion in all types of media.
14	2002	WHA 55.25 Infant and young child nutrition	<p>ENDORSES the global strategy for infant and young-child feeding;</p> <ol style="list-style-type: none"> 1. EXHORTS Member States, as a matter of urgency to adopt and implement the global strategy 2. Ensure that the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding;
15	2005	WHA 58.32 Infant and young child nutrition	<p>CALLS ON Member States to ensure that:</p> <ol style="list-style-type: none"> 1. to continue to protect, promote and support exclusive breastfeeding for six months as a global public-health recommendation, taking into account the findings of the WHO Expert Consultation on optimal duration of exclusive breastfeeding,¹ and to provide for continued breastfeeding up to two years of age or beyond, by implementing fully the WHO global strategy on infant and young child feeding that encourages the formulation of a comprehensive national policy 2. nutrition and health claims are not permitted for breast-milk substitutes, except where specifically provided for in national legislation; 3. clinicians and other health-care personnel, community health workers and families, parents and other caregivers, are informed that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately; and, where applicable, that this information is conveyed through an explicit warning on packaging; 4. financial support and other incentives for programmes and health professionals working in infant and young-child health do not create conflicts of interest.”
16	2006	WHA 59.21 Infant and Young Child Nutrition 2006	<p>URGES Member States to support activities on this Call for Action and, in particular, to renew their commitment to policies and programmes related to implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions and to revitalization of the Baby-Friendly Hospital Initiative to protect, promote and support breastfeeding;</p>
17	2008	WHA 61.20 Infant and young child nutrition: biennial progress report	<p>URGES Member States to:</p> <ol style="list-style-type: none"> 1. Strengthen implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions by scaling up efforts to monitor and enforce national measures in order to protect breastfeeding while keeping in mind the Health Assembly resolutions to avoid conflicts of interest;

No	Year	Title	Recommendations to Member Countries/States
			2. Implement, through application and wide dissemination, the WHO/FAO guidelines on safe preparation, storage and handling of powdered infant formula in order to minimize the risk of bacterial infection and, in particular, ensure that the labelling of powdered formula conforms with the standards, guidelines and recommendations of the Codex Alimentarius Commission and taking into account resolution WHA58.32;
18	2010	WHA 63.23 Infant and young child nutrition	<p>CALLS ON Member States to:</p> <ol style="list-style-type: none"> 1. Increase political commitment in order to prevent and reduce malnutrition in all its forms; 2. Strengthen and expedite the sustainable implementation of the global strategy for infant and young child feeding including emphasis on giving effect to the aim and principles of the International Code of Marketing of Breast-milk Substitutes, and the implementation of the Baby-friendly Hospital Initiative; 3. Develop and/or strengthen legislative, regulatory and/or other effective measures to control the marketing of breast-milk substitutes in order to give effect to the International Code of Marketing of Breast-milk Substitutes and relevant resolution adopted by the World Health Assembly; 4. End inappropriate promotion of food for infants and young children, and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex Alimentarius standards or national legislation 5. Ensure that national and international preparedness plans and emergency responses follow the evidence-based Operational Guidance for Emergency Relief Staff and Programme Managers² on infant and young child feeding in emergencies, which includes the protection, promotion and support for optimal breastfeeding, and the need to minimize the risks of artificial feeding, by ensuring that any required breast-milk substitutes are purchased, distributed and used according to strict criteria; <p>CALLS UPON infant food manufacturers and distributors to comply fully with their responsibilities under the International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly resolutions;</p>
19	2012	WHA 65.6 Maternal, infant and young child nutrition	<p>URGES Member States to:</p> <ol style="list-style-type: none"> 1. put into practice, as appropriate, the comprehensive implementation plan on maternal, infant and young child nutrition, including: <ul style="list-style-type: none"> - developing or, where necessary, strengthening nutrition policies so that they comprehensively address the double burden of malnutrition and include nutrition actions in

