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Further submission of information in relation to ACCC draft determination on proposal on marketing of infant formula

World Health Organization (WHO), 2001, Infant formula and related trade issues in the context of the International Code of Marketing of Breast-milk Substitutes.

Believing that, in the light of the foregoing considerations, and in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products.

No breast-milk substitute, not even the most sophisticated and nutritionally balanced formula, can begin to offer the numerous unique health advantages that breast milk provides for babies. Nor can artificial feeding do more than approximate the act of breastfeeding, in physiological and emotional significance, for babies and mothers alike. And no matter how appropriate infant formula may be from a nutritional standpoint, when infants are not breastfed or are breastfed only partially, feeding with formula remains a deviation from the biological norm for virtually all infants. Therefore, infant formula should not be marketed or distributed in any environment in ways that may interfere with the protection and promotion of breastfeeding."

Further submission of information in relation to ACCC draft determination on proposal on marketing of infant formula*

Overview

In late 2015, the Australian Competition and Consumer Commission considered an application by the Infant Nutrition Council Limited for an authorisation to restrict the marketing of infant formula in Australia by its members. The proposed industry agreement is said to reflect the aims of the WHO International Code of Marketing on Breastmilk Substitutes, of contributing to the provision of safe and adequate nutrition for infants by the protection and promotion of breastfeeding and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

Arguments for the <u>public benefit</u> of the proposed authorisation were well canvassed in submissions and at the ACCC's pre-decision conference. The ACCC was asked by many submitters to require undertakings or impose conditions on any such authorisation.

INC has submitted that there is minimal public detriment from authorisation of the proposed agreement. The argument elaborated below is that, to the contrary, and despite a considerable <u>potential public</u> benefit from restraining marketing of infant formula to the public, there is also important potential <u>public detriment</u> that the ACCC needs to consider fully, as this could influence whether authorisation of the proposed agreement <u>as it stands</u>, is of overall public benefit, and/or for determining conditions or undertakings which the ACCC might require.

Public detriment potentially arises in this case especially because the proposed agreement facilities INC members agreeing to market through the health system by making donated or low-priced supplies or samples of infant formula to health workers and/or health institutions. Such pricing practices distort pricing, reduce productive and allocative efficiency, and harm valuable innovations which benefit infant health and nutrition by increasing breastmilk provision and health care system support for breastfeeding. Authorisation of the proposed marketing agreement may facilitate rather than restrain coordinated marketing through health system channels by the major milk formula manufacturers and importers (i.e. INC members), at the expense of new entrants and competing suppliers in the relevant market. These competing suppliers include enterprises engaged in activities to increase human breastmilk supply, which compete with commercial infant formula.

In the following, we discuss how to define 'the relevant market', arguing that as infant formula is a breastmilk substitute, the relevant 'market' should be defined broadly, to include breastfeeding, human breastmilk and breastfeeding-related products and services. The relevant market for assessing effects of restraints on marketing is unlikely to be the same as used by the ACCC for assessing the merger of Nestle Australia and Pfizer Nutrition in 2013. We identify an 'infant and young child (IYC) food economy', which includes the for profit, not for profit, and household sectors, and where breastmilk, breastfeeding, and breastfeeding-related services compete for IYC 'meal-share' with a small number of large commercial producers of breastmilk substitutes.

^{*} The valuable contributions of Dr Libby Salmon and Dr Phil Baker to this submission are gratefully acknowledged. Responsibility for the submission remains with the author.

Also discussed are aspects of marketing strategies, market participation, and market failure which affect the efficient and fair functioning of this 'relevant market'. The proposed agreement has impacts on both for-profit and not-for-profit as well as household sector participants in this market. We note that women are key participants in supplying the IYC food and related markets, including for example, as private lactation consultants or as donors to human milk banks. In this IYC food economy, decisions by health workers and women about breastfeeding, breastfeeding support, and human milk provision are influenced by economic pricing, especially the price of commercial breastmilk substitutes supplied to health workers and/or health institutions.

It is concluded in this submission that low-priced infant formula provided to health professionals and/or health institutions creates price distortions which adversely affect economic efficiency and reinforce potential disadvantage to consumers from pervasive market failures influencing IYC feeding practices. This is because, firstly, such marketing distorts the incentives for health services incentives to use an appropriate mix of goods and services which better supports breastfeeding, such as human milk banks. Secondly, it disrupts and creates barriers to competition against commercial formula products, such as increased provision of various innovative products and services supporting the provision of human milk to infants and young children and breastfeeding. Thirdly it undermines consumer preferences for breastfeeding. Allowing companies to market to health workers and/or health institutions through providing free or low cost supplies and samples of infant formula legitimises infant formula companies using aggressive and discriminatory pricing strategies to encouraging early formula use and thereby hinder the establishment of breastfeeding. Undermining women's decisions to breastfeed in this way exploits new mothers' and babies' vulnerabilities and is unfair to consumers, as well as economically inefficient.

It is also concluded that authorisation of the proposed agreement would allow INC members to maintain their dominance of marketing through health care channels, without necessarily improving the quality of IYC feeding information or advice available to consumers. Hence, there is potentially a high 'public detriment' to economic efficiency from the current proposal.

Finally, it is emphasised that failure to give visibility to competing producers against milk formula within the IYC food economy is particularly detrimental to women. It perpetuates a structural discrimination against those women running businesses such as professional lactation consultant or health professional education on breastfeeding and lactation, and undermines the viability of women's not-for-profit companies such as ABA which provides free breastfeeding support services to mothers using revenues earned from sales of breastfeeding-related goods and services such as lactation aids and breastfeeding consultancy services to employers. It also undermines the economic and other opportunities available for breastfeeding women in the household sector who are supplying economically valuable products and services - breastmilk, breastfeeding, or breastfeeding support, including through human milk donation or sale, and milk sharing or wet-nursing.

Introduction

In late 2015, the Australian Commerce and Consumer Commission considered an application by the Infant Nutrition Council Limited (INC) for an authorisation to make an agreement to restrict the marketing of infant formula in Australia by INC membersⁱ. It called for public submissions on the proposals in August 2015, and following a draft decision to authorise the proposed agreement, called a pre-decision conference in December 2015.

Such authorisation is required because trade practices law in Australia makes unlawful any 'cartel', 'exclusionary', or other contracts which substantially lessen competition. However, the ACCC may authorise such agreements where there is overall public benefit from doing so. The current INC proposal is said to reflect the aims of the WHO International Code of Marketing on Breastmilk Substitutes, of contributing to the provision of safe and adequate nutrition for infants by the protection and promotion of breastfeeding and by ensuring the proper use of breastmilk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

The arguments about whether there is public benefit from the proposed agreement were well canvassed in submissions and at the pre-decision conference. It was submitted by many that the MAIF and especially the proposed marketing agreement do not adequately implement the 1981 WHO International Code and subsequent World Health Assembly (WHA) Resolutions, and therefore does not effectively restrain inappropriate marketing of breastmilk substitutes in the current market environment; hence the public benefit of authorising the proposal as it stands was argued to be significantly overstated by INC. The public benefit was said to be overstated because important aspects such as the complaints mechanism, independent monitoring and enforcement differ from the previous MAIF agreement, making the proposed agreement less effective, and less transparent than its predecessor, with reduced public accountability. Furthermore, the proposal does not meet the ACCC's own standards for self-regulatory agreements. Moreover, the proposed agreement was criticised for excluding Australian companies' export marketing activities despite the evident need for Australia to play a leadership role.

The ACCC was therefore asked by many submitters to require undertakings or impose conditions on any such authorisation to make the proposed agreement more effective in restraining inappropriate marketing, and therefore increasing the public benefit and making such benefit more certain. Many submissions also proposed that the ACCC could increase the public benefit by building in an early review, through granting authorisation for no more than 2 years. WHO has recently set out draft guidelines defining inappropriate marketing of all commercial IYC products for children 0-36 months including complementary foods and 'growing up milks' (World Health Organization (WHO) 2015). This follows statements of concern by WHA in 2010, and the issuing of an information statement in 2013 where WHO also set out the lack of necessity for growing up milks, as well as the potential harm to children's nutrition and health from inappropriate promotion of these products (World Health Assembly (WHA) 2010; World Health Organization (WHO) 2013). A WHA Resolution on these guidelines is expected in 2016. Australia is also reviewing its National Breastfeeding Strategy 2010-2015. An early review of any authorisation would also ensure the Australian government can promptly and fully attend to its international and international responsibilities, including under the United Nations Convention on the Rights of the Child.

INC has submitted that there is minimal public detriment from authorisation of the proposed agreement for 10 years. The argument elaborated below is that, to the contrary, and despite a considerable potential public benefit from restraining marketing of infant formula to the public, there is also important potential public detriment that the ACCC needs to consider fully, as this could influence whether authorisation of the proposed agreement as it stands, is of overall public benefit, and/or for determining conditions or undertakings which the ACCC might require.

Section 1 below identifies the relevant detrimental aspects of the proposed agreement as being the agreement by INC members to engage in marketing via health care channels using free or low priced supplies and samples, a key strategy employed by INC members to expand sales of milk formulas, which thereby undermine the purported aims of the WHO Code and MAIF of protecting and promoting breastfeeding, and ensuring the proper use of breastmilk substitutes.

Section 2 discusses how to define 'the relevant market', arguing that as infant formula is a breastmilk substitute, the relevant 'market' should be defined broadly, to include breastfeeding, human breastmilk and breastfeeding-related products and services. This section also argues that the proposed agreement should include export marketing, so as to anticipate rather than stifle industry compliance with evolving international norms on inappropriate marketing of commercial IYC foods.

Section 3 sets out the potential public detriment in Australia from authorising a proposal which, as it stands, facilitates INC members agreeing to market through the health care system by supplying cheap infant formula, and thereby distorting pricing, reducing productive and allocative efficiency, and harming valuable innovations to benefit infant health and nutrition by increasing breastmilk provision and health care system support for breastfeeding.

1. The WHO International Code and the MAIF

Using discriminatory pricing strategies to market breastmilk substitutes through health care channels

The WHO International Code of Marketing of Breastmilk Substitutes (henceforth, 'The WHO International Code') bans the use of the health care system to promote breast milk substitutes (BMS); and in particular,

- bans free or low-cost supplies of breast milk substitutes; and
- allows health professionals to receive samples only for research purposes.

The Marketing Agreement on Infant Formula which was in place from 1992 to 2013 (henceforth 'MAIF') consequent to Australia's ratification of the WHO International Code differed in several ways from the WHO International Code, and has not been updated since in response to subsequent relevant World Health Assembly (WHA) resolutions.ⁱⁱ The important weaknesses in MAIF compared to the WHO International Code have been noted in previous submissions, including its exclusion of marketing activity of all commercial foods for infants and young children (IYC) other than 'infant formula'; exclusion of bottles and teats; and the exclusion of marketing activities of retailers, distributers and exporters. These differences between the WHO International Code and the MAIF are summarised in Figure 1 below.

