



# **Review of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement**

Final Report

*05 October 2023*

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## Acknowledgements

Allen + Clarke Consulting would like to thank all the stakeholders who contributed to the Review of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement.

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## GLOSSARY AND ACRONYMS

Term	Definition
2012 MAIF Review	2012 independent review of the effectiveness and validity of operations of the MAIF Agreement
2017 Complaints Review	2017 independent review of the MAIF Agreement's complaints handling processes
ACCC	Australian Competition and Consumer Commission
APMAIF	Advisory Panel on the Marketing in Australia of Infant Formula
DALYs	Disability-adjusted life years. A measure of healthy life lost, either through premature death or living with disability due to illness or injury.
Exclusive breastfeeding	Exclusive breastfeeding can be defined as the infant only receiving breastmilk with no other food or drink. The infant may also receive oral rehydration solution, drops, and syrups (vitamins, minerals, and medicines), but nothing else (Australian Institute of Health and Welfare, 2011).
FSANZ	Food Standards Australia and New Zealand
INC	Infant Nutrition Council
Infant	An infant means a person under the age of 12 months (FSANZ, 2016)
Infant formula	Any food described or sold as an alternative to human milk for the feeding of infants up to the age of 12 months and formulated in accordance with all relevant clauses of the Australia New Zealand Food Standards Code, including Infant Formula Products Standard 2.9.1, which covers 3 types of products: <ul style="list-style-type: none"> <li>• infant formula (suitable for infants aged 0 - &lt;12 months)</li> <li>• follow-on formula (suitable for infants aged from 6 - &lt;12 months)</li> <li>• infant formula products for special dietary use.</li> </ul>
KRQ	Key Review Question
MAIF Agreement	The Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement ( <a href="#">Appendix A</a> ). A voluntary, self-regulatory code of conduct between manufacturers and importers of infant formula products in Australia.
NHMRC	National Health and Medical Research Council
Proposal P1028	A review currently being undertaken by FSANZ of regulatory requirements for infant formula. This review is yet to be finalised, and accordingly no decisions have been made.
Signatories	Infant formula companies who have signed the MAIF Agreement
Toddler	A toddler is a child between the age of 1 to 3 years








Term	Definition
Toddler Milk Products	Toddler milk products are targeted at infants and young children from 1 to 3 years old. They can also be known by other names including growing-up milk, growing-up formula, or formulated milk.
The Review	The current independent review of the MAIF Agreement being undertaken by <a href="#">Allen + Clarke Consulting</a> ( <i>Allen + Clarke</i> )
The Strategy	<a href="#">Australian National Breastfeeding Strategy 2019 and beyond</a>
UNICEF	United Nations Children's Fund
WHA	World Health Assembly
WHO	World Health Organization
WHO Code	<a href="#">World Health Organization: International Code of Marketing of Breast-milk substitutes</a>

# 1.0 EXECUTIVE SUMMARY

This Review of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement) presents findings and recommendations from independent reviewers *Allen + Clarke Consulting*.

The MAIF Agreement is a voluntary, self-regulatory code of conduct between manufacturers and importers of infant formula products in Australia. The MAIF Agreement is one of the ways in which Australia implements the World Health Organization's International Code of Marketing of Breastmilk Substitutes (WHO Code). Aligning with the WHO Code, the MAIF Agreement's key objectives are to ensure safe and adequate nutrition for babies, encourage breastfeeding as the first option for babies, ensure parents make informed decisions, and ensure the proper use of breastmilk substitutes.

This independent Review of the MAIF Agreement has five key objectives.

	Consider contemporary policy issues for the marketing of infant formula and toddler milk
	Assess the effectiveness of the MAIF Agreement in achieving its aims
	Determine whether the voluntary, self-regulatory approach remains fit for purpose or if alternative regulatory models should be considered
	Assess the benefits, costs and any limitations of changes and expansion of the MAIF Agreement scope, alternative regulatory models and MAIF Agreement processes
	Any other related matters deemed appropriate

This Review considered a range of issues which were identified through a literature review and consultation with stakeholders. During consultation, industry stakeholders generally indicated that the MAIF Agreement appropriately restricts the marketing of infant formula and makes a positive contribution to infant nutrition. Whereas other stakeholders advised that there remains significant room for improvement in the coverage and operation of the existing regulatory framework and that changes could result in significant benefits to the Australian community.

Particular concerns were highlighted regarding the use of toddler milk drink marketing as a proxy for infant formula marketing. In addition, there were calls for the inclusion of supermarkets and pharmacies in the regulation of infant formula marketing. The Review heard that there is a lack of public confidence in the MAIF Agreement's ability to restrict electronic advertising and marketing activity, and a need for more effective approaches to monitoring and enforcement.

## Key findings

This Review has determined that the voluntary, self-regulatory approach is no longer fit for purpose, and recommends the establishment of a stronger regulatory framework in the form of a legislated, prescribed, mandatory code. This will more effectively restrict the



inappropriate marketing of infant formula in Australia, promote and protect public health, and create a level playing field for industry.

While this Review recommends that the Australian Government should enhance the model for regulating the marketing of infant formula, it does not recommend increasing the scope of regulation to include other products or types of parties.

This Review finds that the current review of the regulation of infant formula in the Food Standards Code being progressed by Food Standards Australia New Zealand (FSANZ) has the potential to address stakeholder concerns relating to:

- consumer confusion around the differences between infant formula and toddler milk drinks,
- the marketing of toddler milk drinks as a proxy for the marketing of infant formula products.

It is recommended that the Department of Health and Aged Care continues to monitor outcomes from the FSANZ review and respond as needed to ensure ongoing alignment between a revised MAIF framework and Food Standards Code.

In relation to the scope of parties covered by the MAIF Agreement, the Review finds that the evidence around inappropriate marketing of infant formula by retailers is not strong enough to warrant the inclusion of these parties under the regulatory framework. It is recommended that the Department of Health and Aged Care continues to monitor and review the scale and impact of inappropriate marketing of infant formula by supermarkets and pharmacies to determine whether the regulatory framework should be broadened to include retailers. In the interim, an awareness campaign should be implemented to educate retailers about the role they can play in communicating the positive impacts associated with breastfeeding and best practice around the appropriate use of infant formula.

This Review has also found that there is significant scope to improve the monitoring and enforcement of existing regulatory arrangements. A stronger system of monitoring should be established to support implementation of the regulatory framework and reduce the burden of monitoring that currently falls on civil society and members of the public. If the current model of complaints management continues into the future, there will be a need for significant changes to its processes and membership to support achievement of efficient and effective regulation that has broad public support.

**Table 1** outlines the 10 key recommendations arising from this Review. Further detail on each of these recommendations can be found at [section 4](#).

**Table 1. Summary of recommendations**

<b>Stronger regulatory model</b>	
<b>1</b>	Develop a stronger regulatory framework to restrict the marketing of infant formula in Australia by adopting a prescribed mandatory code.
<b>2</b>	Retain the current scope of regulated products without expanding to include other products. Monitor, and adopt as necessary, findings and recommendations arising from the FSANZ review of infant formula regulation to ensure consistency between the Food Standards Code and any future regulation of infant formula marketing.
<b>3</b>	Conduct a review of the scale and impact of inappropriate marketing of infant formula by supermarkets and pharmacies to determine whether the regulatory framework should include retailers in its scope.
<b>4</b>	Amend the wording of the regulation of the marketing of infant formula to include explicit reference to electronic marketing and advertising.
<b>Enhanced monitoring and enforcement</b>	
<b>5</b>	Implement a stronger monitoring system to support the regulation of infant formula marketing.
<b>6</b>	Pending the implementation of Recommendation 1 and the regulatory framework selected, improve the efficiency, transparency and robustness of the complaints management mechanism so that decisions can be reached and complaints outcomes published in a timely manner.
<b>7</b>	Pending the implementation of Recommendation 1, if the regulatory framework continues to require a committee to respond to complaints, changes should be made to its membership.
<b>Other initiatives to support regulation and improve infant nutrition</b>	
<b>8</b>	Improve mechanisms for monitoring infant feeding (including breastfeeding) in Australia.
<b>9</b>	Raise awareness among healthcare professionals and parents/consumers about the appropriate use of infant formula.
<b>10</b>	Establish policies and guidelines to enable donations of infant formula in emergency and disaster contexts through reputable charities.








## 2.0 BACKGROUND TO THE REVIEW

The [Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement](#) (MAIF Agreement) is a key way in which Australia implements the WHO International Code of Marketing of Breast-Milk Substitutes (WHO Code). The MAIF Agreement is a voluntary, self-regulatory code of conduct between manufacturers and importers of infant formula products in Australia. In alignment with the WHO Code, the MAIF Agreement's key objectives are to ensure safe and adequate nutrition for babies, encourage breastfeeding as the first option for babies, ensure parents make informed decisions and ensure the proper use of breastmilk substitutes (Department of Health and Aged Care, 2022).