No	Year	Title	Recommendations to Member Countries/States
			<p>overall country health and development policy, and establishing effective intersectoral governance mechanisms in order to expand the implementation of nutrition actions with particular emphasis on the framework of the global strategy on infant and young child feeding;</p> <ul style="list-style-type: none"> - -developing or, where necessary, strengthening legislative, regulatory and/or other effective measures to control the marketing of breast-milk substitutes; <p>2. establishing a dialogue with relevant national and international parties and forming alliances and partnerships to expand nutrition actions with the establishment of adequate mechanisms to safeguard against potential conflicts of interest;</p>
20	2016	WHA 69.9 Ending inappropriate promotion of foods for infants and young children	<p>URGES Member States in accordance with national context to:</p> <ol style="list-style-type: none"> 1. to take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children 2. to establish a system for monitoring and evaluation of the implementation of the guidance recommendations; 3. to end inappropriate promotion of food for infants and young children, and to promote policy, social and economic environments that enable parents and caregivers to make well informed infant and young child feeding decision 4. to continue to implement the International Code of Marketing of Breast-milk Substitutes and WHO recommendations on the marketing of foods and non-alcoholic beverages to children; <p>CALLS UPON manufacturers and distributors of foods for infants and young children to end all forms of inappropriate promotion, as set forth in the guidance recommendations; 4.</p> <p>CALLS UPON health care professionals to fulfil their essential role in providing parents and other caregivers with information and support on optimal infant and young child feeding practices and to implement the guidance recommendations;</p> <p>URGES the media and creative industries to ensure that their activities across all communication channels and media outlets, in all settings and using all marketing techniques, are carried out in accordance with the guidance recommendations on ending the inappropriate promotion of foods for infants and young children;</p>

No	Year	Title	Recommendations to Member Countries/States
			CALLS UPON civil society to support ending inappropriate promotion of foods for infants and young children, including activities to advocate for, and monitor, Member States' progress towards the guidance's aim;
21	2018	WHA 71.9 Infant and Young Child Feeding	<p>URGES Member States^{2,3,4} in accordance with national context and international obligations:</p> <ol style="list-style-type: none"> 1. to increase investment in development, implementation and monitoring and evaluation of laws, policies and programmes aimed at protection, promotion, including education and support of breastfeeding, including through multisectoral approaches and awareness raising; 2. to implement and/or strengthen national mechanisms for effective implementation of measures aimed at giving effect to the International Code of Marketing of Breast-milk Substitutes, as well as other WHO evidence-based recommendations; 3. to continue taking all necessary measures in the interest of public health to implement recommendations to end inappropriate promotion of foods for infants and young children.

Source: World Health Organization 2020, Code and subsequent resolutions [75]

ANNEX C Baby Food in Australia

In 2012, the retail market value of baby food sales in Australia was estimated by Euromonitor International as A\$372 million. Milk formula totalled \$181.8 mill, \$73.9 being standard formula, \$54.0 million follow on formula, \$16.6 million toddler formula and the balance (\$37.3 million) being ‘special baby milk formula’. In 2007, the respective values had been \$119 million, \$47.5 million, \$35.4 million, \$10.2 million and \$25.9 million. The volume of sales in 2012 was 7,960.0 tonnes, 3,311.8 tonnes, 2,473.9 tonnes, 858.1 tonnes and 1,316.2 tonnes respectively, up from 2007 when sales totalled 6,181.5 tonnes a year, 2,560.0 tonnes, 1,930.0 tonnes, 581.5 tonnes, and 1,110.0 tonnes for toddler formula.

In 2020, reported total sales were \$1,164.7 million, being \$314.3 for standard formula, for follow on \$293.9 million, and toddler formula \$375.0 million, and \$ 181.5 for ‘special baby milk formula’. This represented volumes of 41.4 million tonnes in total, 10.9 million tonnes for standard formula, 9.3 million tonnes for follow up and 15.6 million tonnes of toddler formula, 5.6 million tonnes of ‘special baby milk formula’ [24, 25, 76].