For the purposes of this submission, it is important to note that the MAIF allowed donated or low-priced supplies, and samples of infant formula for 'professional evaluation' to be provided to the health care system.^{III} These provisions, allowing marketing of breastmilk substitutes to health workers and/or health facilities at prices significantly below retail levels, remain in the new agreement proposed by INC (henceforth 'the proposed agreement'), at clause 6e and 7d. This aspect of marketing activity, using free or low-priced supplies and samples to market infant formula to health care providers, is the main focus of this submission.

Because it has relied heavily on the MAIF to implement relevant provisions of the WHO International Code, Australia performs poorly in its implementation of key elements of the WHO International Code. A recent report by WHO (World Health Organization (WHO) 2012), assessed Australia as having very incomplete legislation and regulations compared to low and middle income countries in the Western Pacific region (Figure 2 below).

Most notably, Australia is one of the few countries in the region that has not implemented WHO International Code restraints on promotion to health workers and health facilities through free or low-cost supplies of BMS, and through materials or gifts to health workers and/or health facilities.

After receiving evidence from many health professionals and the public that the MAIF Agreement was not operating effectively, the Parliamentary Best Start Inquiry in 2007 recommended full implementation of the WHO International Code in Australia, (House of Representatives Standing Committee on Health and Aging 2007). Significant evidence was provided to the Committee that demonstrated 'infant formula manufacturers in Australia advertise their products in a manner which would clearly breach the WHO Code'.

AUSTRALIA

Code Violations • 2 0 0 7

A survey of the state of the International Code of Marketing of Breastmilk Substitutes and subsequent WHA Resolutions

The International Code, adopted by the World Health Assembly in 1981 promotes, protects and supports breastfeeding by prohibiting promotional activities by baby-food companies.

As a response to the Code, Australia adopted the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF) in May 1992. MAIF is a voluntary code between 6 major food companies and the Australian Government. MAIF falls short of the recommended minimum standards set by the International Code and subsequent WHA resolutions which Australia has endorsed at the international level.

This report is not intended to be comprehensive. It highlights some marketing practices in Australia which undermine breastfeeding and violate the Code, its spirit and intent.

National figures show that only 10% of Australian babies are still being breastfed exclusively at six months, falling far short of the National Health and Medical Research Council (NHMRC) recommended target of 80% and is also under the 34% world average

— Australian Breastfeeding Association

The International Code versus MAIF

Some notable differences:

International Code

Applies to all countries and companies as a minimum standard.

Applies to all breast milk substitutes including other milk products, foods and beverages marketed to replace breast milk, feeding bottles and teats.

 Covers "retailers" under its definition of "Distributor", and forbids promotion at retail level.

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- Governments have the responsibility to ensure that objective and consistent information is provided on infant feeding.
- No point-of-sale advertising or any other promotion device such as special displays, discount coupons, premiums, special sales, loss leaders and tie-in sales at the retail level
- Health authorities have the responsibility to encourage and protect breastfeeding and promote the principles of the Code.
- Free or subsidised supplies are banned in any part of the health care system (WHA resolution 47.5 [1994]).
- Information to health professionals should be restricted to scientific and factual matters, and should not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding.
- Governments have overall responsibility to implement and monitor the Code. Monitoring should be carried out in a transparent and independent manner.

MAIF Code of Practice

- Coverage is limited to six major baby food companies Heinz Watties, Nestlé, Nutricia, Wyeth, Abbott and Snow Brand. Others are not bound to follow MAIF.
- Applies only to infant formula. Products such as baby cereals, infant meals and drinks are not covered even if marketed for infants below 6 months of age. MAIF does not cover feeding bottles and teats.
- Distributors are not covered and MAIF is silent on promotion at the retail level.
- No equivalent responsibility exists. Information materials by companies are often distributed through health care systems and usually contain conflicting messages about breastfeeding.
- No equivalent provision on promotion at the retail level. Thus promotion at the retail level is not forbidden.
- No equivalent responsibility exists
- Allows certain free supplies as it is based on 1981 Code Article 6.6 which is superseded by WHA resolution 47.5.
- Requires companies to give health care professionals product information reflecting current knowledge and responsible opinion which are clearly identified with company and brand names.
- Advisory Panel which administers MAIF and decides on complaints is partly represented and funded by industry, giving rise to conflict of interests.

Figure 1 Differences between WHO Code and the 1992-2013 MAIF. Source IBFAN, 2007, Australia Code Violations

Table 2.6 Key provisions of legislation/regulations in countries and areas in the WHO Western Pacific Region

				LEGISLATION AN	D REGULATIONS				
	Scope of the Code	Promotion to the general public		Promotion to health workers and health facilities		Labelling			
Country or area	Age limit (months)	Advertising of BMS prohibited	Sales promotions prohibited	Free or low-cost supplies of BMS	Materials or gifts to health workers and/or health facilities	Recommended age for designated product	Message on superiority of breastfeeding	Functioning implementation and monitoring mechanism	Source
Australia	0-12	-	-	-	-	Yes	Yes	Full	WHO, 2008
Brunei Darussalam	-	-	-	-	-	-	-	-	WHO, 2008
	0-24	Full	Full	Full	Full	Yes	Yes	-	WHO, 2008
Cambodia	0-24	Full	Full	Full	Full	Yes	Yes	Full	WHO, 2010
China	0-4	Full	Full	Full	Full	No	Yes	No	WHO, 2010
Cook Islands	-	-	-	-	-	-	-	-	-
Fiji	-	Full	Full	Full	Full	Yes	Yes	No	WHO, 2010
rench Polynesia	0-12	Full	Full	Full	Full	Yes	Yes	Full	WHO, 2010
Japan	-	-	-	-	-	-	-	-	-
Kiribati	-	-	-	-	-	-	-	-	WHO, 2010
Lao People's Democratic Republic	0-24	Full	Full	Full	Full	Yes	Yes	No	WHO, 2010
Malaysia	-	-	-	-	-	-	-	-	WHO, 2010
Marshall Islands	-	-	-	-	-	-	-	-	WHO, 2008
Micronesia (Federated States)	-	-	-	-	-	-	-	-	-
Mongolia	-	Full	Full	Full	Full	Yes	Yes	Full	WHO, 2010
Vauru	-	-	-	-	-	-	-	-	-
New Zealand	0-36	-	-	-	-	Yes	Yes	Full	WHO, 2008
Niue	-	-	-	-	-	-	-	-	-
^o alau	-	-	-	-	-	-	-	-	-
Papua New Guinea	-	-	-	-	-	-	-	-	WHO, 2008

				LEGISLATION AN	D REGULATIONS				
	Scope of the Code	Promotion to the general public		Promotion to health workers and health facilities		Labelling			
Country or area	Age limit (months)	Advertising of BMS prohibited	Sales promotions prohibited	Free or low-cost supplies of BMS	Materials or gifts to health workers and/or health facilities	Recommended age for designated product	Message on superiority of breastfeeding	Functioning implementation and monitoring mechanism	Source
Philippines -	0-24	Full	Full	Full	Full	Yes	Yes	Full	WHO, 2008
	0-36	Full	Full	Full	Full	Yes	Yes	Full	WHO, 2010
Republic of _ Korea	-	Full	-	Full	Full	-	Yes	Full	WHO, 2008
	0-6	Full	Full	Full	Full	-	Yes	Full	WHO, 2010
Samoa	-	-	-	-	-	-	-	-	WHO, 2008
Singapore	-	-	-	-	-	-	-	-	WHO, 2008 8 2010
Solomon Islands	-	-	-	-	-	-	-	-	-
Tonga	-	-	-	-	-	-	-	-	-
Tuvalu	-	-	-	-	-	-	-	-	WHO, 2010
Vanuatu	-	-	-	-	-	-	-	-	-
Viet Nam	0-12	Partial	Partial	Full	Full	Yes	Yes	Full	WHO, 2010

Figure 2 Country implementation of WHO International Code of Marketing of Breastmilk Substitutes: Australia compared to other countries in the region. Source: (World Health Organization (WHO) 2012).

The Parliamentary Committee expressed particular concerns 'at the practice of manufacturers using health professionals as surrogate marketers of their products via distribution of free infant formula sample packs to new mothers', and reported receiving 'consistent evidence that samples of infant formula are being made available to mothers through health professionals such as early childhood nurses, doctors and hospitals'.

It also warned that 'the implicit endorsement of a product given when a health professional provides a free sample to a person should not be underestimated'.

The effectiveness of marketing of infant formula to health workers and through the health system in undermining breastfeeding has been confirmed in many high quality studies, but most recently, a study by WHO researchers in the Philippines showed that a) doctor's recommendations, and b) exposure to advertising were the primary factors influencing decisions to introduce formula (Sobel, Iellamo et al. 2011). Introduction of formula was statistically significantly associated with a <u>seven-fold</u> increase in the likelihood of ceasing breastfeeding before 12 months.^{iv}

Counter-regulatory marketing strategies

Implementation of the WHO International Code at national level has been observed in several countries to generate industry responses and strategies to ameliorate any adverse effects on sales of such regulatory restraints. For example, a 2008 Euromonitor study reported that in response to increasing regulation of marketing in developed countries, industry was increasing its marketing focus on developing countries, especially in Asia (Euromonitor International 2008).

A study published in the *Australian and New Zealand Journal of Public Health* in 2013 provides Australian evidence of such strategic counter regulatory behaviour, presenting data (see Figure 3a) on print advertising which showed that immediately following the introduction of the MAIF in Australia there was a rapid expansion of advertising of toddler milk and cross branded baby food, products that were not included in the self-regulatory industry agreement (Smith and Blake 2013).

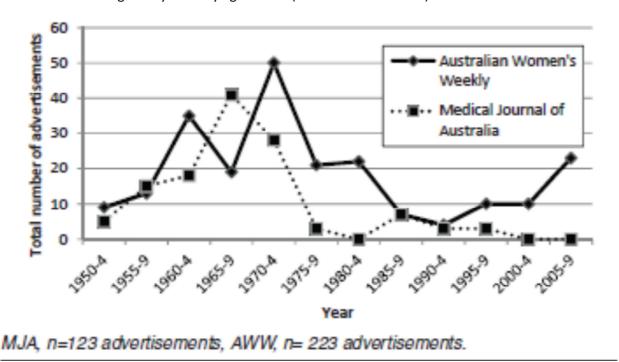


Figure 3a Longitudinal trends in volume of breastmilk substitute advertising in the *Australian Women's Weekly* and the *Medical Journal of Australia*, 1950-2009. Source: (Smith and Blake 2013)

Figure 3b presents unpublished data from that same study showing a rapid rise in the amount of advertising of IYC food products which were excluded from the 1992-2013 MAIF, as well as demonstrating a pattern of restrained marketing of all IYC food products during the 1970s and 1980s. The timing of this

counter-regulatory marketing activity suggests that adverse public opinion, and relatedly, an ongoing threat of mandatory regulation, not industry self-restraint, is the important motivation for compliance with WHO guidance on inappropriate marketing. In fact, the continued decline in overall IYC food marketing activity from 1970 until 1992 and the sudden expansion after that date suggests that new infant formula marketing strategies were being developed to avoid the forthcoming MAIF regime even during the ten years from 1981 to 1992 that the companies were formulating and negotiating the MAIF with the Australian government.