In 2019, the Australian Government launched the [Australian National Breastfeeding Strategy 2019 and Beyond](#) (the Strategy). The Strategy *'provides an enduring policy framework for all Australian governments to provide a supportive and enabling environment for breastfeeding.'* One of the Strategy's key principles is to *'ensure that governments and health care and education institutions protect the community from false and misleading marketing and advertising of breastmilk substitutes'* (COAG, 2019).

Under Priority Area 1.2 of the Strategy, the Department of Health and Aged Care committed to commissioning a review of regulatory arrangements for restricting the marketing of breastmilk substitutes (COAG, 2019), and in particular, reviewing the effectiveness and scope of the MAIF Agreement. Allen + Clarke Consulting (*Allen + Clarke*) has been commissioned by the Department of Health and Aged Care to conduct an independent review of the MAIF Agreement (the Review). **Figure 1** outlines the objectives of this Review.

**Figure 1: Objectives of the Review**

	Consider contemporary policy issues for the marketing of infant formula and toddler milk
	Assess the effectiveness of the MAIF Agreement in achieving its aims
	Determine whether the voluntary, self-regulatory approach remains fit for purpose or if alternative regulatory models should be considered
	Assess the benefits, costs and any limitations of changes and expansion of the MAIF Agreement scope, alternative regulatory models and MAIF Agreement processes
	Any other related matters deemed appropriate

## 2.1 Infant feeding in Australia

### 2.1.1 The benefits of breastfeeding

Breastfeeding provides many health benefits for babies and mothers and has significant economic benefits. Exclusive breastfeeding ensures that the infant receives the full nutritional and other advantages of breastmilk, including developmental benefits and protection against infection and some chronic diseases. In Australia, it is recommended that infants are exclusively breastfed until around 6 months of age when solid foods are introduced, and that breastfeeding is continued until 12 months of age and beyond, for as long as the mother and child desire (National Health and Medical Research Council, 2012).

Breastmilk is safe, clean, and contains antibodies that help protect infants from many illnesses, such as diarrhoea, respiratory illness, intestinal inflammation, middle ear infection, type 1 diabetes, and childhood leukemia (Department of Health and Aged Care, 2022). Breastfeeding also benefits mothers by promoting faster recovery from childbirth, reducing the risk of breast and ovarian cancers, reducing the risk of maternal depression, and helping infant-mother bonding (Department of Health and Aged Care, 2022).

### 2.1.2 Reasons for the use of breastmilk substitutes

The Australian National Health and Medical Research Council (NHMRC) Infant Feeding Guidelines (NHMRC, 2012) recommend that if an infant is not breastfed or is partially breastfed, commercial infant formulas should be used as an alternative to breastmilk until 12 months of age.

There are a range of social, cultural, and economic factors which influence infant feeding decisions. These include, *inter alia*, varying family structures, different cultural norms, education levels, return to work or study, financial barriers, personal attitudes, experiences and beliefs, adoption, and lack of family and social support (Heck, KE, et al 2006).

There are also a range of infant and maternal conditions that can necessitate the use of breastmilk substitutes instead of, or in addition to, breastmilk (WHO, 2009). For example, infants with classic galactosemia, maple syrup urine disease, or phenylketonuria 'should not be breastfed and require a specialised formula' (WHO, 2009). Pre-term babies may require a supplemented infant formula to provide an adequate nutrient supply (Aggett, PJ, et al, 2006). Maternal conditions such as HIV or herpes simplex virus type 1 may justify the permanent or temporary avoidance of breastfeeding (WHO, 2009).

## 2.2 The WHO Code

In 1979, the WHO convened a meeting at which government, consumer, and industry delegates agreed to stop the promotion of breastmilk substitutes in view of the '*vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices*' (WHO, 1981). Subsequently, the World Health Assembly (WHA) adopted the International Code of Marketing of Breast-milk Substitutes (the WHO Code) in 1981.

The WHO Code's primary aim is to:



*Contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breastmilk substitutes, when they are necessary, on the basis of adequate information and through appropriate marketing and distribution (WHO, 1981).*

The WHO Code was developed to restrict the marketing of infant formula and address ‘dramatic increases in maternal and infant morbidity and mortality’ (UNICEF, n.d.), (WHO, n.d.) arising due to the uptake of breastmilk substitutes. While recognising there is a legitimate market for breastmilk substitutes, the WHO Code sought to ensure products were not marketed and distributed to mothers and health professionals in ways that interfered with breastfeeding (Smith, J, Blake, M, 2013). Since its establishment, there have been over 20 WHA resolutions that refer to the marketing and distribution of breastmilk substitutes and clarify issues covered in the WHO Code.<sup>1</sup>

Infant nutrition, breastfeeding, and the WHO Code are embedded in international human rights frameworks. The United Nations Convention on the Rights of the Child states that nutrition is a crucial, universally recognised component of the child’s right to the highest attainable standard of health. Article 24 enshrined the obligation held by States to ensure that ‘*all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents*’ (United Nations, 1989).

Article 12 of the United Nations Convention on the Elimination of All Forms of Discrimination Against Women states that mothers have the right to make decisions about their own lives and their children’s (including infant and young child feeding decisions) (United Nations, 1979). In 2016, the Office of the United Nations High Commissioner on Human Rights released a joint statement urging member states to do more to support and protect breastfeeding and to end inappropriate marketing of breastmilk substitutes. The statement recognises that breastfeeding is a human rights issue for both the child and the mother (United Nations, 1979).

## 2.3 The MAIF Agreement

The MAIF Agreement was implemented in 1992. It is a voluntary code of conduct between manufacturers and importers which governs the marketing of infant formula in Australia for infants up to 12 months. Signatories to the MAIF Agreement are listed in [Appendix B](#).

Prior to this, a 1983 industry agreement disallowed direct advertising of infant formula by manufacturers and importers to the public but continued to allow almost all other advertising in Australia (Minchin, MK, 1998).

Key requirements of the MAIF Agreement are:

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<sup>1</sup> See <https://www.who.int/teams/nutrition-and-food-safety/food-and-nutrition-actions-in-health-systems/code-and-subsequent-resolutions>

- The advertisement or promotion of infant formulas (up to 12 months of age) to the public are prohibited.
- Samples of infant formulas cannot be provided to the general public, and gifts of articles or utensils which promote the use of breastmilk substitutes or bottle-feeding are prohibited.
- Marketers employed by MAIF signatories must not seek contact with pregnant people or parents of infants and young children.
- Infant formulas must conform to the FSANZ Code, provide information about the 'appropriate use' of infant formula, and not discourage breastfeeding.

While the MAIF Agreement establishes responsibilities for its signatories, there is no financial penalty for breaching the MAIF Agreement. The only mechanisms to support compliance with the MAIF Agreement are public pressure or adverse publicity from the [publication of alleged breaches](#) by the MAIF Complaints Committee.

While the aim of the MAIF Agreement aligns closely with the WHO Code, the WHO Code is broader in scope. **Table 2** below outlines the key differences between the intent of the WHO Code (and subsequent WHA resolutions) and the MAIF Agreement.

**Table 2: Key differences between the WHO Code and the MAIF Agreement<sup>2</sup>**

Key differences between the WHO Code and the MAIF Agreement		
Categories	WHO Code	MAIF Agreement
Regulatory model	Proposes mandatory regulatory approaches. Applies to all countries and companies as a minimum standard.	Voluntary agreement.
Products regulated	Applies to all breastmilk substitutes defined by the WHO as including other milk products, foods and beverages marketed to replace breastmilk, feeding bottles and teats.	Applies only to infant formula products. Products such as those aimed at infants aged over 12 months, baby food, feeding bottles, teats and dummies are outside the MAIF Agreement's scope
Parties in scope	Covers 'retailers' under its definition of 'Distributor' and forbids promotion at retail level.	The marketing activities of retailers including pharmacies and supermarkets are outside the MAIF Agreement's scope.
Monitoring	Governments have the responsibility to ensure that objective and consistent	No equivalent responsibility exists as the MAIF Agreement is technically a self-regulated code. Signatories have the responsibility to monitor their own

<sup>2</sup> Table 2 has been adapted from (International Baby Food Action Network, 2007) for this Review.

### Key differences between the WHO Code and the MAIF Agreement

	information is provided on infant feeding.	compliance and the compliance of other signatories. Monitoring is also undertaken by members of the public, and public health and breastfeeding advocacy groups (ACCC, 2021).
Advertising and promotion	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.	No equivalent provision exists for promotion at the retail level.
Responsibilities on health authorities	Health authorities have the responsibility to encourage and protect breastfeeding and promote the principles of the Code.	No equivalent responsibility exists in the MAIF Agreement. However, this responsibility is enshrined in other documents including the Infant Feeding Guidelines.
Free/subsidised supplies	Free or subsidised supplies are banned in any part of the health care system (WHA resolution 47.5 [1994]).	Allows free supplies for use in health care settings for specific professional evaluation or research.
Information for health professionals	Outlines that 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.	Requires companies to give health care professionals product information reflecting current knowledge and responsible opinion which are clearly identified with company and brand names.
Monitoring and implementation	Governments have overall responsibility to implement and monitor the Code. Monitoring should be carried out in a transparent and independent manner.	The MAIF Complaints Committee administers the MAIF Agreement and assesses complaints made against organisations that have signed the MAIF Agreement.