ANNEX D – Annotated bibliography

Baker, P., et al. (2020). "First-food systems transformations and the ultra-processing of infant and young child diets: The determinants, dynamics and consequences of the global rise in commercial milk formula consumption." Matern Child Nutr: e13097.

The inappropriate marketing and aggressive promotion of breastmilk substitutes (BMS) undermines breastfeeding and harms child and maternal health in all country contexts. Although a global milk formula 'sales boom' is reportedly underway, few studies have investigated its dynamics and determinants. This study takes two steps. First, it describes trends and patterns in global formula sales volumes (apparent consumption), by country income and region. Data are reported for 77 countries, for the years 2005-19, and for the standard (0-6 months), follow-up (7-12 m), toddler (13-36 m), and special (0-6 m) categories. Second, it draws from the literature to understand how transformations underway in first-food systems - those that provision foods for children aged 0-36 months - explain the global transition to higher formula diets. Total world formula sales grew by 115% between 2005 and 2019, from 3.5 to 7.4 kg/child, led by highly-populated middle-income countries. Growth was rapid in South East and East Asia, especially in China, which now accounts for one third of world sales. This transition is linked with factors that generate demand for BMS, including rising incomes, urbanisation, the changing nature of woman's work, social norms, media influences and medicalisation. It also reflects the globalization of the baby food industry and its supply chains, including the increasing intensity and sophistication of its marketing practices. Policy and regulatory frameworks designed to protect, promote and support breastfeeding are partially or completely inadequate in the majority of countries, hence supporting industry expansion over child nutrition. The results raise serious concern for global child and maternal health.

Belamarich, P. F., et al. (2016). "A Critical Review of the Marketing Claims of Infant Formula Products in the United States." Clinical Pediatrics **55**(5): 437-442.

A highly competitive infant formula market has resulted in direct-to-consumer marketing intended to promote the sale of modified formulas that claim to ameliorate common infant feeding problems. The claims associated with these marketing campaigns are not evaluated with reference to clinical evidence by the Food and Drug Administration. We aimed to describe the language of claims made on formula labels and compare it with the evidence in systematic reviews. Of the 22 product labels we identified, 13 product labels included claims about colic and gastrointestinal symptoms. There is insufficient evidence to support the claims that removing or reducing lactose, using hydrolyzed or soy protein or adding pre-/probiotics to formula benefits infants with fussiness, gas, or colic yet claims like "soy for fussiness and gas" encourage parents who perceive their infants to be fussy to purchase modified formula. Increased regulation of infant formula claims is warranted.

Berry, N. J. and K. D. Gribble (2017). "Health and nutrition content claims on websites advertising infant formula available in Australia: A content analysis." Maternal Child Nutrition **13**(4).

The use of health and nutrition content claims in infant formula advertising is restricted by many governments in response to WHO policies and WHA resolutions. The purpose of this study was to determine whether such prohibited claims could be observed in Australian websites that advertise infant formula products. A comprehensive internet search was conducted to identify websites that advertise infant formula available for purchase in Australia. Content analysis was used to identify prohibited claims. The coding frame was closely aligned with the provisions of the Australian and New Zealand Food Standard Code, which prohibits these claims. The outcome measures were the presence of health claims, nutrition content claims, or references to the nutritional content of human milk. Web pages advertising 25 unique infant formula products available for purchase in Australia were identified. Every advertisement (100%) contained at least one health claim. Eighteen (72%) also contained at least one nutrition content claim. Three web pages (12%) advertising brands associated with infant formula products referenced the nutritional content of human milk. All of these claims appear in spite of national regulations prohibiting them indicating a failure of monitoring and/or enforcement. Where countries have enacted instruments to prohibit health and other claims in infant formula advertising, the marketing of infant formula must be actively monitored to be effective.

Boyle, R. J., et al. (2016). "Hydrolysed formula and risk of allergic or autoimmune disease: systematic review and meta-analysis." British Medical Journal **352**: i974.