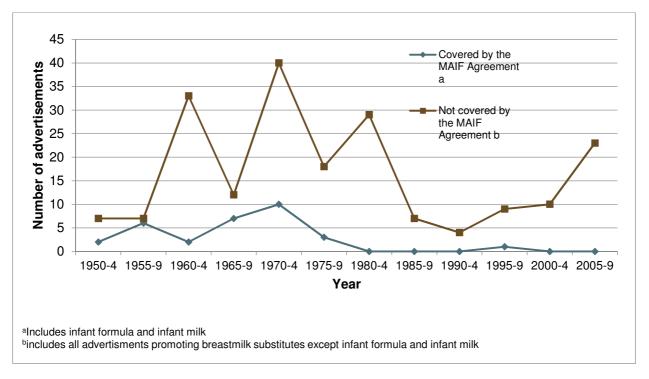


Figure 3b Advertisements promoting breastmilk substitutes in the Australian Women's Weekly according to coverage under the MAIF Agreement as a proportion of all advertisements, 1950-2009

Likewise, a recent study in the UK observed that after the imposition of legislation on marketing of toddler formulas industry marketing altered in a way which undermined the effectiveness of the regulation (Dickinson, Gunter et al. 2013).

Such counter-regulatory marketing strategies are also strongly evident from a detailed investor study of the formula industry in New Zealand (Coreolis 2014). This detailed industry assessment clearly articulates the milk formula industry's regional and global marketing strategies. Importantly, it also highlights the significance of marketing infant formula to health care workers and/or institutions, through market segmentation.

As can be seen in Figure 4 below, formula for infants under six months is described in the Coreolis study as 'mainly marketed through health professionals'; formula products for babies older than six months are then 'renamed', and the market segmented 'primarily to avoid regulation and restrictions on advertising'. 'Brand loyalty developed before 6 months is used to retain customers with older infants and toddlers'.

HOW IS IT SEGMENTED?



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)

Five stage segmentation of infant/child nutrition products Model: 2013

	Stage 1/Step 1	Stage 2/Step 2	Stage 3/Step 3	Stage 4/Step 4	Stage 5/Step 5	Pregnant mothers	
Common name	Infant formula	Infant formula Follow on formula Follow up formula		Children's nutrition Toddler formula "Growing up milk"			
Regulatory environment	Highly regulated Advertising banned (by law or voluntarily) Manufacturers focus on selling through doctors & nurses	Advertising allowedTraditional FMCG sal	raditional FMCG sales & marketing ake advantage 1 and 2 to retain consumers as they grow				
Defined target age range	Birth to 6mo.	6mo. to 1 year	1 to 3 years	3 to 6 years	6 years +	Pregnant & lactating women	
EXAMPLE range:							
Meadjohnson -	Enfamit A [‡]	Enfamil A+ 9 28	Enfagrow A+	Enfagrow A+	Enfagrow A+	EnfaVlama A Mayor phase analog for the second sec	

Source: photo credit (fair use; low resolution; complete product/brand for illustrative purposes); Coriolis from a range of published sources

Figure 4 'Marketing strategies to avoid regulation and restrictions on advertising'. Source: (Coreolis 2014).

Benefits of self-regulation, industry self-interest and incentives for compliance

Authorisation by a respected government authority such as the ACCC gives the infant formula industry important benefits in the form of reputation and respectability, and consumer confidence in the safety and scientific credibility of commercial milk formula products. Rightly or wrongly, some consumers may believe that 'the government wouldn't allow it if it weren't OK'. An unintended adverse consequence from the ACCC authorising the proposed agreement maybe therefore that the Australian public may be therefore wrongly led to believe that the ACCC endorses and oversights the industry's marketing practices and that infant formula marketing is being effectively regulated.

INC has submitted that the industry is well suited to effective self-regulation, citing a study for the New Zealand Commerce Commission (Burgess and QUigley 2011). This study identified features of the infant formula industry which create incentives for compliance with self-regulation in some areas. This supports that the likely counterfactual to effective government legislation or regulation is a form of industry self-restraint of marketing, rather than unrestrained industry marketing. As the New Zealand study point out however, this does not imply a totally passive government, and there a range of government responses which can enhance compliance in self-regulatory regimes. Importantly, the same study points out that industry may respond strategically to the threat of regulation by acting to self-regulate, and may choose to enforce compliance only to the extent needed to ward off mandatory regulation which is more

burdensome to industry. Furthermore, the New Zealand study also noted conditions under which selfregulatory authorities are likely to be 'captured', such as where the dominant industry player was able to 'corrupt' the self-regulatory body in the dominant player's own interest (Burgess and QUigley 2011).

This is highly pertinent to the current proposal, because the milk formula industry is highly concentrated. That is, INC member incentives for compliance and effective self-regulation are likely to be low, with the self-regulatory body highly susceptible to 'capture' by dominant industry players. Indeed, in its 2013 Public Competition Assessment of the merger of Nestle and Pfizer Nutrition, the ACCC noted its concerns that the proposed acquisition would result in substantially reduced competition and highly concentrated markets in formula milks (both 'IFFO Milk and GUMs), particularly because of the strong brand equity of the companies' products. Nestle, Pfizer/Aspen Nutritionals and Danone together represent 85-90% of the market for milk formula (Table 1 below, from (Australian Competition and Consumer Commission (ACCC) 2013)).

Even if there is some commercial incentive through the proposal for INC members to monitor and challenge inappropriate marketing to the public by new and emerging formula industry competitors (which disturbs established industry market shares), the proposed agreement like MAIF entrenches current brands with health workers such as those who provide neonatal or maternity care because it allows ongoing 'behind the scenes' marketing of low-priced, branded supplies to the key institutional market.

Table 1 – Shares of supply – Starter Infant Formula and Follow-on Milk (IFFO Milk) and Growing-Up Milks (GUMs) (2011)

Supplier	IFFO Milk	GUMs
Nestlé	21.5%	14.6%
Pfizer Nutrition	38.2%	34.8%
Merged entity	59.7%	49.4%
Nutricia	30.7%	37.2%
Heinz	4.5%	6.5%
Bellamy's Organic	1.8%	6.8%
Bayer	2.2%	n.a.
Abbott	0.7%	n.a.
Other	0.4%	n.a.
TOTAL	100%	100%

Source: AC Nielsen Scan Data FY2011 by value (retail sales – grocery and pharmacy)

Significantly to the arguments of this paper, the ACCC formed the view that barriers to entry and expansion are high for IFFO milk and GUMs because of brand loyalty formed through marketing through the health system:

'Retail consumers exhibit a high degree of brand loyalty to their preferred brand which continues throughout the lifecycle of a consumer's use of IFFO Milk and GUMs. The ACCC considered that the primary barrier to entry and expansion is the high degree of brand loyalty attached to the brands of the major incumbent suppliers'. [emphasis added]

Indeed the ACCC concluded (at page7-8), that because advertising or promotion direct to consumers was restricted by MAIF,

the reputation and credibility of a brand of infant formula is established over many years through suppliers actively engaging in building relationships with healthcare professionals and through a history of supply to, and association with, the hospital channel'. [emphasis added]

In the case of the infant formula industry, the marketing activities of INC members under MAIF are not externally monitored or documented. Health professionals' distribution and use of milk formula samples such as to generate pharmacy sales or for distribution to mothers experiencing breastfeeding difficulties is likewise a practice which reduces access by new competitors to established health system marketing channels. The issue of samples distribution has been important in past authorisations (e.g. Generic Medicines, 2010). In the case of medicines, the ACCC has required reporting details of the samples provided, including the basis on which they were provided. Such activity in the infant formula market is by contrast completely invisible and unaccountable to either the public, to the ACCC, or to non-INC industry competitors.

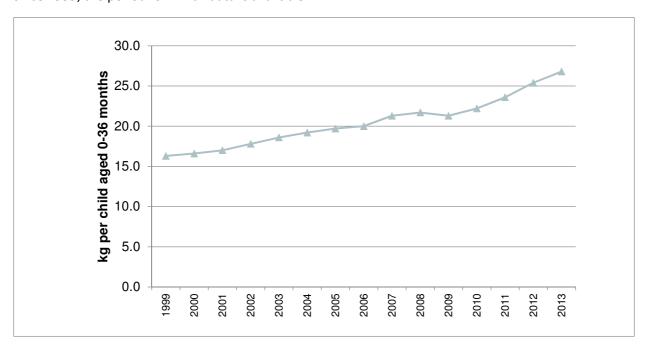
The current proposal therefore entrenches arrangements which allow marketing to and through the health system to remain un-transparent and anti-competitive, potentially to the detriment of health care consumers who are 'left in the dark' about how their health care provider interacts with, and benefits from materials, gifts, free supplies or samples, free education and training, or sponsorship by infant formula companies.

Does MAIF support or undermine the aims of protecting breastfeeding?

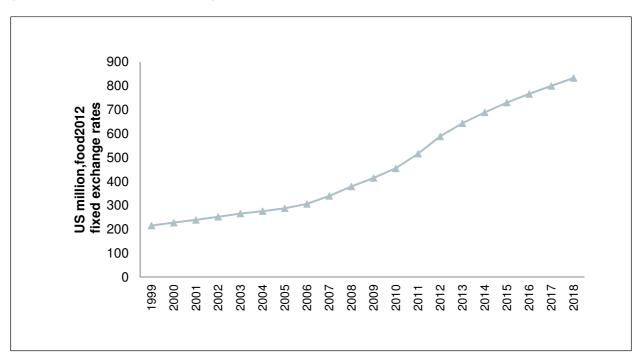
The MAIF cannot ever be proven to 'cause' public detriment such as reducing breastfeeding, just as it cannot be conclusively shown to protect breastfeeding. Nevertheless, As WHO has stated in its 2001 review of infant formula and trade regulatory issues (World Health Organization (WHO) 2001), 'those who suggest that direct advertising has no negative effect on breastfeeding should be asked to demonstrate that such advertising fails to influences a mothers decision about how to feed her infant'. A similar argument can be made regarding marketing to health workers and health institutions through free or low cost formula supplies. No evidence has been presented by INC that the MAIF industry self-regulation since the early 1990s has protected breastfeeding against emerging strategies to market commercial breastmilk substitutes via the promotion of special needs formula through health care channels, or of toddler milks marketed directly to the public. While the first of these strategies is facilitated by legitimising it within the MAIF, the second is secured by excluding toddler milk products from the MAIF altogether.