## 2.4 Previous reviews of the MAIF Agreement

There have been several previous reviews of the MAIF Agreement and its operations, including:

- the 2001 Report by the Hon. Rob Knowles
- the 2012 MAIF Review by Nous Group
- the 2017 Complaints Handling Process Review by Nous Group.

The 2001 Knowles Report was an independent review of the operations of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) and scope of the MAIF Agreement. The report found that:

*the existing MAIF Agreement should remain the basis for the co-regulatory agreement on infant formula with no change to the actual agreement...the Government should consider legislation to create a framework for implementing the WHO Code if formula manufacturers withdraw from the existing MAIF Agreement (Knowles, R, 2001).*

The report made recommendations aimed at enhancing the operation of the MAIF Agreement and protecting breastfeeding rates. These recommendations included:

- Establishing a partnership between the Commonwealth, States and Territories to enable a longer-term strategic approach to the promotion of breastfeeding
- Improving the operation of the APMAIF
- Incorporating pharmacies and supermarkets into public health efforts to improve breastfeeding rates, including through a formal or informal agreement on a code of practice (Knowles, R, 2001).

In 2011, the Department of Health and Aged Care commissioned an independent review of the effectiveness and validity of operations of the MAIF Agreement (the 2012 MAIF Review). The 2012 MAIF Review found that *'the voluntary, self-regulatory nature of the MAIF Agreement should remain in operation provided it continues to promote the aim of the MAIF Agreement and industry coverage remains high'* (Nous Group, 2012).

The 2012 MAIF Review made a number of findings relating to the coverage and operation of the MAIF Agreement and the governance arrangements of the complaints process. The 2012 MAIF Review concluded that the content and coverage of the MAIF Agreement should be revised to ensure measures to protect and enhance breastfeeding and infant health remain effective and relevant in the modern marketing and regulatory environment.

In 2017, the Department commissioned an independent review of the MAIF Agreement's complaints handling processes. The review was intended to inform Australia's current and future commitment to the WHO Code and to ensure best practice in the complaints handling process. The review made recommendations aimed at improving the complaints process (Nous Group, 2018).



Following the review of the complaints handling process, the Department resumed overarching responsibility for the handling of complaints received in relation to the MAIF Agreement, and in 2018 established the MAIF Complaints Committee.

## 2.5 Re-authorisation of the MAIF Agreement by the ACCC

As a voluntary industry code of conduct, the MAIF Agreement is subject to regulation by the Australian Competition and Consumer Commission (ACCC). The ACCC does not draft, approve, or put industry-led voluntary codes of conduct into action. As a form of industry self-regulation, the MAIF Agreement is not enforced under the *Competition and Consumer Act 2010*. However, given the MAIF Agreement is focused on product marketing, it is likely to impact competition within the infant formula industry and is therefore subject to ACCC authorisation and re-authorisation.

In 2020, the Infant Nutrition Council (INC)<sup>3</sup> lodged an application to re-authorise the MAIF Agreement and associated guidelines for 10 years.<sup>4</sup> Authorisation is a transparent process whereby the ACCC may grant protection from legal action for conduct that might otherwise breach the *Competition and Consumer Act 2010 (Cth)*. Under subsections 90(7) and 90(8) of the Act, the ACCC must not grant authorisation unless it is satisfied in all the circumstances that the Conduct is likely to result in a benefit to the public, and the benefit would outweigh the detriment to the public that would be likely to result from its actions.

The authorisation process involves the ACCC conducting a public consultation process when it receives an application for authorisation, inviting interested parties to lodge submissions outlining whether they support the application or not (ACCC, n.d.).

In 2021, the ACCC re-authorised the MAIF Agreement for three years. This was less than the 10 years sought by the INC and the five-year authorisation requested by the Department, but more than the two years some other interested parties had called for. The ACCC raised concerns about the effectiveness of the MAIF Agreement, in particular:

- The ability of signatories to advertise toddler milk products
- That the MAIF is voluntary and carries no sanctions for a breach, other than publication of the breach on the Department of Health and Aged Care website
- Issues relating to the independence and transparency of the complaints handling process.

The ACCC found that *‘(t)he combined effect of these factors significantly reduces the effectiveness of the MAIF Agreement in protecting breastfeeding rates, and therefore the magnitude of the likely public benefit from the MAIF Agreement’* (ACCC, 2021).

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<sup>3</sup> The INC represents the interests of the infant formula and toddler milk industry in Australia and New Zealand. Its members include global and local companies, formula manufacturers, and ingredient manufacturers and suppliers.

<sup>4</sup> Submissions and Determinations from this process can be found at <https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/infant-nutrition-council-limited>

The ACCC also stated that it '*strongly encourages the Department of Health and Aged Care to consider the following issues closely in its upcoming review*':

- Whether the scope of products covered under the MAIF Agreement should be expanded to all breastmilk substitutes, including toddler milk
- Whether the scope of parties under the MAIF Agreement should be expanded to capture retailers, including supermarkets and pharmacies
- Ways in which the complaints handling process can be improved.

The ACCC noted that authorisation for three years until 31 August 2024 provides sufficient time for the Department of Health and Aged Care to undertake its review of the MAIF Agreement and to implement recommendations arising from it before reauthorisation becomes necessary (ACCC, 2021).

## 2.6 Other mechanisms for implementing the WHO Code

Australia has a number of other mechanisms to implement the WHO Code. For instance:

- The Food Standards Australia and New Zealand Code (FSANZ Code) contains mandatory labelling and composition provisions for infant formula products (Food Standards Australia and New Zealand, 2015).
- The NHMRC's Infant Feeding Guidelines review evidence and provide recommendations on infant feeding to assist health workers to provide consistent advice (NHMRC, 2012).

## 2.7 The FSANZ review of regulatory requirements for infant formula

In Australia, all infant formula products must comply with the composition, safety, and labelling requirements in the FSANZ Code, [Standard 2.9.1 – Infant Formula Products](#). The three types of products are defined as:

- Infant formula (suitable for infants aged 0 - <12 months)
- Follow-on formula (suitable for infants aged from 6 - <12 months)
- Infant formula products for special dietary use.

All commercially produced infant formula products available in Australia and New Zealand must comply with the composition and safety requirements outlined in Standard 2.9.1 of the FSANZ Code. Standard 2.9.1 mandates some labelling and composition provisions for infant formula that are consistent with the WHO Code, including a prohibition on labelling infant formula products using pictures of an infant, with words claiming that the formula is suitable for all infants, or with information relating to the nutritional content of human milk.



FSANZ is currently undertaking a review of regulatory requirements for infant formula (known as Proposal P1028).<sup>5</sup> This review *'aims to ensure regulation of infant formula is clear and reflects the latest scientific evidence.'* FSANZ states that through the review and the development of Proposal P1028, *'We have sought to clarify and revise standards relating to the regulatory framework, composition, labelling, category definitions and representation of infant formula products.'* The second call for submissions for responding to Proposal P1028 closed in July 2023.

The FSANZ review and any resultant regulatory changes will not be finalised during the current Review of the MAIF Agreement. Several areas of the FSANZ review are relevant to the MAIF Agreement and may serve to address limitations about the MAIF Agreement detailed in this current Review. These include potential changes to nutrition information statements on infant formula products, requirements for stage labelling, and measures to reduce the impact of 'proxy advertising' across product lines. These potential areas of regulatory change, and their relevance to this Review, are further discussed in [Section 4.3.1.3](#).

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<sup>5</sup> Background and documents can be found at <https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx>

## 3.0 REVIEW METHODOLOGY




The Review seeks to answer the Key Review Questions (KRQs) outlined in **Figure 2**.

**Figure 2: Key Review Questions**

1	Is the MAIF Agreement effective in achieving its aims?
2	Is the scope of the MAIF Agreement appropriate in the current policy environment?
3	Are the MAIF Agreement processes appropriate?
4	Is the voluntary, self-regulatory approach fit for purpose or should alternative regulatory models be considered?
5	What are the benefits, costs and any limitations of changes and expansion of the MAIF Agreement scope, alternative regulatory models and MAIF Agreement processes?

As detailed below, this Review has adopted a comprehensive approach to data collection. Key sources of data are outlined in **Figure 3**.