OBJECTIVE: To determine whether feeding infants with hydrolysed formula reduces their risk of allergic or autoimmune disease. DESIGN: Systematic review and meta-analysis, as part of a series of systematic reviews commissioned by the UK Food Standards Agency to inform guidelines on infant feeding. Two authors selected studies by consensus, independently extracted data, and assessed the quality of included studies using the Cochrane risk of bias tool. DATA SOURCES: Medline, Embase, Web of Science, CENTRAL, and LILACS searched between January 1946 and April 2015. ELIGIBILITY CRITERIA FOR SELECTING STUDIES: Prospective intervention trials of hydrolysed cows' milk formula compared with another hydrolysed formula, human breast milk, or a standard cows' milk formula, which reported on allergic or autoimmune disease or allergic sensitisation. RESULTS: 37 eligible intervention trials of hydrolysed formula were identified, including over 19,000 participants. There was evidence of conflict of interest and high or unclear risk of bias in most studies of allergic outcomes and evidence of publication bias for studies of eczema and wheeze. Overall there was no consistent evidence that partially or extensively hydrolysed formulas reduce risk of allergic or autoimmune outcomes in infants at high pre-existing risk of these outcomes. Odds ratios for eczema at age 0-4, compared with standard cows' milk formula, were 0.84 (95% confidence interval 0.67 to 1.07; I(2)=30%) for partially hydrolysed formula; 0.55 (0.28 to 1.09; I(2)=74%) for extensively hydrolysed casein based formula; and 1.12 (0.88 to 1.42; I(2)=0%) for extensively hydrolysed whey based formula. There was no evidence to support the health claim approved by the US Food and Drug Administration that a partially hydrolysed formula could reduce the risk of eczema nor the conclusion of the Cochrane review that hydrolysed formula could allergy to cows' milk. CONCLUSION: These findings do not support current guidelines that recommend the use of hydrolysed formula to prevent allergic disease in high risk infants. REVIEW REGISTRATION: PROSPERO CRD42013004252.

Cattaneo, A., et al. (2015). "Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy." *Arch Dis Child* **100**(4): 323-328.

OBJECTIVE: To assess how follow-on formula milks for infants aged 6-12 months are presented to and understood by mothers. DESIGN: A quantitative and qualitative cross-sectional study including (1) an analysis of advertisements in three magazines for parents; (2) in-depth semi structured qualitative interviews to pregnant women on their perception of two advertisements for follow-on formula and (3) self-administered questionnaires for mothers to explore their exposure to and perception of formula advertisements. PARTICIPANTS: Eighty pregnant women 32-36 weeks of gestation with no previous children and 562 mothers of children <3 years old. SETTING: Maternal and child health centres in eight cities of Italy. RESULTS: Advertisements of formula (n=89) represented about 7% of all advertisements in the three magazines, the majority (58%) being for follow-on formula. Advertisements were parent-oriented, aimed at helping parents solve health problems of their babies or at eliciting good feelings, or both. The qualitative interviews to pregnant women showed inability to define the advertised products at first glance due to the ambiguity of the numeral 2 and the presumed age of the portrayed baby; this inability did not disappear after carefully viewing the advertisements and reading the text. When asked in the self-administered questionnaires whether they had ever come across advertisements of infant formula, 81% of mothers reported that they had, despite the legal inexistence of such advertisements, and 65% thought that it was for a product to be used from birth. CONCLUSIONS: Advertisements of follow-on formula are perceived by pregnant women and mothers as promoting infant formula.

Granheim, S. I., et al. (2017). "Interference in public health policy: examples of how the baby food industry uses tobacco industry tactics." *World Nutrition Journal* **8**(2): 288-310.