Nevertheless, is evident from the above, Australasian commercial infant formula manufacturers including INC members have acted to segment the market for milk formulas in order to continue marketing breastmilk substitutes for infants younger than 6 months. The examples above also show that marketing to health workers or health institutions through free or low cost supplies of infant formula is intended to influence mothers to early use of formula. Such marketing through the health care system creates brand awareness and brand loyalty which evades and circumvents the restrictions on direct advertising to the public of infant formula. That these strategies have been effective in promoting sales of commercial IYC food products is evident in industry data on sales.

Figures 4a and 4b below shows the rapid growth in sales of commercial baby food in Australia since the 1990s, and the forecast rise to 2018. Sales of these products per child 0-36 months have nearly doubled since 1999, the period for which data is available.



Figures 4a Volume of commercial baby food sales, Australia, 1999-2013 (kg per child. Source: (Euromonitor International 2013)



Figures 4b Value of commercial baby food sales, Australia, 1999-2013, \$US, 2012 prices. Source: (Euromonitor International 2013)

Figure 5 below presents data on the total volumes of key types of milk formula sold in Australia for the period 2009 to 2014, and shows that sales volumes of milk formula expanded rapidly from the 1990s. This has been driven by rapid growth in sales of 'special baby milk formula' and 'toddler milk', but sales of 'standard milk formula' also rose substantially over the same period. The data does not show the supply channels for each of these product categories.

However, 'special baby milk formula', defined by the ACCC in the Nestle/Pfizer Nutrition assessment (Australian Competition and Consumer Commission (ACCC) 2013) as 'specialty formulas' are said to be 'specifically formulated to address digestive problems or designed for infants and toddlers with special needs, and are made available across all stages'. Most sales of 'special baby milk formula' are likely to be generated through marketing via health care channels. These 'specialty formula' products thus serve as a potential vehicle for major formula manufacturers gain medical endorsement for the early introduction of breastmilk substitutes.

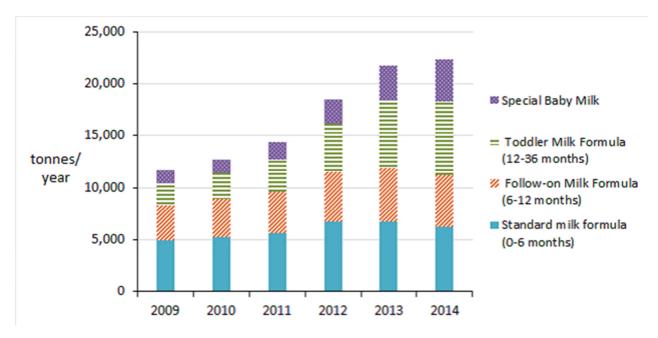


Figure 5 Product proportion of Australian milk formula market covered by the 1992-2013 MAIF, 2009-2014. Source: (Euromonitor International 2013)

Along with various health and nutrition claims for toddler milks, the marketing of these 'speciality formula' products have strong parallels with the phenomenon of 'disease-mongering'. As defined by Wikipedia, disease mongering is a pejorative term for the practice of widening the diagnostic boundaries of illnesses and aggressively promoting their public awareness in order to expand the markets for treatment. Health experts have drawn attention to the increasing prevalence of this pharmaceutical industry marketing strategy in recent years to expand potential consumer markets for drug products (Moynihan and Henry 2006). The pervasive marketing, and cheap and ready availability of 'specialty formula' products to health workers and/or health care institutions such as to address problems of 'regurgitation', 'colic' or sleep problems, may likewise reflect marketing drives aimed at increasing formula product awareness and demand, and undermining health care models directed at establishing exclusive breastfeeding in vulnerable newborns.

In the US paediatric researchers have recently challenged the health and medical claims made for such specialised infant formulas, with calls from pediatric experts for a moratorium on their marketing and use in the absence of an evidence base for their effectiveness. As Belamarich and colleagues states in a study just published in *Clinical Pediatrics* (Belamarich, Bochner et al. 2015),

'the manufacture and sale of specialized infant formulas with small compositional changes such as reduced lactose or the addition of probiotics is not evidence based and has little if any benefit to infants, parents, or paediatricians."

As demonstrated in more detail below, the free or low priced supply of specialised infant formula products may reduce the financial viability and profitability of human milk products and breastmilk feeding and undermine incentives in the health care system to better support breastfeeding such as through establishing human milk banks.

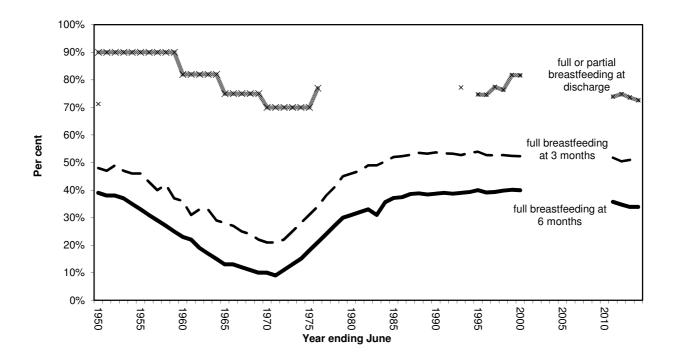


Figure 6 Long term breastfeeding trends in Australia. Source: Maternal & Child Health Services Annual Report, Victoria, 2013.

With ongoing promotion of the major milk formula brands through free or low cost supplies to the health system including 'speciality formulas', and rising sales of milk formula products in Australia due to toddler milk marketing, it is unsurprising to see that neither breastfeeding exclusivity nor duration have improved since around 1980 in Australia. Figure 6 above shows trends in breastfeeding establishment and full breastfeeding at 3 and 6 months in Australia from 1950 to 2013, as indicated by a Victorian department of health time series. This series indicates a pattern of declining breastfeeding in recent years. Breastfeeding peaked between the early 1980s (when the WHO Code was introduced globally) and the mid-1990s, when the MAIF commenced in Australia. Notably, this decline appears to correspond to declining rates of breastfeeding at discharge from hospital, and corresponds to recent data showing more than 30% of Australian infants have already been introduced to milk other than breastmilk by one month of age (AIHW 2010).

In summary, it can be argued that although it has permitted expanded sales of breastmilk substitutes and has not protected breastfeeding from the effects of marketing, the MAIF has played a significant role in fending off effective regulation of the milk formula industry and preserving industry reputation and credibility in the Australian market, whilst allowing the 2-3 major incumbent suppliers to maintain and increase their dominant position by marketing their IYC food brands through Australian healthcare workers and/or health institutions. Meanwhile, coverage of milk formula products by MAIF has declined to less than 50% of the milk formula market (excluding special baby milks) compared to 75% five years ago (Figure 5).

This shrinking of effective coverage of MAIF whilst marketing and sales of other (cross promoted) milk formula products have been extended, is a trend over which INC has considerable control, given their continued dominance of the market in these products by Nestle, Pfizer/Aspen and Danone.

Taking into account its impacts on breastfeeding, MAIF can be seen as an instrument which not only advantages the commercial milk formula ('breastmilk substitute') industry dominated by INC, in competition with smaller, emerging milk formula manufacturers, but also substantially advantages the formula industry in its competition with breastmilk and breastfeeding and related goods and services, characterised in Section 2 below as the 'Infant and Young Child (IYC) food economy'. This illustrates that the 'relevant market' for assessing the impact of the proposed agreement is not commercial infant formula for up to 12 months old. Rather the relevant market must be defined widely to include impacts on economic efficiency (and public benefit or detriment) in a wider sphere.

In the following section, Section 2, the IYC food economy is outlined in relation to the commercial baby food industry including milk formula in order to define the 'relevant market'. Section 3 then analyses the detrimental competitive effects (in the milk formula market and in the wider IYC food economy) of authorising an INC agreement dominated by Nestle, Aspen and Danone, to use free or low cost supplies of commercial milk formula to market through health care channels.

2. The 'relevant market' for assessing impact of INC restraining its infant formula marketing - the IYC food economy'

INC has submitted that the relevant market for assessing its proposal is that for the supply of <u>infant formula</u> for the feeding of infants up to the age of 12 months in Australia, and that this automatically follows from the relevant market identified for ACCC assessment of the Nestle/Pfizer Nutrition merger. That submission is challenged below, as is the INC submission that only the <u>Australian market</u> is relevant. Below it is argued that the market for infant formula should be defined broadly, reflecting the unique nature of this market, and infant formula is, by its nature, a 'breastmilk substitute'. Also, the authorisation relates to an <u>agreement to restrain marketing activity</u>; hence any impact assessment should relate to a different 'market' to that resulting from a <u>merger</u> of formula companies. Furthermore the 'relevant market' for assessing the impact of a merger on consumers and retail prices due to a lessening of competition is <u>unlikely</u> to be same as the relevant market for assessing the public benefit or detriment <u>due to self-regulation of marketing by INC members</u> (which protects their established capacity to market to health workers and/or health services and thereby affect early decisions to introduce branded infant formula products, and shorten the duration of exclusive and ongoing breastfeeding).

Commercial formula manufacturers are not the only suppliers of milk for infants up to the age 12 months, nor are they the most important suppliers. Consumer preferences for breastfeeding in Australia are strong, with most mothers intending to breastfeed. A wider variety of enterprises, both for-profit and not-for-profit, are involved in supplying IYC foods and/or a range of breastfeeding related products and services (Smith and Ingham 2005; Smith 2013). The largest competing suppliers of milk for IYC in Australia are lactating mothers in the household sector, not other commercial suppliers of milk formula.

These suppliers are potentially affected by ACCC authorisation of an agreement on marketing of infant formula in Australia, and the potentially detriment impact of the proposed agreement on these parties needs to be considered. The question is, does allowing INC to maintain its privileged position in marketing of infant formula via health channels adversely affect the market for breastfeeding related products and services, including breastfeeding support and donated breastmilk supplied by for-profit and not-for-profit enterprises in the market sector, and breastfeeding women in the household sector donating, sharing or selling their milk. If the interactions between the commercial baby food sector and these other parts of the economy are neglected, there may be unintended consequences of authorisation, and national welfare may not be maximised because of detrimental health and other externalities associated with higher than optimal infant formula sales.

Although most breastmilk or breastfeeding is not exchanged or sold to a third party (ignoring the mothers own baby) decisions about its production are influenced by its 'price'. Commercial milk formula for IYC is a breastmilk 'substitute', implying there are relevant economic relationships between the supply of that commercial product and breastfeeding, or breastmilk, including cross price elasticities. That is, the extent of breastfeeding is influenced by economic pricing, and its costs relative to breastmilk substitutes affect relevant consumer and producer decisions.