**Figure 3: Data sources informing the Review**

Review information sources	
	<p><b>Desktop Analysis and Literature Review, and review of further submitted documents:</b></p> <ul style="list-style-type: none"> <li>150 documents were reviewed including the MAIF Agreement and MAIF Complaints Committee guidance materials, the WHO Code, grey literature, published reports, journal articles and websites of WHO, UNICEF, the Department of Health and Aged Care, the ACCC, health research organisations and other agencies relevant to the marketing of breastmilk substitutes in Australia and internationally.</li> </ul>
	<p><b>Stakeholder Consultation:</b></p> <ul style="list-style-type: none"> <li>28 focus groups and interviews with representatives from Government, MAIF signatories and other industry bodies, the public health and breastfeeding research and advocacy sectors, consumers and relevant international organisations.</li> <li>11 written submissions from interested parties.</li> </ul>
	<p><b>Online Survey</b></p> <ul style="list-style-type: none"> <li>443 responses to an online survey that was publicly available on the Department of Health and Aged Care's Consultation Hub for 6 weeks.</li> </ul>

### 3.1 Desktop analysis

A desktop analysis reviewing a range of documents was undertaken to inform the Review of the MAIF Agreement. It supported the identification of areas that required further analysis and identified gaps that subsequent phases of this Review addressed. It supported the

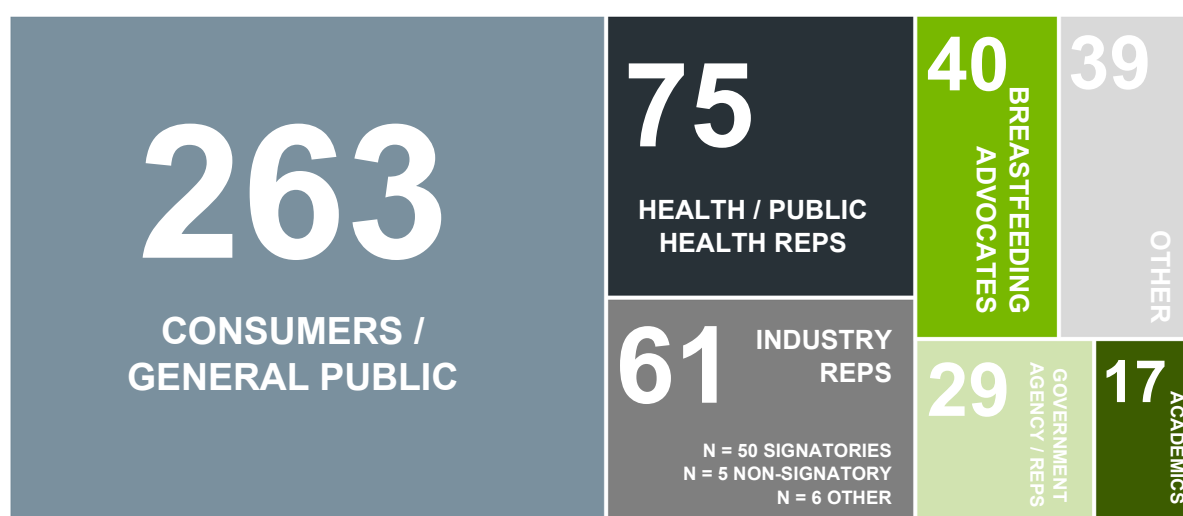
development of documents that were used during the Review, including the Consultation Paper, and the public survey and questions that were utilised in focus groups and interviews.

Documents considered in the desktop analysis and literature review were supplemented as the Review progressed, by documents that were subsequently published, or which were provided by Review stakeholders for consideration. A total of 150 documents were analysed during the Review. A reference list is provided in [Appendix F](#).

## 3.2 Consultation process

A total of 524 individuals and organisations participated in the stakeholder consultation for this Review by completing the survey or participating in an interview or focus group. Consultation included a cross-section of key stakeholder groups including consumers, industry, government agencies, public health representatives, breastfeeding and public health advocacy groups, and academics. **Figure 4** below provides a breakdown of consulted individuals by type of stakeholder.

**Figure 4: Stakeholders who participated in the Review, by sector**



### 3.2.1 Online survey

An online public consultation survey was launched on the Department of Health and Aged Care's Consultation Hub on 31 March 2023 and remained open for responses until 12 May 2023.

443 individuals responded to the survey. 63% of respondents were Consumers and members of the general public. The survey also captured responses from a range of other stakeholder groups including: health and public health representatives and organisations; breastfeeding advocacy groups; industry (signatories and non-signatories to the MAIF Agreement); government agencies; and academics. Survey data is provided in the MAIF Review Consultation Report.

### 3.2.2 Stakeholder interviews and focus groups

84 individuals from 49 organisations participated in a focus group or interview. Participants included:



- State and Territory Departments of Health
- MAIF Agreement signatories, and companies who have chosen not to sign the MAIF Agreement
- Industry representatives
- MAIF Complaints Committee members
- Public health and breastfeeding advocates
- Academics.

### 3.3 Analytical approach

The consultation process employed a mixed-methods (predominantly qualitative) approach for data collection and analysis. A structured approach was utilised for analysis of data and evidence gathered during this Review.

The Review team undertook a desktop analysis and literature review which comprised a broad range of relevant documents (see **Figure 3**). The Review team also undertook analysis of both quantitative and qualitative data from the online survey, written submissions, and interviews and focus groups with key stakeholders to inform key findings. Survey data were exported into a Microsoft Excel spreadsheet, and minor data cleaning was undertaken in preparation for analysis.

Interview and focus group data were recorded, transcribed, and collated with survey and written submission data. All qualitative data were imported into NVivo, a qualitative data coding software package (QSR International Pty Ltd, 2021) and analysed using a thematic approach to identify key themes across stakeholder sectors. Thematic analysis was reviewed critically to identify shared themes and provide insights into shared and sector-specific sentiment. Key findings were synthesised by KRQ and are presented throughout this Review with support / evidentiary excerpts from the data.

### 3.4 Strengths and limitations

A key strength of this Review was the comprehensive, mixed-method approach to document review and stakeholder consultation. A total of 150 documents were reviewed, and 524 individuals and organisations participated in the consultation process by completing the survey or participating in an interview or focus group. This included strong coverage across key stakeholder groups including consumers and members of the public, industry, government agencies, health sector representatives, breastfeeding and public health advocates, and academics.

There are some limitations of the data that should be acknowledged. These include:

- Availability of data showing a direct causal link between breastfeeding rates and the marketing of infant formula. See [Section 4.5.2](#).






- Engagement with infant formula consumer voices was limited within the interview and focus groups able to be conducted. However, this is balanced out by the large number of consumers and members of the general public who responded to the online survey.
- As with any online public survey, there is a risk of individuals or organisations submitting multiple responses.

## 4.0 FINDINGS

Section 4 details the key findings and recommendations arising from this Review.

**Table 3** provides an overview of recommendations arising from this Review. It includes a summary of expected benefits and costs, implementing parties and timeframes, and whether the recommendation is regulatory in nature.

**Table 3: Recommendations**

Stronger regulatory model		
<b>Recommendation 1</b> Develop a stronger regulatory framework to restrict the marketing of infant formula in Australia. Of the options outlined in this report, a prescribed mandatory code is the recommended approach. Introducing a prescribed mandatory code would create a level playing field among industry, embed stronger monitoring and reporting and be enforceable under law, while still providing flexibility in relation to policy decisions around scope of parties and products.		
 <b>Regulatory</b>		
Implementation	Benefits	Costs
Australian Government At least two years	<ul style="list-style-type: none"> <li>Improved public health and associated economic benefits</li> <li>Even playing field for industry</li> <li>Improved public confidence</li> <li>Monitoring burden removed from the public</li> </ul>	<ul style="list-style-type: none"> <li>Regulatory development and administrative costs for Government</li> <li>Costs to industry potentially passed on to consumers</li> <li>More anti-competitive</li> </ul>

## Recommendation 2

Retain the current scope of regulated products. This Review has not found sufficient justification for expanding the scope of products covered under the MAIF Agreement, or future strengthened regulatory arrangements. In relation to toddler milk drinks, the Department of Health and Aged Care should continue to monitor, and adopt as necessary, findings and recommendations arising from the FSANZ review of infant formula regulation to ensure consistency between the Food Standards Code and any future regulation of infant formula marketing.



Implementation	Benefits	Costs
Australian Government, infant formula industry	<ul style="list-style-type: none"> <li>Changes in relation to labelling being explored by FSANZ are expected to tangibly address concerns raised around toddler milk marketing</li> <li>Avoids costs and detriments that may arise from including products such as toddler milk drinks within the scope of the MAIF Agreement or alternative regulation</li> </ul>	<ul style="list-style-type: none"> <li>There may be costs to Government and industry that arise from the FSANZ review under Proposal P1028</li> </ul>

## Recommendation 3

Conduct a review of the scale and impact of inappropriate marketing of infant formula by supermarkets and pharmacies to determine whether the regulatory framework should include retailers in its scope. At this stage, insufficient evidence exists to justify the expansion of the scope of parties to regulation of infant formula marketing to supermarkets and pharmacies. There remains significant uncertainty around the scope of inappropriate marketing in these environments, and regarding the impacts of including these parties within the regulatory scope.



Implementation	Benefits	Costs
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Australian Government  
Medium term

- Better evidence for health policy and regulation
- Costs to Government associated with engagement and review

#### Recommendation 4

Amend the wording of the proposed new regulation of the marketing of infant formula to include explicit reference to electronic marketing and advertising. This would serve to increase public confidence and reduce confusion.