Despite countries' commitments to improve nutrition, starting with the protection of breastfeeding, aggressive marketing of breastmilk substitutes continues to promote their indiscriminate use. The baby food industry appears to use similar interference tactics as the tobacco industry to influence public health, promote their products and expand their markets. Learning from the tobacco experience, this paper assesses whether the baby food industry uses any of the six tobacco industry interference tactics recognized by the World Health Organization (WHO) and summarizes examples of documented evidence. We conclude that the baby food industry uses all six tactics: (1) manoeuvring to hijack the political and legislative process; (2) exaggerating economic importance of the industry; (3) manipulating public opinion to gain appearance of respectability; (4) fabricating support through front groups; (5) discrediting proven science; and (6) intimidating governments with litigation. There is abundant anecdotal evidence. Published evidence is limited and varies by tactic. Examples of interference are provided for the Philippines, Vietnam, Laos, Turkey, Ecuador, Hong Kong, Mexico and

the United Kingdom, and most for tactic 3. Interference in public health policies shows commonalities between the two industries. The tobacco control movement offers a useful framework for classifying and addressing interference with public policy by the baby food industry. Revealing the depth and extent of interference used by the baby food industry is critical if countries are to counter interference and implement commitments to improve nutrition.

Grummer-Strawn, L. M., et al. (2017). "New World Health Organization guidance helps protect breastfeeding as a human right." Maternal & Child Nutrition **13**(4): n/a-n/a.

Written by the WHO/UNICEF NetCode author group, the comment focuses on the need to protect families from promotion of breast-milk substitutes and highlights new WHO Guidance on Ending Inappropriate Promotion of Foods for Infants and Young Children. The World Health Assembly welcomed this Guidance in 2016 and has called on all countries to adopt and implement the Guidance recommendations. NetCode, the Network for Global Monitoring and Support for Implementation of the International Code of Marketing of Breast-milk Substitutes and Subsequent Relevant World Health Assembly Resolutions, is led by the World Health Organization and the United Nations Children's Fund. NetCode members include the International Baby Food Action Network, World Alliance for Breastfeeding Action, Helen Keller International, Save the Children, and the WHO Collaborating Center at Metropol University. The comment frames the issue as a human rights issue for women and children, as articulated by a statement from the United Nations Office of the High Commissioner for Human Rights.

Hastings, G., et al. (2020). "Selling second best: how infant formula marketing works." Global Health **16**(1): 77.

BACKGROUND: Despite the clear policy intent to contain it, the marketing of formula milk remains widespread, powerful and successful. This paper examines how it works. METHODS: The study comprised a mix of secondary analysis of business databases and qualitative interviews with marketing practitioners, some of whom had previously worked in formula marketing. RESULTS: The World Health Assembly Code aims to shield parents from unfair commercial pressures by stopping the inappropriate promotion of infant formula. In reality marketing remains widespread because some countries (e.g. the USA) have not adopted the Code, and elsewhere industry has developed follow-on and specialist milks with which they promote formula by proxy. The World Health Assembly has tried to close these loopholes by extending its Code to these products; but the marketing continues. The campaigns use emotional appeals to reach out to and build relationships with parents and especially mothers. Evocative brands give these approaches a human face. The advent of social media has made it easier to pose as the friend and supporter of parents; it is also providing companies with a rich stream of personal data with which they hone and target their campaigns. The formula industry is dominated by a small number of extremely powerful multinational corporations with the resources to buy the best global marketing expertise. Like all corporations they are governed by the fiduciary imperative which puts the pursuit of profits ahead of all other concerns. This mix of fiscal power, sophisticated marketing, and single-mindedness is causing great harm to public health. CONCLUSIONS: Formula marketing is widespread and using powerful emotional techniques to sell parents a product that is vastly inferior to breast milk. There is an urgent need to update and strengthen regulation.

Pomeranz, J. L., et al. (2018). "Toddler drinks, formulas, and milks: Labeling practices and policy implications." Preventative Medicine **109**: 11-16.