Markets are emerging in human milk, raising new regulatory dilemmas (Smith 2015). Human milk is now bought and sold in a variety of ways. In late 2015, a commercial company even began collecting and exporting human milk from Cambodia (Jackson 2015). In December 2015, a for-profit milk bank also

commenced operations in Australia (Chase 2016). Pasteurised human milk products are already being marketed and sold to US hospitals by a commercial enterprise for some US\$1200 a litre (Prolacta 2013), compared to \$100 a litre or more from donor milk banks. Human milk is exchanged, through various forms of milk sharing between mothers, and through donation of milk to other mothers informally or through formal human milk banks (Phillips 2011). Human milk is also purchased indirectly through the hire of commercial wet-nurses, which has been re-establishing in some countries such as China (see for example Fowler and Ye (2008) and the US (see Robb (2014)), and is not unknown in Australia (Thorley 2008; Thorley 2008; Thorley 2009). Recent developments in markets for human milk, discussed in more detail below, illustrate clearly that breastmilk is a marketable commodity and breastfeeding a potentially commercial service, and are competing with infant formula. The market for breastfeeding and lactation support services and lactation aids such as breast-pumps is also considerable, and expanding.

Having a market value, breastmilk can be better accounted for in monetary terms, and can be compared directly with the market value of commercial milk formulas manufactured from bovine milk or other sources (Smith 1999; Smith and Ingham 2005). Human milk supply in Australia as in other countries (Smith 2012) has a substantial economic value and is currently valued at just under \$4 billion a year in Australia (Smith 2013). By comparison, commercial milk formula sales in Australia are estimated by Euromonitor at less than \$200 million in 2012, with total baby food category sales around A\$400 million (Euromonitor International 2013). If breastfeeding practices in Australia were closely in line with those considered optimal by national and international health authorities such as WHO, the economic value of human milk production in Australia would be some \$7 billion a year. These 'market shares' - in what can be characterised as 'the IYC food economy' - might be illustrated graphically as in Figure 7.

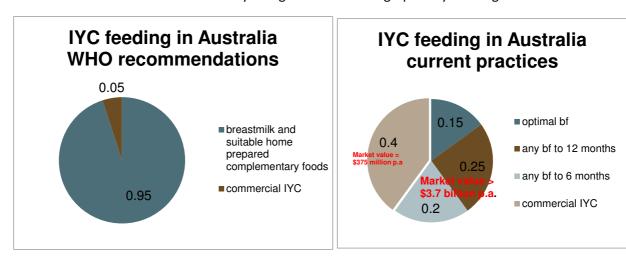


Figure 7 'The IYC food economy'. Note: approximate market shares only. Valuation of breastmilk based on Smith (2013)); excludes valuation of home prepared complementary foods.

The value of this production of human milk, some of which enters the market sector, and some of which is exchanged privately, is excluded from economic output measures such as GDP (Smith 1999; Smith and Ingham 2005; Smith 2012; Smith 2013). The policy bias resulting from excluding human milk from GDP is explicitly acknowledged and cited by Joseph Stiglitz and Amartya Sen, in a report for the French President on measuring economic progress (Stiglitz, Sen et al. 2009). These Nobel Laureate economists used the example of breastmilk to illustrate the undesirable bias in economic policy from ignoring home production:

"There is a serious omission in the valuation of home-produced goods – the value of breast milk. This is clearly within the System of National Accounts production boundary, is quantitatively nontrivial and also has important implications for public policy and child and maternal health."

Commercial IYC food marketing activity influences breastfeeding decisions, reducing breastfeeding. As female labour force participation has increased in the past decade, the potential competition for mothers' time from employment also interacts with breastfeeding decisions because exclusive breastfeeding is time costly and workplaces are not sufficiently 'breastfeeding friendly' (Smith, McIntyre et al. 2013). Commercial marketing to employed mothers is observed to be increasing not just in Australia but in the Asia Pacific region more generally (Euromonitor International 2008). Lack of adequate accommodation of breastfeeding mothers in employment along with the rising commodification of human milk is likely to be associated with increased 'economic pricing' in infant feeding decisions (Shakespeare and Smith 2013).

The vulnerability of IYC feeding practices to market forces, economic pricing and financial incentives may have serious population health consequences. In a paper in the *Australian Journal of Labour Economics*, it was shown that increased competition in the infant formula market in Australia due to import liberalisation in the 1950s resulted in a surge in marketing activity in the hospital sector, with the effect of dramatically reducing breastfeeding (Smith 2007). This had significant impact in increasing long term population health risks for obesity and chronic disease in Australia (Smith and Harvey 2011).

Comparable chronic disease risk issues at the population level are now in evidence in China, where Australia and New Zealand exporters are major players and exclusive breastfeeding has declined from over 60% to around 28% in less than a decade (Gribble and Smith 2014). China has comprehensive implementation of the WHO International Code but no monitoring and enforcement of compliance (Figure 2)(AAP 2013; Harney 2013).

This draws attention to the question of whether the MAIF should cover the export marketing activities of Australian milk formula manufacturers. The recent WHO draft guidelines point to the need for strong regulation of cross border marketing (World Health Organization (WHO) 2015). WHO identified evidence of cross-border promotion to avoid national restrictions on IYC marketing and has called for governments 'ensure that national action applies to promotion originating from their territory and reaching other countries.'

Many Western Pacific region countries are significant export markets for Australian formula manufacturers. There is a trend for countries to strengthen their implementation of the WHO International Code for example, Cambodia and Philippines (more recently also Hong Kong). As Australian exporters are not explicitly included in the MAIF, INC marketing activities may undermine neighbouring governments' efforts to implement the WHO International Code more effectively.

Furthermore, in 2014 INC chief executive Jan Carey stated publicly that INC members should, and were taking the lead on ethical behaviour in export markets (Carey 2014);

The council is aware that there are some less experienced or more opportunistic companies that do not abide by the same codes of behaviour, both here and overseas. When these companies are identified, the council approaches them to discuss their obligations. But parents and the public can be assured that the vast majority of the industry in Australia and New Zealand behaves honourably. Furthermore, council members have not only made a commitment to this ethical behaviour in

Australia and New Zealand but in all the countries we export to and market in. We agree the industry in Australia should be taking the lead and that is what we are doing. [emphasis added]

Parent companies of INC members such as Nestle, Danone and Mead Johnson were recently found to be marketing inappropriately through the health system in major Asian markets, including by bribery and other forms of corruption in the health system, and through price fixing (Harney 2013; Reuters 2013).

This raises questions as to how fully the Australian subsidiaries of these companies comply with appropriate community and regulatory standards for marketing of infant formula in Australia, as well as in their export markets. Any agreement authorised by the ACCC should anticipate rather than stifle industry compliance with international norms on marketing, including of complementary foods and toddler formulas. It is appropriate for the ACCC to consider the export marketing activities of INC members to not only to assess whether the proposed agreement discourages Australian industry from aligning with global regulatory standards, but also to consider the public health impact of its infant formula marketing in Australia's key export markets (Galtry 2013; Galtry 2013; Salmon, Smith et al. 2013).

A final consideration regarding the relevant market is that the current proposal relates to a <u>potentially collusive restraint on marketing</u> of infant formula, <u>rather than a merger of dominant participants</u> in the infant formula market, which is covered by a different part of the Act. This means that the legal tests regarding any lessening of competition, and the relevant market for assessing such impacts, are different. The definition of the relevant market used in the Nestle/Pfizer nutrition assessment focusses on the potential competition-reducing effect of fewer competitors in the supply of commercial milk formula products. The ACCC assessment in that case included all milk formulas for infants and young children, including 'toddler milks'.</u> However, the commercial milk formula market is not necessarily the relevant market for consideration of the wider issues raised by the proposed agreement on marketing restraint, which has a much wider range of public benefit and public detriment impacts including on breastfeeding and information provision. Hence the relevant market should be defined more broadly for the current purpose of assessing the impact of an agreement for restraining marketing of <u>breastmilk substitutes</u>. Below we discuss the conceptual basis for defining this more appropriate broader 'relevant' market.

What products define 'the relevant market'

The main 'products' competing with commercial infant formula broadly comprise: mothers' own milk (fed from the breast, or expressed for others to feed to the child), or other mothers' milk (donated or sold to milk banks or supplied through informal milk sharing or hired wet nurses); and other commercial baby foods such as complementary foods and juices and toddler milks for older babies and young children (all of which can be considered as 'breastmilk substitutes') (World Health Organization (WHO) 2015).

Responding to health promotion of breastfeeding which has shaped women's preferences towards breastfeeding, various providers of breastfeeding related goods and services have emerged in the past decade. Such enterprises sell breastfeeding related goods and services in the market sector including;

 <u>Lactation aids</u> including supply lines, breastfeeding pillows, breast shells and nipple shields, breastpumps (sold, hired or supplied by companies such as Medela, Avent, and Ameda), retailed by major retailers such as Target, by pharmacists, and by the ABA. Some pharmacists, hospitals and ABA groups hire breast-pumps to mothers, including to those whose baby is still hospitalised, or who may be returning to employment and need to express breastmilk. Lactation aids have mainly been supplied to consumers on a not-for-profit basis in Australia, but commercial involvement is both longstanding, and growing rapidly (http://www.lactaid.com/thelactaidstory/)

- Lactation consultant services, for example, by members of the Lactation Consultants Association of Australia and New Zealand (LCANZ) are becoming more widely available, a growing number having internationally recognised qualifications in breastfeeding management. International Board Certified Lactation Consultants (IBCLCs) are health professionals, expert in the management of breastfeeding and human lactation. A large percentage work in hospitals, but a growing percentage works in community-based facilities. These community health care facilities include public health clinics, lactation centres, milk banks, medical practices, midwifery practices, and private lactation consultant practices. (http://www.lcanz.org/find-a-lactation-consultant/).
- A number of businesses deliver independent health professional education and training in breastfeeding and lactation. An important market niche has developed for online or other education and training for health workers which is independent of food or pharmaceutical industry influence, and WHO Code compliant. It includes businesses such as iLactation (http://www.ilactation.com/) or Health e-learning (www.health-e-learning.com). It also includes the conferences, workshops and events such as the ABA's Health Professionals Seminars and its online lactation consultant (IBLCE) training modules; these are important income sources for funding the organisation's free mother- to-mother support for breastfeeding.
- The <u>Australian Breastfeeding Association (ABA)</u> established as the <u>Nursing Mothers Association in 1964</u>, provides a variety of breastfeeding support services and products. The Association earns revenues to fund its public services from selling services and products such as ABA membership, books and information on breastfeeding management, lactation aids, and from selling or hiring breast-pumps and ancillary products (www.breastfeeding.asn.au). It also obtains revenues through contracts with government or businesses, such as for delivering specialised breastfeeding support services, such as the National Breastfeeding Helpline or ABA Breastfeeding Friendly Workplace accreditation.