Implementation	Benefits	Costs
<p>Australian Government</p> <p>At least two years, if progressed as part of broader regulatory change</p>	<ul style="list-style-type: none"> <li>• Increased public confidence</li> <li>• Increased clarity of regulation to support monitoring and enforcement</li> </ul>	<ul style="list-style-type: none"> <li>• None expected</li> </ul>


#### Enhanced monitoring and enforcement

#### Recommendation 5

Implement a stronger monitoring system to support the regulation of infant formula marketing. This would support implementation of a regulatory framework and would reduce the burden of monitoring that currently falls on civil society and members of the public.



Implementation	Benefits	Costs
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Australian Government and/or industry	<ul style="list-style-type: none"> <li>• Support implementation of regulation and strengthen compliance</li> <li>• Reduce the burden of monitoring that currently falls on civil society and members of the public</li> </ul>	<ul style="list-style-type: none"> <li>• Costs to Government and/or industry to develop a stronger monitoring system</li> </ul>
Medium term		
<b>Recommendation 6</b>		
<p>Pending the implementation of Recommendation 1 and the regulatory framework selected, improve the efficiency, transparency and robustness of the complaints management mechanism so that decisions can be reached and complaints outcomes published in a timely manner. This Review has identified several mechanisms that would strengthen the complaints management process, including:</p>		
<ul style="list-style-type: none"> <li>• Embedding clear timeframes and standards of practice in the Committee's governance documents</li> <li>• Increasing the frequency of meetings to ensure that complaints can be discussed, considered, and responded to in a timely manner</li> <li>• Limiting the length of time, following a potential breach, within which a complaint can be made about an online post</li> <li>• Implementing processes to eliminate duplication ('double handling') of complaints if the same complaint is made by several parties</li> <li>• Updating complaints management documentation and website to improve transparency and accessibility</li> </ul>		
 <b>Regulatory</b>		
<b>Implementation</b>	<b>Benefits</b>	<b>Costs</b>
Australian Government Medium term	<ul style="list-style-type: none"> <li>• Improved complaints management mechanism to support implementation of regulation</li> <li>• Increased stakeholder confidence</li> </ul>	<ul style="list-style-type: none"> <li>• Costs to Government to establish and implement new complaints management mechanism</li> </ul>

## Recommendation 7

Pending the implementation of Recommendation 1, if the regulatory framework continues to require a committee to respond to complaints, changes should be made to its membership. The committee should be expanded to include at least five members, with increased expertise in areas including legal interpretation and marketing/communications. Public confidence would be significantly strengthened by removing industry influence from the complaints process.



**Regulatory**

Implementation	Benefits	Costs
Australian Government Short term	<ul style="list-style-type: none"> <li>Greater effectiveness and impartiality</li> </ul>	<ul style="list-style-type: none"> <li>Costs to Government associated with increased number of Complaints Committee members</li> </ul>

## Other initiatives to support regulation and improve infant nutrition

## Recommendation 8

Improve mechanisms for monitoring infant feeding (including breastfeeding) in Australia.



**Non-regulatory**

Implementation	Benefits	Costs
Australian Government Short to medium term	<ul style="list-style-type: none"> <li>Improved data collection on infant feeding including breastfeeding prevalence and duration in Australia</li> <li>Stronger evidence for health policy and regulation</li> </ul>	<ul style="list-style-type: none"> <li>Financial and staff costs to Governments for the development and implementation of survey or data collection mechanisms</li> </ul>



**Recommendation 9**

Raise awareness among healthcare professionals and parents/consumers about the appropriate use of infant formula. Resources should be developed by an independent body to enable healthcare professionals and parents to access objective, evidence-based information regarding infant formula products, their ingredients, and indications for use.

**Non-regulatory**

Implementation	Benefits	Costs
Australian Government Medium to long term	<ul style="list-style-type: none"> <li>• More effective engagement with parents and consumers in relation to the appropriate use of infant formula</li> <li>• More informed decision making</li> </ul>	<ul style="list-style-type: none"> <li>• Financial costs to Government</li> </ul>

**Recommendation 10**

Establish policy and guidelines to enable donations of infant formula in emergency and disaster contexts through reputable charities. To support the MAIF Agreement's aim to 'contribute to the provision of safe and adequate nutrition for infants', the Australian Government should provide clearer guidance supporting provision of infant formula to families who need it during disasters or other emergency contexts.

**Non-regulatory**

Implementation	Benefits	Costs
Australian Government Short term	<ul style="list-style-type: none"> <li>• Provision of safe and adequate nutrition for infants</li> </ul>	<ul style="list-style-type: none"> <li>• Financial and staff costs to Government</li> </ul>

## 4.1 Is the MAIF Agreement effective in achieving its aims?

This Review has found that the MAIF Agreement contributes positively to the provision of safe and adequate nutrition for infants by restricting the marketing of infant formula. However, there remains significant room for improvement in the coverage and operation of regulation of infant formula marketing that, if implemented, would more effectively meet the aims of the MAIF Agreement and result in a range of benefits.

The MAIF Agreement in its current form has been found to contribute to several unintended negative outcomes. Efforts should be made to address these through future amendments to the MAIF Agreement or the broader regulatory environment.

In re-authorising the MAIF Agreement in 2021, the ACCC noted that:

- It *'is likely that direct advertising and broader promotion of infant formula, such as through direct contact with parents, medical facilities and social media influencers, would increase in the absence of the MAIF Agreement.'*
- Given the long-standing operation of the MAIF Agreement, it *'is likely to contribute to an industry norm of behaviour that infant formula is not marketed in Australia, which appears to constrain the advertising behaviour of both signatory and non-signatory infant formula manufacturers'* (ACCC, 2021).

The 2012 Review noted that the effectiveness of the MAIF Agreement may be limited due to poor awareness and a lack of consistency in understanding of the WHO Code and MAIF Agreement in the community, particularly among healthcare professionals. It was suggested that the MAIF Agreement needs to be more widely disseminated to improve awareness and understanding among healthcare professionals. This could be achieved by the development of a comprehensive website or general education and media content, as well as harnessing existing professional development pathways to educate health professionals (Nous Group, 2012).

### 4.1.1 Consultation findings

The Review consultation process examined views on whether the MAIF Agreement remains fit for purpose and is effective in achieving its aims. A summary of the relevant consultation findings is provided below. More detailed information is provided in the MAIF Review Consultation Report.

Views on the effectiveness of the MAIF Agreement were highly polarised. Non-industry stakeholders largely considered the MAIF Agreement to be ineffective and not fit for purpose, and industry stakeholders described it as effective in achieving its aims.

The majority of survey respondents (71.4%) viewed the MAIF Agreement as ineffective in achieving its aims, while less than 20% of survey respondents considered the MAIF Agreement to be effective.

Stakeholders, particularly those from industry, highlighted the following reasons for why the MAIF Agreement is effective:



- Individual companies have their own compliance obligations and mechanisms that support the aims of the MAIF Agreement.
- The MAIF Complaints Committee develops and publicises guidance documents for interpreting the MAIF Agreement that help ensure the MAIF Agreement remains fit for purpose.
- Signatories are committed to complying with the MAIF Agreement and take their obligations and the risk of reputational damage seriously. Accordingly, public reporting of breaches provides sufficient deterrence for non-compliance. This is a stronger motivator than financial penalties would be if implemented.
- The industry body the Infant Nutrition Council (INC) has internal processes for managing allegations against its members and educates members and non-members about the MAIF Agreement.
- MAIF obligations are regularly discussed in industry forums.
- Signatories engage with retailers to highlight obligations under the MAIF Agreement.

Stakeholder views relating to the ineffectiveness of the MAIF Agreement included that:

- The MAIF Agreement does not reflect international best practice on infant feeding and does not fully deliver on international agreements (i.e., the WHO Code and subsequent WHA resolutions).
- The MAIF Agreement is voluntary and not all manufacturers/suppliers are signatories.
- Monitoring of compliance is inadequate and there are insufficient deterrents and penalties for breaches.
- Widespread marketing of infant formula may still occur, particularly on social media platforms, through cross-promotion (via similar packaging/design and line extension), and via retail product promotions and price discounting.
- There is a conflict of interest in relation to industry representation on the MAIF Complaints Committee.

#### **4.1.1.1 Unintended negative outcomes**

This Review has heard that the MAIF Agreement results in unintended negative outcomes that undermine the MAIF Agreement's positive contribution to the provision of safe and adequate nutrition for infants. These include limiting access to information that would support informed decision-making in relation to the use of infant formula, negative impacts on mental health, and restrictions on product donations in disasters and emergencies that may provide a public health benefit.

A range of industry and non-industry stakeholders suggested that the MAIF Agreement limits access by parents and caregivers to evidence-based information to support informed decision-making in relation to breastfeeding and using infant formula. Views particularly focused on the appropriateness of engagement by members of the infant formula industry



with healthcare professionals, and the role healthcare professionals should play in providing balanced and accurate information to parents and caregivers about breastfeeding and the use of infant formula. A common view among stakeholders was that health professionals do not receive adequate training to support the breastfeeding process or educate parents about appropriate infant feeding.