Toddler drinks are a growing category of drinks marketed for young children 9-36months old. Medical experts do not recommend them, and public health experts raise concerns about misleading labeling practices. In the U.S., the toddler drink category includes two types of products: transition formulas, marketed for infants and toddlers 9-24months; and toddler milks, for children 12-36months old. The objective of this study was to evaluate toddler drink labeling practices in light of U.S. food labeling policy and international labeling recommendations. In January 2017, we conducted legal research on U.S. food label laws and regulations; collected and evaluated toddler drink packages, including nutrition labels and claims; and compared toddler drink labels with the same brand's infant formula labels. We found that the U.S. has a regulatory structure for food labels and distinct policies for infant formula, but no laws specific to toddler drinks. Toddler drink labels utilized various terms and images to identify products and intended users; made multiple health and nutrition claims; and some stated

there was scientific or expert support for the product. Compared to the same manufacturer's infant formula labels, most toddler drink labels utilized similar colors, branding, logos, and graphics. Toddler drink labels may confuse consumers about their nutrition and health benefits and the appropriateness of these products for young children. To support healthy toddler diets and well-informed decision-making by caregivers, the FDA can provide guidance or propose regulations clarifying permissible toddler drink labels and manufacturers should end inappropriate labeling practices.

Smith, J. P. (2017). "Without better regulation, the global market for breast milk will exploit mothers." The Conversation from <https://theconversation.com/without-better-regulation-the-global-market-for-breast-milk-will-exploit-mothers-79846>.

Markets in mothers' milk could be a good or a bad thing for women and their children, depending on how governments respond. Making breast milk more easily available may help more mothers breastfeed, and improve the economics of the situation for women. With maternal breastfeeding now promoted as a choice rather than a biological imperative, it is hypocritical and duplicitous for governments to authorise companies to sell breast milk without strengthening the rights of women to breastfeed, sell or share their own milk. Markets in mothers' milk could be a good or a bad thing for women and their children, depending on how governments respond. Making breast milk more easily available may help more mothers breastfeed, and improve the economics of the situation for women. With maternal breastfeeding now promoted as a choice rather than a biological imperative, it is hypocritical and duplicitous for governments to authorise companies to sell breast milk without strengthening the rights of women to breastfeed, sell or share their own milk.

The international market for breast milk has grown from both demand and supply factors, and from difficulties common to new mothers worldwide. The huge accumulation of scientific evidence on the importance of breastfeeding for both women and babies has resulted in an increase in market demand for milk. This is led by health professionals treating medically vulnerable babies. Potential bacterial or viral contamination of traded breast milk can be avoided by pasteurisation. The risks are comparable to those associated with cow milk infant formula. The buyers for breast milk in the United States include women having trouble breastfeeding, especially after difficult childbirth. Lack of paid maternity leave for women after childbirth also increases demand for breast milk in the US. Bodybuilders also buy it for sports nutrition. On the supply side, new technologies are helping lactating women in the US and elsewhere to extract, store and exchange their milk safely and independently. Exchange increasingly occurs online. For some, selling surplus milk makes maternity leave affordable. Others provide milk to babies of relatives and friends through informal networks. However, breast milk is in short supply where formula is cheap and breastfeeding rates are low.

Only a small number of companies are involved in the global trade, the biggest being Prolacta. The US company has been collecting milk through milk banks for around US\$30 a litre and turning into a commercial product sold to US hospitals for nearly US\$300 a litre. Alongside the not-for-profit breastmilk banks, several million ounces of breastmilk are processed in North America each year. The Australian government recently approved a local dairy entrepreneur, Neolacta, to import and sell breast milk. Neolacta has attracted controversy in India around plans to collect milk without remuneration from poor mothers at a Bangalore hospital and sell it publicly for US\$300 a litre, in return for donating some of the processed milk to a hospital neonatal unit. Another company, Ambrosia Milk, was selling breast milk in the United States. Unlike the Indian proposal, the company paid Cambodian mothers for their milk, so they earned at least twice the local wage. Ambrosia's scheme barred mothers from contributing milk until babies had been breastfed for six months, and required health checks. Offering women around US\$15 a litre for breast milk, Ambrosia found willing suppliers. However, Cambodian officials shut down the trade this year, declaring: Even though we are still poor, we are not so poor that we have to sell human breast milk.