Informal milk sharing among new mothers was not unusual in maternity services in the 1980s, and donor breastmilk banks were formally established in Australia in the past decade, the first being the PREM in Western Australia (Australia. Department of Health 2014). The Mercy Hospital milk bank in Melbourne is reported as collecting over 1500 litres from donors in the past four years ('Breast milk bank gives vulnerable babies а better start at life' February 10, 2015, http://www.heraldsun.com.au/news/victoria/breast-milk-bank-gives-vulnerable-babies-a-better-start-atlife/news-story/634d1a5c57b799197a0277727969307e). These and other milk banks in Australia and other countries have traditionally been not for profit. However, a for-profit milk bank has now been established in Australia (Chase 2016).

<u>Breastmilk sharing</u> social media sites such as *Eats on Feets* (http://www.eatsonfeets.org/) or *Human Milk 4 Human Babies* (http://hm4hb.net/) also increasingly facilitate the exchange of human milk with other mothers in Australia. Nursing other mothers' babies is usually not widely spoken about, but is not an uncommon practice within families and local communities in Australia (Thorley 2008). *Only the Breast* is a

commercial website which facilitates the buying and selling of human milk, currently mostly in North America and the United Kingdom (Only The Breast 2013). This website is affiliated with the *International Milk Bank* which has recently been established to facilitate both the collection and sale of human breastmilk including across national borders (http://www.internationalmilkbank.com/).

Who are the participants?

The high level of public interest in the current ACCC process points to the number of participants in the <u>relevant market</u> who have a vital economic and financial interest this determination. Participation in ACCC processes on this issue illustrates the potential impacts on both the <u>breastfeeding-related market economy</u>, and those representing the <u>non-market economy</u>.

The relevant producers affected by this determination include professional lactation consultants, nurses, midwives, and human milk banks operating in the market (for profit or not for profit) sector providing breastfeeding support services, as well as lactating women producing breastmilk for their own, or other infants in the household sector of the economy. Also affected include business enterprises providing independent education and training for health professionals in IYC feeding, breastfeeding and lactation management. Companies supplying equipment and technologies such as breast-pumps, human milk pasteurising units, and specialised lactation aids such as 'supply lines' to meet the breastfeeding support needs of hospital milk banks and neonatal wards or neonatal intensive care units, are other players in the 'IYC food economy'.

Many participants in the production, exchange and trade of IYC food and breastfeeding related goods and services are women, in both market and non market sectors. Failure by the ACCC to account for these participants in the IYC food economy perpetuates a structural discrimination against women, as they are the predominant suppliers of both pro-bono breastfeeding support services, and economically valuable breastmilk, and breastfeeding, as well as virtually all professional lactation consultants and educators. It also maintains structural discrimination against owners or employees of firms supplying breastfeeding related support services and products.

What are the features of competition in the relevant market?

It is well recognised that there is a public economic benefit in protecting the unpaid production of food for babies through breastfeeding, but there is little systematic analysis of the important market failures that need to be addressed to ensure the socially optimal level of its production. The operation of the IYC food economy is strongly influenced by market failures such as externalities, principal/agent problems, information asymmetry, market power imbalances, and price distortions. These imperfections within the 'market' for infant food are more fully analysed elsewhere (Smith 2004), but in summary, a market analysis demonstrates that unrecognised social costs and information failures, principal/agent problems and unequal power relationships, along with unfair competition in the market for infant food, lead to a variety of market failures that result in economically inefficient (and unfair) outcomes for society:

the dominant share of this market for infant food is accounted for by commercial baby foods and ... the dominance of commercial baby food at the expense of breastmilk and breastfeeding reflects ignorance of scientific evidence on the health risks associated with consumption of formula milk; agency problems arising from the mother necessarily making decisions on behalf of the infant; a

pricing structure which does not recognise or incorporate the negative externalities associated with consumption of formula milk (for example, health-related costs incurred by individuals and society later on in life); and the unfair competitive and marketing advantage that commercial producers of breastmilk substitutes (private companies) have over other suppliers to the market (in this case mothers).

Such market failures reduce efficiency in resource use and production, disempower mothers preferring to breastfeed, and entrench various forms of unfairness and inequity. The IYC food economy is also affected by structural discrimination which creates barriers to breastfeeding by employed mothers (Smith, Javanparast et al. 2013; Smith, McIntyre et al. 2013).

Reflecting these pervasive market failures, vulnerabilities, and inequities, a 'buyer beware!' approach to commercial IYC food marketing has long been recognised by governments as inadequate protection to consumers. In this case, the consumer is the infant or young child, who has no power over purchasing decisions that can have far reaching consequences. The mother, or caregiver, is in effect, acting as an agent for the child, including making decisions on its nutrition, health and survival, and is not simply a consumer purchasing an ubiquitous and benign product on her own behalf.

Mothers or other caregivers including health workers acting, in effect, as an agent for the child, may not themselves face the consequences of the recommended or chosen IYC feeding practices. With no requirement for producers of infant formula to account for adverse health externalities of infant formula feeding by higher pricing, externalities such as additional financial costs to the health system or to families from a less healthy infant will not be taken into account in industry marketing activity – such additional health care costs among non-breastfed infants are documented in studies in the United States, Australia, and Europe (Smith, Thompson et al. 2002; Bartick and Reinhold 2010; Pokhrel, Quigley et al. 2014).

Breastmilk (or breastfeeding) is also an unusual product. It is the dominant source of food and nutrition for infants and young children, and an important global and national food resource. Importantly, because of the physiology of lactation, it is difficult to reverse a decision to introduce formula: supplementation ends exclusive breastfeeding and often disrupts ongoing breastfeeding. Giving infants or young children any foods or drinks other than breastmilk may displace breastfeeding (Galpin, Thakwalakwa et al. 2007; World Health Organization (WHO) 2015). Hence, infant formula can be considered an 'addictive' product in an economic sense, with circumstances facing a new mother creating a complex and dynamic 'demand' decision where the conditions for fully informed and rational choice may be lacking. Unlike most commercial products, increased consumer access, affordability and advertising of infant formula is not necessarily beneficial for consumers, mother or baby, and may increases the potential risk of harm.

While competition is usually valued for reducing prices, to the benefit of consumers, in the case of IYC food, the market environment and consumer decision-making is more complex, and impacts on competition within the IYC food economy less apparent. Paradoxically, consumers may suffer detriment (and INC members profit) both from cheap supply of infant formula to the health care system (creating dependency on infant formula), as well as from a high retail price of formula (unavoidable once the infant is reliant on it). That is, a proposed agreement to beneficially restrain promotion of infant formula to the public can simultaneously give rise to substantial public detriment by allowing marketing through artificially low pricing in the health system, as discussed in more detail in the following section.

3. Public detriment: Economic efficiency costs from allowing marketing to health care channels using free or low-priced supplies or samples of infant formula

This section addresses the question of public detriment from allowing an agreement which lessens competition through a restraint on marketing direct to the public, whilst endorsing certain marketing activities to and through the health system.

INC has submitted that 'no material anti-competitive or other public detriments' result, including from restraining product research and innovation in the industry. This submission argues to the contrary that public detriment potentially arises in particular because clauses in the proposed agreement allow INC members - who have exceptionally well-established channels of market access to the health system - to make free or low-priced infant formula supplies to institutions, and supply samples for 'professional evaluation'. As noted earlier, health professionals are highly influential in advising for or against the introduction of formula, and in establishing mothers' preferences for formula brands.

As pricing is a crucial element of marketing, allowing a joint agreement which facilitates a common approach to marketing to health workers and/or health institutions using price has particularly detrimental impacts on productive, dynamic and allocative efficiency. Adverse effects on economic efficiency arise from low-priced supplies a) distorting health provider decisions on inputs to health care services such as maternity care; b) reducing incentives across the IYC food economy to develop and introduce innovations and improve products to assist breastfeeding, and; c) underpinning a system of institutional/retail market segmentation and price discrimination which undermines early breastfeeding thereby introducing a consumer dependency on purchasing formula brands at high retail prices.

Market failures are a well-recognised feature of consumer decisions on IYC feeding. Market failures in the health care sector such as price insensitivity and principal-agent problems, inadequate or asymmetric information, and the potential for conflicts of interest and unethical behaviour further reinforces the potential for reduced consumer welfare from collusive marketing.

Competition is generally valued for promoting productive, allocative and dynamic efficiency, to the benefit of consumers and society, in the absence of market failures. Public detriment may arise, for example, where a lessening of competition in the market has effects such as reducing the number of competitors, increasing difficulty of entry, adversely affecting the ability of businesses to innovate effectively or operate efficiently and independently or reducing information for consumers' informed choice (Nagarajan 2013).

As the WHO has noted regarding trade in infant formula products, 'producers competing in the market place do so for two reasons, to expand the market for a given class of product, whatever its type; and to expand their share of the market'. That is, 'the marketing of infant formula pre-supposes a market increasing in size as more infants are fed artificially' (World Health Organization (WHO) 2001). This highlights that under the proposed agreement there is no incentive for the proponents to take action against new entry or other marketing of commercial formula milk sales in new market segments if this new activity is at the expense of breastfeeding, or if at the expense of breastfeeding related goods and services. The agreement will be enforced only to the extent that marketing disturbs existing market shares in the milk formula market held mainly by INC members Nestle, Danone and Aspen Nutritionals. The efficient

functioning of the broader IYC food economy is not protected by relying on the dominant players in the infant formula industry to regulate effectively and against their own self-interest.

Several clauses in the proposed agreement facilitate INC members to engage collusively in the marketing of infant formula to health workers and/or health institutions, especially by reducing its effective price. In particular, the agreement includes [emphasis added];

- "Clause 6(e): Manufacturers and importers of infant formulas may make donations, or low-priced sales, of infant formulas to institutions or organisations, whether for use in the institutions or for distribution outside them. Such provisions should only be used or distributed for infants who have to be fed on breast milk substitutes. If these provisions are distributed for use outside the institutions, this should be done only by the institutions or organisations concerned. Manufacturers or importers should not use such donations or low price sales as a sales inducement."
- Clause 7(d): Manufacturers and importers of infant formulas should not provide samples of infant formulas, or of equipment or utensils for their preparation or use, to health care professionals except when necessary for the purpose of professional evaluation or research at the institutional level."

Other clauses permit various other forms of marketing to health professionals including pharmacists and/or health professionals such as gifts or sponsorship, sometimes in the guise of supporting health professional education or training, or in providing product information.

Below, we focus on those aspects of formula company interactions with Australian health care providers which involve the price at which formula is available to consumers through health workers (including pharmacists) and/or health institutions (including maternity care and maternal and child health services) in Australia.