Many consumers highlighted their frustrations at not being able to access accurate information and advice on the proper use of infant formula, and that this is a barrier to being able to make informed decisions about infant feeding. Some consumers, members of the public, and industry stakeholders advised that the MAIF Agreement stigmatises the use of infant formula and contributes to feelings of guilt, shame, and stress among mothers and caregivers.

A range of consulted stakeholders suggested that resources should be developed to support access by healthcare professionals and consumers to objective, evidence-based information about the use of infant formula. It was suggested that information regarding the safe preparation, storage, and use of infant formula products should be provided by health professionals to every mother using infant formula.

Industry stakeholders suggested that the MAIF Agreement impedes the provision of infant formula to families during disasters and emergency contexts, which may undermine infant nutrition and increase the stress experienced by families in these contexts. The Review heard that requests had previously been made by food relief charities and state/territory governments for donations of infant formula during bushfires, floods and COVID-19 related lockdowns, but there was a lack of clarity around mechanisms for donations and a perception that donations might constitute a breach of the Agreement.

#### **4.1.1.2 The MAIF Agreement should be implemented alongside other policy measures and strategies to ensure safe and adequate nutrition for infants.**

Several stakeholders indicated that the MAIF Agreement should not be perceived as a standalone mechanism and should be integrated with other policies and strategies, including the NHMRC Infant Feeding Guidelines, the Australian National Breastfeeding Strategy: 2019 and Beyond, the Food Standards Code, the Baby Friendly Health Initiative, and the Breastfeeding Friendly Childcare Program. The Early Years Strategy provides one mechanism to connect the MAIF Agreement to these other strategies. The Review heard that a range of levers should be utilised to increase breastfeeding rates in Australia, and that these strategies should be aligned and consistent.

## **4.2 Is the voluntary, self-regulatory approach fit for purpose or are there alternative regulatory models?**

The existing regulatory model is no longer fit for purpose for regulating the marketing of infant formula in Australia. It currently lacks broad community support and trust, burdens a large proportion of compliance costs on volunteers (mainly women), and does not include all marketers of infant formula.

A new regulatory model should be established to address the inadequacies of the existing model in order to promote confidence in the information disclosure settings for infant formula, and to foster better health outcomes for Australians. There are different regulatory models the Australian Government could adopt, including quasi-regulation, co-regulation, and statutory regulation. This chapter outlines these options, and broadly reflects on their benefits and costs to the Australian community. Of the regulatory options outlined, a prescribed mandatory code is recommended.

## 4.2.1 Background

### 4.2.1.1 International regulatory context

The WHO has stated that '*Full application of the 1981 Code and subsequent resolutions...is essential to ensuring that parents and other caregivers are protected from inappropriate and misleading information*' (WHO, 2022).

Under Article 11.1 of the WHO Code, governments are requested to:

*Take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulation or other suitable measures.*

In resolution WHA34.22 (1981), in which the WHO Code was adopted, the WHA stressed that adoption of and adherence to the WHO Code is a minimum requirement for all Member States and urges all Member States to implement it 'in its entirety'.

The WHO provides a four-level classification for national implementation of the WHO Code:

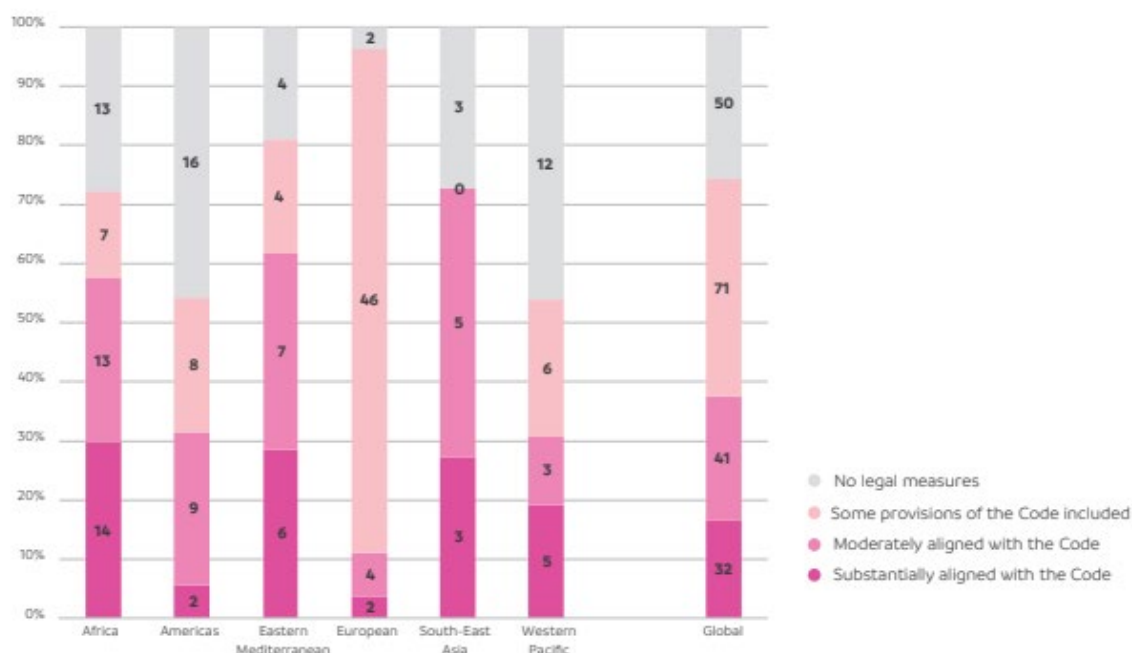
- **Substantially aligned with the WHO Code:** countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing a significant set of provisions of the WHO Code.
- **Moderately aligned with the WHO Code:** countries have enacted legislation or adopted regulations, decrees or other legally binding measures encompassing a majority of provisions of the WHO Code.
- **Some provisions of the WHO Code included:** countries have enacted legislation or adopted regulations, decrees or other legally binding measures covering less than half of the provisions of the WHO Code.
- **No legal measures:** countries have taken no action or have implemented the WHO Code only through voluntary agreements or other non-legal measures (this includes countries that have drafted legislation but not enacted it).

As of March 2022, 144 of the 194 (74%) WHO Member States have adopted legal measures to implement at least some of the provisions in the WHO Code. Of these, 32 countries have measures in place that are substantially aligned with the WHO Code. This is seven more than reported in 2020, indicating that new legislation and regulations closely aligned with the WHO Code have been implemented internationally (WHO, 2022, p. 12).

**Figure 5** outlines the legal status of the WHO Code as enacted in countries by WHO region. Notably, over 90% of European countries have some provisions of the WHO Code enacted compared to the Americas where over 50% of countries have some provisions of the WHO Code enacted. Globally, over 30% of countries are substantially or moderately aligned with

the WHO Code. The African, Eastern Mediterranean and South-East Asian WHO regions have the highest percentage of countries substantially aligned with the Code (WHO, 2022).

**Figure 5: Legal status of the Code as enacted in countries, by WHO region (WHO, 2022)**



**Source: World Health Organization, Marketing of breast-milk substitutes: national implementation of the international code, status report 2022**

Measured against the WHO's criteria for assessing national compliance with the WHO Code, the MAIF Agreement is among the weakest measures internationally. However, the INC has contested that the MAIF Agreement is already more restrictive than the regulations that apply in comparable overseas jurisdictions (Infant Nutrition Council, 2021). The INC has noted that:

- Canada and the United States have not implemented the WHO Code through legislation, and there is no voluntary industry self-regulation.
- Japan has not implemented the WHO Code through legislation, and its national laws and regulations relating to the manufacture and sale of infant formula do not include detailed prohibitions on marketing as required by the WHO Code.
- The European Union and United Kingdom have implemented aspects of the WHO Code, though regulation addressing marketing and promotion of infant formula products applies only to products for children up to six months.
- New Zealand has a similar voluntary self-regulatory code to the MAIF Agreement which covers infant formula products for children up to 12 months.

Analysis undertaken for this Review of data published by the WHO in 2022 shows that, of the 38 members of the Organisation for Economic Co-operation and Development (OECD):



- Five have no legal measures in place to implement the WHO Code<sup>6</sup>
- Only three are considered to be ‘moderately aligned with the Code’<sup>7</sup>
- The remaining OECD countries (including Australia) are regarded as having legislated ‘some provisions of the Code.’ The remaining OECD countries received slightly higher overall ratings than Australia, with the exception of New Zealand which received the same score.

#### 4.2.1.2 Australian regulatory context

The Australian Government’s regulatory reform agenda ‘*aims to achieve effective and fit-for-purpose regulation while minimising the administrative burden on businesses, community organisations and individuals*’ (Department of Health and Aged Care, 2022). The Government ‘*is looking at ways to boost productivity through reducing unnecessary or duplicative regulatory costs*’ (Department of Finance, 2022). Priorities of the Government’s reform agenda that are relevant to this review include:

- Removing unnecessary duplication across regulatory frameworks to help consumers access a better and cheaper range of goods and services and reduce compliance costs for business.
- Working with business and the community to identify opportunities to lower the regulatory costs and burdens, while maintaining high quality regulatory outcomes.
- Making connections with and learning from international peer regulators and international organisations and bilateral partners. (Department of Finance, 2022).