Tarrant, M., et al. (2015). "Effect of a hospital policy of not accepting free infant formula on in-hospital formula supplementation rates and breast-feeding duration." *Public Health Nutrition* 18(14): 2689-2699.

OBJECTIVE: To investigate the effect of public hospitals in Hong Kong not accepting free infant formula from manufacturers on in-hospital formula supplementation rates and breast-feeding duration. DESIGN: Prospective cohort study. SETTING: In-patient postnatal units of four public hospitals in Hong Kong. SUBJECTS: Two cohorts of breast-feeding mother-infant pairs (n 2560). Cohort 1 (n 1320) was recruited before implementation of the policy to stop accepting free infant formula and cohort 2 (n 1240) was recruited after policy implementation. Participants were followed

prospectively for 12 months or until they stopped breast-feeding. RESULTS: The mean number of formula supplements given to infants in the first 24 h was 2.70 (sd 3.11) in cohort 1 and 1.17 (sd 1.94) in cohort 2 ($P<0.001$). The proportion of infants who were exclusively breast-fed during the hospital stay increased from 17.7 % in cohort 1 to 41.3 % in cohort 2 ($P<0.001$) and the risk of breast-feeding cessation was significantly lower in cohort 2 (hazard ratio=0.81; 95 % CI 0.73, 0.90). Participants who non-exclusively breast-fed during the hospital stay had a significantly higher risk of stopping any or exclusive breast-feeding. Higher levels of formula supplementation also increased the risk of breast-feeding cessation in a dose-response pattern. CONCLUSIONS: After implementation of a hospital policy to pay market price for infant formula, rates of in-hospital formula supplementation were reduced and the rates of in-hospital exclusive breast-feeding and breast-feeding duration increased.

Zakarija-Grkovic, I., et al. (2018). "Compliance With WHO/UNICEF BFHI Standards in Croatia After Implementation of the BFHI." *Journal of Human Lactation* **34**(1): 106-115.

BACKGROUND: The primary goal of the Baby-Friendly Hospital Initiative (BFHI) is to create conditions in maternity facilities that enable women to initiate and sustain the practice of breastfeeding exclusively. Research aim: This study aimed to determine hospital practices and breastfeeding rates before and after BFHI implementation and assess compliance with UNICEF/World Health Organization (WHO) standards for seven of the BFHI's Ten Steps to Successful Breastfeeding (Ten Steps). METHODS: Mothers of healthy, term infants (N = 1,115) were recruited from the postnatal ward of the University Hospital of Split, Croatia, between February 2008 and July 2011 and followed for 12 months in a repeated-measures, prospective, longitudinal, three-group, nonequivalent, cohort study. Breastfeeding rates, hospital practices-including seven of the Ten Steps-and maternal sociodemographic data were collected. RESULTS: Parts of all seven Ten Steps that were assessed improved significantly post-BFHI. Step 3 ("antenatal education") showed the least improvement, whereas Step 7 ("rooming-in"; 2.6% pre-BFHI vs. 98.5% post-BFHI) and Step 9 ("no pacifiers/teats"; 21.8% pre-BFHI vs. 99.4% post-BFHI) showed the greatest improvement. Six months after Baby-Friendly designation, only Steps 7 and 9 were in full compliance with UNICEF/WHO standards. In-hospital, exclusive-breastfeeding rates rose markedly ($p < .001$), but no change occurred in breastfeeding rates at 3, 6, or 12 months. CONCLUSION: Full implementation of the BFHI was associated with significant improvement in hospital practices and in-hospital, exclusive-breastfeeding rates, but it did not affect breastfeeding rates postdischarge, emphasizing the vital role of community support. Baby-Friendly Hospital Initiative standards declined rapidly post-hospital designation, indicating the need for regular monitoring and reassessment as well as ongoing, effective training for hospital staff.