Pricing practices and marketing to the health sector

Pricing is of the four main elements of marketing. Low prices for consumers in a competitive market are generally agreed to benefit consumers, and this underpins the ACCCs approach to consumer policy. However, an agreement permitting INC members to provide free or low-priced infant formula or samples for use by health providers has various adverse impacts on consumers and economic efficiency, and might be described a form of 'dumping' or 'loss leading', due to its impacts on incentives for health institutional breastfeeding support and promotion, and on the profitability of firms providing breastfeeding related goods and services.

Providing free or low-priced formula to the health system reinforces long-established and contemporary marketing strategies targetting health care professionals and/or institutions in order to represent milk formula products for children as 'scientific' and 'trustworthy' (Gong and Jackson 2013; Thorley 2015), though these broader marketing strategies are not the focus of this submission.

Preliminary analysis of the infant formula value from retail in Asia through to the farm gate return shows most of the value being added beyond the New Zealand border

Waterfall chart of value chain from retail shelf price of a can of infant formula through to farm gate value to dairy farmer in New Zealand NZ\$; actual; 2012

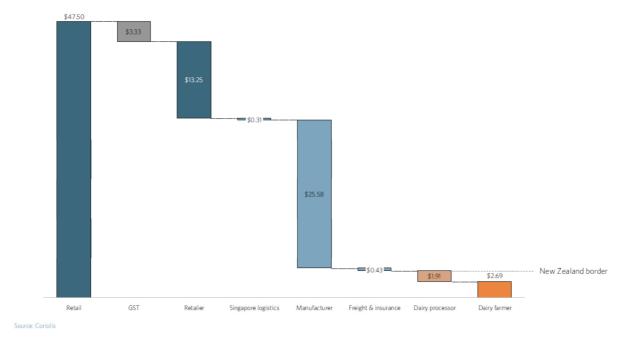


Figure 8 Wholesale pricing of formula supplies to healthcare institutions mean substantial discounts on retail prices - free or low-priced supplies. Source (Coreolis 2014)

Milk formula is usually supplied by Australian milk formula manufacturers to healthcare institutions at wholesale prices or less. Wholesale prices can be very low in relation to retail values of \$25-30 per 900g tin because of high margins on these products. For example, the Coreolis study of the infant formula industry documents (see Figure 8) that manufacturers retain around NZ\$25 of a NZ\$50 retail value tin of formula and retailers NZ\$15, with less than NZ\$5 retained by farmers or processor (Coreolis 2014).

Likewise, this and previous inquiries have received reports from consumers or health professionals themselves, of the distribution to mothers of free samples supposedly provided 'for professional evaluation'.

The overall effect of this marketing technique is that the price of formula to the health system is much lower than its retail price for consumers.

Economic efficiency considerations

Below we consider the efficiency impacts of low-priced infant formula provided to health professionals and/or health institutions, within a perspective which accounts for the effect on both the market and non market sector of the IYC food economy. It is shown that this price distortion adversely affects economic efficiency and reinforces potential disadvantage to consumers from pervasive market failures. This is because, firstly, such marketing distorts the incentives for health services incentives to use an appropriate mix of goods and services which better supports breastfeeding. Secondly, it disrupts and creates barriers to competition against commercial formula products, such as increased provision of goods and services supporting breastfeeding and the provision of human milk to infants and young children. Thirdly it

undermines consumer preferences for breastfeeding. These impacts are discussed in turn below under 'productive', 'dynamic', and 'allocative efficiency', alongside consideration of other aspects of market failure affecting the optimal feeding of infants and young children.

Productive efficiency

Promoting infant formula by selling it at less than retail price to health professionals and/or health institutions fails to achieve the objectives of ensuring best quality and the lowest cost provision of appropriate nutrition and health care for mothers of infants and young children.

Marketing of formula to health providers by selling formula at less than retail price reduces productive efficiency as it distorts decision-making in the health sector away from using the best mix of available resource inputs, such as donated or purchased breastmilk, or lactation aids or services which help maintain breastmilk production and consumption and support breastfeeding. Where milk formula products are donated or low priced, health provider decision-making will be oriented by price towards using infant formula to address early feeding problems even though this increases health risk or risk of rehospitalisation of the child or mother (Smith, Thompson et al. 2002; Bartick and Reinhold 2010; Renfrew, Pokhrel et al. 2012; Bartick, Stuebe et al. 2013). Manufacturers or suppliers of 'breastfeeding related' products or services such as lactation consultants, lactation aids or human milk products will be underutilised by the health system, and an artificial barrier created to their competing effectively in supplying IYC feeding-related goods and services to the health system.

That is, the ready availability of low-priced formula means that health care providers will be less likely to employ lactation consultants, invest in breast-pumps or other lactation aids to assist mothers to breastfeed or express milk or their infants, or seek to engage mothers with breastfeeding support and lactation consultancy services in the community. Early cessation of breastfeeding due to introducing formula in hospital will reduce a mother's demand for breastfeeding-related goods and services after hospital discharge from hospital.

The financial incentives created by low-priced formula and related formula industry interactions with health professionals also reduce the likelihood of human milk banks being able to compete effectively with commercial infant formula manufacturers, and reduces health services' willingness to make investments in staff who are adequately qualified and trained in lactation support. Hospitals typically provide infant formula at no cost where a mother is discharged earlier than her premature or ill baby, but do not supply a breast-pump for her to supply milk to her baby, thus creating financial incentives against the supply of breastmilk or continued breastfeeding. By contrast, in Tasmania, hospitals which have been formally accredited as 'Baby Friendly Hospitals' under the WHO/UNICEF initiative require mothers using their maternity services to purchase formula at retail prices, to avoid any financial incentive for introducing formula. Few maternity services provide access to lactation consultants as part of their services, or implement evidence-based practices such as the WHO 'Tenth Step for Successful Breastfeeding' - referral to community based mother to mother support groups (World Health Organization (WHO) 1998). Recently published research from Europe demonstrates that meeting the standards of a Baby Friendly Hospital including for health professional training, and other evidence-based WHO guidelines, is undermined by strong financial incentives for the institution to continue current practices which undermine breastfeeding (Rouw, Hormann et al. 2015).

Low-priced formula to health providers adds to risk of conflict of interest for health care workers and health care institutions created through other interactions offered by major formula manufacturers. These include industry-provided training and education activities, or sponsorship and travel support, which work against professional motivations to better support breastfeeding and obtain relevant education and training from sources independent of the commercial baby food industry.

Hence, allowing marketing to the health sector through low-priced supplies of infant formula is detrimental to productive efficiency as it increases health system use of commercial product and formula industry education services which ultimately is higher cost and poorer quality that offered by competing providers in the IYC food economy.

Dynamic efficiency

Promoting infant formula to health professionals and/or health institutions including by selling it at less than retail price undermines dynamic efficiency and reduces innovation. If formula were not cheaply available, there would be greater opportunity in Australia for expanding sales of breastfeeding related goods and services, and investment in new maternity care models, innovative human milk products, and collection and distribution systems which increase breastfeeding, breastmilk production and breastmilk availability.

The detriment to dynamic efficiency is exemplified by institutional resistance to new cost-effective maternity care models, and by the difficulties that milk banks have had in opening and expanding in Australia. Cheap formula supplies to hospitals discourage introducing new more effective models of maternal and child health care because the institution's financial incentives work against changing practices to better support breastfeeding, such as making greater use of skilled nursing or midwife staff, or lactation consultant services. Economic studies have shown the high cost effectiveness of lactation support services in NICU settings (Renfrew, Craig et al. 2009; Rice, Craig et al. 2010), but lactation consultants are rarely employed in hospitals to provide such support. Quality commercial or not for profit education and training on breastfeeding and lactation management for staff provided by independent service providers is often less favoured by hospital administrators, than free or low-cost industry-provided professional development or training activities.

Likewise, human milk provision is highly cost-effective in the care of vulnerable children (Ganapathy, Hay et al. 2012) such as ill, premature and low birthweight infants in neonatal intensive care or post-natal units. However, until recently there was only one milk bank in Australia, despite their very strong cost effectiveness such as for feeding premature infants at risk of very costly conditions such as necrotising enterocolitis (NEC) and sepsis. This is in part because Australian human milk banks struggle to gain economies of scale, and most rely on donations of money and human milk to exist - even within major Australian hospitals (http://www.essentialbaby.com.au/action/printArticle?id=97457430). Despite consumer demand, and their economic cost-effectiveness, financial considerations related to the cheap availability of formula in hospitals has hindered widespread establishment and network development.

As a result, donations or low-priced sales of formula to health institutions are likely to have delayed milk banking and hindered families from gaining access to optimal nutrition and care for vulnerable infants, or to appropriate support for postnatal mothers and their infants in circumstances such as postpartum haemorrhage which may hinder the initiation or establishment of breastfeeding.

Also relevant to economic efficiency are the dynamic factors at play regarding decision-making on infant feeding, because of the complex physiological and psychological effects of birth and lactation. New mothers, particularly viewing IYC food products in a health setting such as a hospital or offered by a pharmacist, may be induced or tempted by its free availability of formula or by the offer of samples to try out formula. This has significant effects in disrupting and reducing women's own milk production, and in marketing terms this physiology of lactation creates a 'return customer' for formula. Randomised controlled trials have shown that exposure to branded formula products and their marketing in hospital induces greater product use and shorter duration of breastfeeding (Frank, Wirtz et al. 1987; Feldman-Winter, Grossman et al. 2012). It also results in a strong attachment to the same brand of formula product as that introduced in the hospital (Huang, Labiner-Wolfe et al. 2013).

Recent economic analyses of addiction explore how psychological distortions to perceptions about short and long term benefits can create dependency and apparently 'irrational choices' despite a consumer's disutility from consuming a product (Culyer 2014). Conclusions from this emerging area of economic research include that there may be a high responsiveness to the price of an addictive product when it is lowered, especially for socially vulnerable groups, while price rises have little effect among those whose preferences are dominated by short-term priorities, or if they become addicted to using products which can later be rationalised as an acceptable choice. A prevailing low infant formula price charged to institutions which helps to gain new customers, and high retail price once consumers are reliant on infant formula, can be viewed as consistent with economic analyses of addiction. A mother or baby may become less motivated to continue breastfeeding once formula is introduced, and withdrawal from use once commenced may be anticipated as difficult and unpleasant. Furthermore, the longer the product is used, the harder it is to return to breastfeeding.

Hence, allowing marketing through low cost supplies of infant formula to the health sector is detrimental to dynamic efficiency as it reduces innovation and undermines sound ethics and business practice in the health care sector.