The Department of Health and Aged Care’s approach to regulation is set out in its Health Regulatory Policy Framework. The Framework outlines that ‘*when considering options to address a public policy issue, policy makers must always ask themselves if there are alternatives to regulation*’. The Framework notes that ‘*sometimes the solution may lie in better enforcement of existing regulation*’ and suggests that ‘*doing nothing could be the best option in some circumstances.*’

The Framework articulates seven guiding principles that ‘guide the decisions and behaviours of our policy makers and regulators in managing regulation’:

1. We will value regulation as an asset that protects the health and safety of Australians
2. We will take into account the regulatory impact of our decisions and minimise regulatory costs
3. We will engage effectively with our stakeholders
4. We will adopt a best practice approach to the compliance and enforcement of our regulation
5. We will build our regulatory capability
6. We will ensure good governance

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<sup>6</sup> Canada, Israel, Japan, Canada, USA

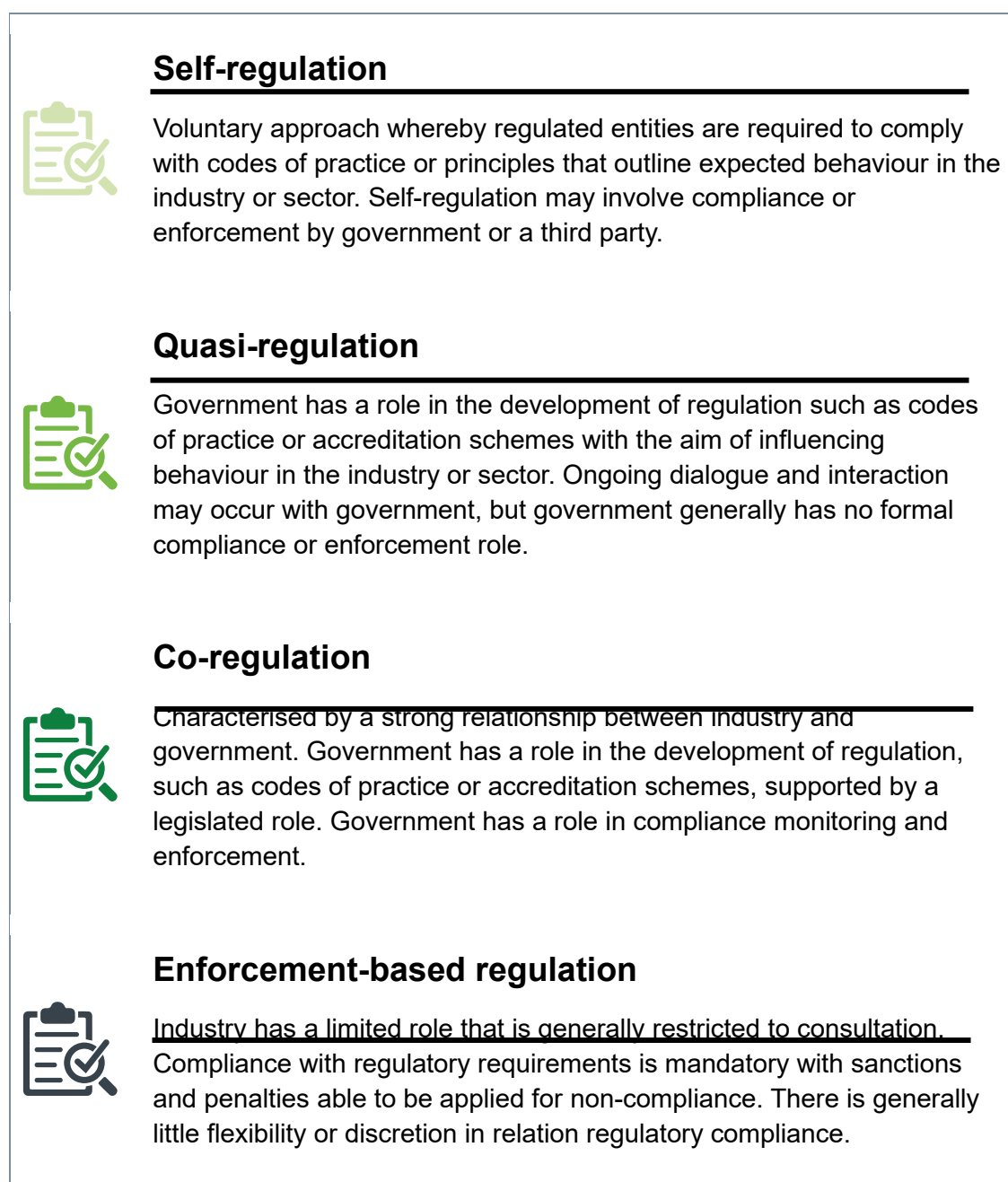
<sup>7</sup> Columbia, Costa Rica, Mexico



7. We will regularly monitor and review our regulation to ensure it remains fit for purpose (Department of Health and Aged Care, 2020).

Regulation can take many forms including self-regulation, such as compliance with industry codes or practice, through to an enforcement-based approach. **Figure 6** is adapted from the Regulatory Policy Framework and demonstrates this regulatory continuum. The MAIF Agreement is an example of self-regulation.

**Figure 6: The regulatory continuum (Department of Health, 2020)**



#### **4.2.1.3 Applicability**

There is a broad diversity of views in the literature regarding whether the current regulatory model is fit for purpose, and about the applicability of other regulatory models (including potential establishment of a legislated statutory framework) in the Australian context. Three reviews of the MAIF Agreement have provided different levels of confidence in the operation of the MAIF Agreement, progressively decreasing over time. This includes the 2001 MAIF Review, 2012 MAIF Review, and 2021 ACCC re-authorisation determination.

##### **2001 MAIF Review**

The 2001 review of the MAIF Agreement found the voluntary model was effective. However, it also concluded, that while *'the existing MAIF Agreement should remain the basis for the*



*co-regulatory agreement on infant formula with no change to the actual agreement...the Government should consider legislation to create a framework for implementing the WHO Code if formula manufacturers withdraw from the existing MAIF Agreement* (Knowles, R, 2001). The 2001 Review also made the following recommendations aimed at enhancing the operation of the MAIF Agreement and protecting breastfeeding rates. They included:

- establishing a public health partnership between the Commonwealth, States and Territories to enable a longer-term strategic approach to the promotion of breastfeeding
- improving the operation of the Operation of APMAIF
- including pharmacies and supermarkets in public health efforts to improve breastfeeding rates, including through a formal or informal agreement on a code of practice (Knowles, R, 2001).

## 2012 MAIF Review

The 2012 MAIF Review found that the voluntary, self-regulatory nature of the MAIF Agreement was *'the most cost-effective regulatory mechanism and should continue, providing that it continued to promote the achievement of the aim of the MAIF Agreement, and that industry coverage remained high'*. This review found that while there had been several regulatory changes since the MAIF Agreement's establishment in 1992, these had not impacted the effectiveness of the MAIF Agreement. The review concluded that the MAIF Agreement should not be expanded to cover other products, including toddler milk; other parties, including retailers and pharmacies; and other infant feeding products.

However, the review did recommend significant changes to the MAIF Agreement to improve its effectiveness in actively monitoring compliance with the MAIF Agreement, including the complaints handling process. The 2012 MAIF Review also recommended that wording in the MAIF Agreement be updated to reflect changes to legislation, standards, marketing practices and modern health terminology, and to address the emergence of electronic marketing and social media (Nous Group, 2012).

## 2021 ACCC re-authorisation

In 2021, the ACCC reauthorised the MAIF Agreement until 31 August 2024, consistent with the *Competition and Consumer Act 2010*. In making its decision, the ACCC considered the public benefit outweighed public detriment arising from *'the reduction in competition resulting from competitors agreeing to limit promotional activity'* created by the MAIF Agreement. However, in making its determination, the ACCC noted its concern about the effectiveness of the MAIF Agreement.

Specifically, the ACCC stated the MAIF Agreement is being 'undermined' by the following factors:

- the ability for signatories to advertise toddler milk products, which often has almost identical packaging to infant formula and can have the effect of promoting infant formula
- the MAIF Agreement is voluntary and carries no sanctions for a breach, other than the publication of a breach finding on the Department of Health and Aged Care website

- significant concerns have also been raised about the independence and transparency of the complaints handling process.

The ACCC concluded by saying, *‘The combined effect of these factors significantly reduces the effectiveness of the MAIF Agreement in protecting breastfeeding rates, and therefore the magnitude of the likely public benefit from the MAIF Agreement’*.

## 4.2.2 Consultation findings

In general, public health officials and breastfeeding advocates considered the regulatory model underpinning the MAIF Agreement was not fit for purpose. In contrast, industry representatives thought it was effective in achieving its stated objectives.