Allocative efficiency

Promoting infant formula to health professionals and/or health institutions including by selling it at less than retail price undermines decisions to breastfeed, reduces allocative efficiency and is unfairly exploitative and detrimental to consumers. Nearly all mothers in Australia choose initially to breastfeed (AIHW 2010). Yet data on breastfeeding at time of hospital discharge in Victoria (see Figure 5), illustrates that by the time of hospital discharge less than 8 in ten new mothers had met their preference to breastfeed. Nationally, over 30% of new mothers have introduced formula milk within a month. Those from lower socioeconomic or disadvantaged background are least likely to continue breastfeeding (Amir and Donath 2008). According to the 2010 *Australian Infant Feeding Survey*, more than a third of mothers have introduced milk formula by the time their infant is one month old.

High quality evidence including from randomised trials has shown that introduction of formula and/or exposure to formula brand marketing in hospital reduces breastfeeding exclusivity and duration. Low prices

for infant formula in a health care context thus can undermine mothers' preferences to breastfeed. As noted above formula is akin to an 'addictive good'.

There are also complexities and 'market failure' features of this market including information asymmetries and principal-agent problems in mother/ health care provider relationships. This may mean for example, that the doctor does not take adequate account from a consumer perspective (e.g. future cost to family of retail formula, or to the health system of future illness or disease), or that the mother is likely to be unable to maintain her own milk supply after introduction of formula, even where she prefers to breastfeed. As noted earlier, exposure to formula in hospital reduces breastfeeding, creates repeat customers, and induces 'brand loyalty'. Brand loyalty can equate to dependence and stress or anxiety for mothers, as recent media reports of formula shortages in Australia well illustrate.

The supply of formula at less than retail prices to the health institutional market also exploits vulnerability and disadvantages consumers. This is because being offered free formula by health providers at a time when a mother is uniquely vulnerable increases the likelihood a mother will need to buy formula after hospital discharge, as establishment of exclusive breastfeeding or breastmilk feeding is likely to be thereby disrupted. A mother introduced to using formula in hospital where it is free or low-priced compared to getting help in resolving breastfeeding difficulties, or in accessing donated or other sources of human milk, is introduced to and becomes reliant on infant formula.

Mothers will subsequently have to pay the full retail price for commercial milk formula for their babies for at least 12 months after they have left the hospital. Donated or low-priced institutional supplies may needlessly create a mother's dependency on commercial formula to feed her own child. This is financially detrimental to the mother, who is no longer able provide her own milk at zero financial cost. Families of infants fed on formula are also likely to face higher health costs than if breastfeeding had continued.

Hence, allowing industry to target health providers with cheap formula to indirectly market brands of commercial breastmilk substitutes to new mothers via health care channels, reduces allocative efficiency by undermining women's preference for breastfeeding, and unfairly exploits women's vulnerability and creates financial detriment.

Conclusion and recommendations

WHO has stated that 'marketing and distribution of breastmilk substitutes is not only, or even primarily, a trade issue', but rather, 'a matter of promoting good health and safe nutrition for all infants, irrespective of the environment'. Hence, as the WHA resolved, 'the marketing of breastmilk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products'. A decision on whether to use infant formula and, if so, which product and how, should not depend upon the effectiveness of commercial advertising; nor should it depend on industry marketing to health care providers through free or cheap supplies, samples, or other benefits.

The ACCC recognises the public benefits of protecting breastfeeding, and the necessity of lessening competition (through restraining marketing of commercial infant formula marketing) in order to do so. The overall public benefit of an effective agreement to restrain promotion of infant formula is potentially very high; government health system savings far exceed government regulatory costs, and households also benefit from protecting breastfeeding. However, net public benefit is much lower in the 10 year current self-regulatory proposal because of inadequate governance and oversight, poor compliance and enforcement incentives, and because it is increasingly out of line with Australia's international health obligations and health policies. Market conditions and regulatory context are changing rapidly and, as the ACCC accepted in 1992, benefit to the public is likely to be increased by a shorter authorisation period. It was therefore argued in the previous submission that the proposed INC agreement to restrain marketing of infant formula to the public should only be authorised if it builds in a full and wide-ranging public review, and is conditional on significant undertakings and/or conditions to increase its effectiveness and ensure immediate public benefit. Any agreement should also anticipate rather than stifle industry compliance with emerging international norms on inappropriate marketing, including of complementary foods and toddler milks and as argued in this submission, require that any authorized agreement cover the Australian milk formula industry's export marketing activities.

Having first considered the question of the relevant market and the efficient functioning of that market, this submission has focussed on the detrimental economic and anti-competitive impacts of an agreement which permits the main industry players, INC members, to agree on marketing infant formula through health care channels by engaging in low pricing. Those adversely affected are mothers, infants and competing providers in relevant markets and in the IYC food economy.

This submission argues that by the current proposal permitting continued coordinated marketing of formula to the health system, and facilitating market segmentation and price discrimination, it undermines breastfeeding and breastmilk, creates barriers to the various health care and other innovations and investments that would promote its wider availability to all mothers and their infants and young children, and exploits consumers who are induced by low prices of formula supplied to the health system to become dependent on buying commercial IYC food products at high retail prices.

There is an important counterfactual - of authorisation subject to certain undertakings and conditions which was not fully considered by the ACCC draft determination. While lower prices generally improve consumer welfare, in this case the unique characteristics of the market, and the special vulnerabilities and responsibilities of new mothers as consumers, allows their exploitation. Although the ACCC's consideration of the MAIF in 1992 was constrained by concerns that regulating the price of formula might contradict

existing trade practice law, the Best Start Inquiry report noted a submitted legal opinion that full implementation of the WHO International Code was not restricted by the *Trade Practices Act*, provided that national competition policy principles were complied with. (Such competition policy principles are now reflected in the *Competition and Consumer Act 2010*.) Against this background, the Best Start committee reported that there was clear evidence of significant public benefit through the introduction of the WHO International Code, and recommended its full implementation. This would include ending free or low cost supplies and samples of infant formula to health care providers.

If the proposed agreement was only authorised on the condition that formula were sold to hospitals at retail prices, there would be considerable efficiency gains, such as described above. Hence, by continuing the out of date provisions in the MAIF which allow free or low cost supplies or samples as a form of marketing to health workers and/or health institutions, authorising the current proposed agreement risks continuing substantial, and unnecessary 'public detriment'.

This submission concludes that MAIF allowing provision of formula at less than retail price to the health system has resulted in 'public detriment' to economic efficiency in several ways. Distortions to pricing distort production efficiency in maternal and child health care by reducing incentives for health workers and/or institutions to offer optimal levels of breastfeeding support. Dynamic inefficiency is affected by the reduced incentive for innovation, and reduced access to scale economies and viability facing producers in the IYC economy. This is particularly detrimental to women; as producers of breastmilk, and as providers of breastfeeding support and lactation consultancy services. The low cost provision of infant formula to the health system is also likely to have adverse indirect implications for consumers in the retail market, who may face consequently higher prices. Such cross subsidisation is not discussed in detail in this submission. To the extent this occurs, this would impact most severely on often socially disadvantaged and vulnerable new mothers and infants. Such mothers are most likely to face difficulties breastfeeding and become reliant on costly commercial milk formula products, whilst also being deprived by the above pricing strategies of the opportunity to establish breastfeeding successfully by accessing higher quality, low cost and innovative health care services and products such as human milk banks, breast-pumps, or quality breastfeeding support from health providers who are educated, trained, and/or operated free of milk formula industry influence.

Authorisation of the proposed agreement also allows the dominant players in the commercial infant formula industry to maintain their privileged access to health workers and/or institutions at the expense of new entrants to the milk formula industry, without no evidence presented that the proposed agreement does not harm product innovation by competing formula manufactures or other participants in the IYC economy. Nor has INC presented evidence that the proposed agreement improves the likelihood that health professionals receive 'accurate and scientific product information' based on 'current knowledge and responsible opinion'. In fact research does not support that marketing to health professionals of drugs or food including of speciality formulas results in higher quality information and advice or prescribing behaviour by health professionals. Several recent high quality scientific studies show that marketing activity by food and pharmaceutical companies uses biased research and unsubstantiated health claims including for formula, which risks being detrimental to consumer choice and the quality of health care decision-making (Loke, Koh et al. 2002; Lesser, Ebbeling et al. 2007; Spurling, Mansfield et al. 2010; Lundh, Sismondo

et al. 2012; Belamarich, Bochner et al. 2015). Industry provision of such information or education on IYC food products to the health sector may well result in more biased and poorer quality decision-making, as well as demotivating health care service providers from obtaining education, training and knowledge from independent sources.

Finally, there are also significant cost externalities of formula consumption for the health system and for the child, relating to heightened illness and disease risk, noted earlier; these external costs are not factored into commercial pricing of milk formula products. The health system cost implications have not been discussed further in this submission as this issue was canvassed previously.

Allowing companies to continue to market to health workers and health institutions through permitting low cost supplies and samples simply legitimises marketing to consumers via the health system using aggressive pricing strategies, which is unfair as well as inefficient.

The ACCC is not prevented from imposing conditions on an authorisation. The ACCC has in the past imposed conditions on authorisations that it has given for comparable anti-competitive arrangements, including conditions involving minimum prices (Nagarajan 2011; Nagarajan 2013). For example, the ACCC could require a minimum price at which any industry member is permitted to supply infant formula or samples to health care workers and health institutions including pharmacies, with independent monitoring and review of pricing arrangements.

This submission recommends that the ACCC should require all milk formula products to be supplied at retail price or above as a condition of authorisation.

The ACCC might also, for example, consider requiring the regular provision of public information detailing all INC members' marketing activities to health workers and/or health institutions, and the independent audit and review of such information. If samples are allowed to be provided for 'professional evaluation', the ACCC might similarly require full public information, audit and review, as well as requiring documented ongoing monitoring including arrangements for provision of free health care to any recipient mothers and infants. Regular public disclosure of which company sponsored health care worker meetings or education and which providers participated would also allow health care consumers to make more informed choices about which caregivers who can provide high quality care and support for breastfeeding and optimal infant and young child feeding that is unbiased by infant formula industry marketing presence in the Australian health care system.

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¹ There is some confusion about INC membership, as there inconsistencies between the INC website, the INC application, and the list of INC members as provided by the Department of Health. This creates difficulties for analysing the milk formula market impact of the proposal, and reduces public transparency and accountability of the parties to the proposed agreement.

These clarify aspects of the WHO International Code including, for example, Resolution 47.5 (1994) which addressed the provision of samples, to ensure that there are no donations of free or subsidised supplies of breast milk substitutes and other products covered by the WHO International Code in any part of the health care system.

The 1992-2013 MAIF also required that product information provided to members of the medical profession and related health care professions be an accurate reflection of current knowledge and responsible opinion, in addition to limiting the provision of product iv 12 months is the minimum recommended duration of breastfeeding in Australia (National Health and Medical Research Council 2013)

V It has been reported to the author informally by a health professional working in an Australian maternity facility that favourable payment terms, notably a practice by suppliers of failing to require institutions to pay invoices, may further reduce the actual prices paid by health institutions for infant formula supplies.