Public health officials and breastfeeding advocates believed the MAIF Agreement had failed because of its lack of industry coverage, insufficient deterrence for non-compliance and inconsistency with intergovernmental agreements. They considered participation in the regulatory model should be mandatory, with some non-industry stakeholders also calling for the inclusion of retailers of infant formula to also be required to comply with infant formula marketing regulations.

In contrast, industry representatives considered the voluntary model to have been effective in achieving the objectives of the MAIF Agreement, noting the reputational incentives which drove compliance with the MAIF Agreement. However, some MAIF signatories considered the MAIF Agreement’s lack of universal coverage created an uneven playing field, and that they would welcome the establishment of a mandatory regulatory system. A MAIF signatory survey respondent described that making the MAIF Agreement mandatory would *‘assist in new/smaller company signatory adherence – where most of the compliance breaches have occurred in recent years.’* One MAIF signatory noted that:

*If there is an opportunity within the MAIF and INC realm to implement a form or process that actually connects smaller companies that aren’t part of MAIF to be actually involved - that would make a level playing field for self-regulation, as fundamentally self-regulation only works if everyone is in the same ballpark.*

A State/Territory Health Department representative outlined that the MAIF Agreement *‘is not signed up to by all manufacturers and importers of breastmilk substitutes which limits its impact creating an uneven playing field for industry and adding to consumer confusion.’*

## 4.2.3 Assessment of self-regulation

The Australian Government’s 2023 Guide to Policy Impact Analysis (The Office of Impact Analysis, 2023) provides a framework for considering whether self-regulation is effective. This Review refers to this framework in considering whether the voluntary self-regulatory approach remains appropriate for the marketing of infant formula (**Table 4**).

**Table 4: Assessing regulatory model effectiveness**

Self-regulation success factors	Do these apply to the marketing of infant formula?
<b>Incentives exist for industry to comply</b>	<p>Partial. There are a relatively small number of non-signatories, and signatories constitute &gt;85% of market share. The Review has heard there is also a strong industry norm supporting compliance with the MAIF, even among some non-signatories. This appears driven by a perceived need for social license, and by strong consumer views/motivations among some companies.</p> <p>However, not all manufacturers and importers are signatories. In the last published annual report (2020-21), 15 of the 55 (27%) reported complaints were considered out of scope as they related to non-signatories.</p>
<b>Low risk to the community in the event of non-compliance</b>	<p>Unclear/partial. In general, non-industry stakeholders consulted during this Review believe there are significant risks around non-compliance. The strong view put forward is that marketing impacts uptake of breastfeeding, and that this has significant public health impacts. However, there remain limitations to our understanding of risk, given complexities around breastfeeding/formula use and limitations of available data. The evidence also does not indicate widespread existing or likely non-compliance.</p>
<b>Market is likely to move towards an optimal outcome by itself</b>	<p>Partial. There is evidence of industry norms and processes in support of the MAIF Agreement. Most infant formula companies are members (with &gt;85% market share). However, some non-compliance continues (smaller/newer signatories), and non-signatories and retailers demonstrate conduct inconsistent with the MAIF Agreement. There also appears to be a decreasing level of trust and confidence in the MAIF Agreement.</p>
<b>Compliance history</b>	<p>Partial. Self-regulation has been in place for decades, and some non-compliance has persisted. Based on consultation, stakeholder trust in self-regulation is low. However, levels of non-compliance are arguably low.</p>

## 4.2.4 Other potential regulatory models

Apart from a voluntary, self-regulatory model, there are other ways the marketing of infant formula could be regulated in Australia. These include quasi-regulation, co-regulation, and statutory regulation models. **Table 5** sets out these models and provides examples of how the marketing of infant formula may be regulated under each model.

**Table 5: Other regulatory models**

Quasi-regulation	Co-regulation	Statutory regulation	
		Principles-based	Prescriptive
Wide range of rules or arrangements that are not part of explicit government regulation. e.g., industry-government agreements e.g., MAIF Agreement, with enhancements	Industry develops and administers its own arrangement and government provides the underpinning legislation to enforce it. e.g., Prescribed MAIF voluntary code	Establishes desired outcomes within legislation and regulation	Sets prescriptive requirements out in laws and regulations
		e.g., Prescribed MAIF mandatory code	

## 4.2.5 Regulatory model options and characteristics

The Review considers there are at least four regulatory model options that could be considered for the regulation of the marketing of infant formula. These include:

- Option 1: Status quo – MAIF Agreement (self-regulation)
- Option 2: MAIF Agreement with enhancements (quasi-regulation)
- Option 3: Prescribed voluntary code (co-regulation)
- Option 4: Prescribed mandatory code (statutory regulation)

Option 1 provides for the continuation of the status quo, with no change to scope, governance, or compliance and enforcement. This option would not increase regulatory burden on industry, but would fail to address the reported deficiencies identified by this Review and the ACCC's 2021 re-authorisation determination.

Under option 2, the MAIF Agreement would remain voluntary. However, enhancements would be made to its governance and compliance monitoring. For example, a consumer representative would be included in the MAIF Complaints Committee, and a compliance

performance reporting regime would be established whereby data would be collected from signatories to monitor and report on compliance. This option could also incorporate an enhanced “name and shame” approach, including making public statements on non-compliant signatories. Efforts could also be made to expand the coverage of marketers, as well as products included. However, increasing the scope and coverage of the MAIF Agreement would be expected to have a limited impact due to its voluntary context.

For option 3, while the regulation of marketing of infant formula would remain voluntary, it would be a prescribed code or regulation under law. The regulation and its complaints process would be governed by a regulator, whether within or independent from government. Non-compliance could attract financial penalties, as well as administrative enforcement action. However, its voluntary nature, combined with a stronger enforcement regime, may increase the risk of non-participation.

In Option 4, participation in the regulatory regime would be mandatory. This option most closely aligns with the views expressed by the public health officials, academics, and breastfeeding and public health advocates to the Review. Prescribed mandatory codes are legally binding on all industry participants specified within that code. Mandatory codes can be used to identify the specific behaviours in an industry that should be prevented and to better ensure risk is allocated efficiently between the parties to enhance market operation. Prescribed industry codes are enforceable by the ACCC or by private action under the *Competition and Consumer Act 2010*, with a wide range of remedies available. These include:

- injunctions to either prevent or require particular conduct (section 80)
- damages to compensate for loss or damage resulting from a contravention of a code (section 82)
- non-punitive orders such as community service orders (section 86C—only on application of the ACCC)
- other compensatory orders (section 87) (Department of the Treasury, 2017).

Combinations of these options could also exist. For example, option 3 could be adopted without financial penalties attached to non-compliance. Further, the MAIF Complaints Committee could continue to exist under options 3 and 4, though may provide more of an advisory role to the regulatory decision maker.

**Table 6** summarises the key characteristics of each regulatory option. Of the regulatory options outlined, a prescribed mandatory code is recommended. This would create a level playing field among industry, embed stronger monitoring and reporting and be enforceable under law, while still providing flexibility in relation to policy decisions around scope of parties and products.



**Table 6: Characteristics of regulatory options**

Option	Coverage	Governance	Complaints	Monitoring and reporting	Enforcement
<b>Option 1</b> Status quo	Signatories only	Complaints Committee	Complaints reviewed by Complaints Committee	Complaints Committee report on complaints received	Website reporting of non-compliant signatories on website
<b>Option 2</b> MAIF Agreement, with enhancements (quasi-regulation)	Signatories only Scope of parties could be expanded Scope of products could be expanded	Complaints Committee, with adjustments e.g., including a consumer representative	Complaints reviewed by Complaints Committee	Complaints Committee reports on complaints, and collects data from signatories to monitor and report on compliance	Optional enhanced 'name and shame' approach, including making public statements on non-compliant signatories
<b>Option 3</b> Prescribed voluntary code (co-regulation)	Signatories only Scope of parties could be expanded Scope of products could be expanded	Regulator e.g., within a department, existing regulator, or new regulator	Complaints considered by a regulator	Monitors and reports on compliance by signatories, based on a range of data including complaints and industry performance information	Enforceable under law. Penalties for non-compliance may include infringement penalties or enforceable undertakings
<b>Option 4</b> Prescribed mandatory code (statutory regulation)	All suppliers Scope of parties could be expanded Scope of products could be expanded	Regulator e.g., within a department, existing regulator, or new regulator	Complaints considered by a regulator	Monitors and reports on compliance, based on a range of data including complaints and industry performance information	Enforceable under law. Penalties for non-compliance may include infringement penalties or enforceable undertakings. May also include civil penalties.

## 4.3 Is the scope of the MAIF Agreement appropriate in the current policy environment?

This Review has found that the regulation of infant formula marketing in Australia should be strengthened to apply to all manufacturers and importers of infant formula. This would further reduce inappropriate marketing of infant formula in Australia and create a 'level playing field' among industry. However, at this stage, insufficient evidence exists to justify the expansion of regulation to include other products, including toddler milk drinks, or other parties, including retailers.

### 4.3.1 Scope of the MAIF Agreement

The WHO Code applies to the marketing of breastmilk substitutes which includes:

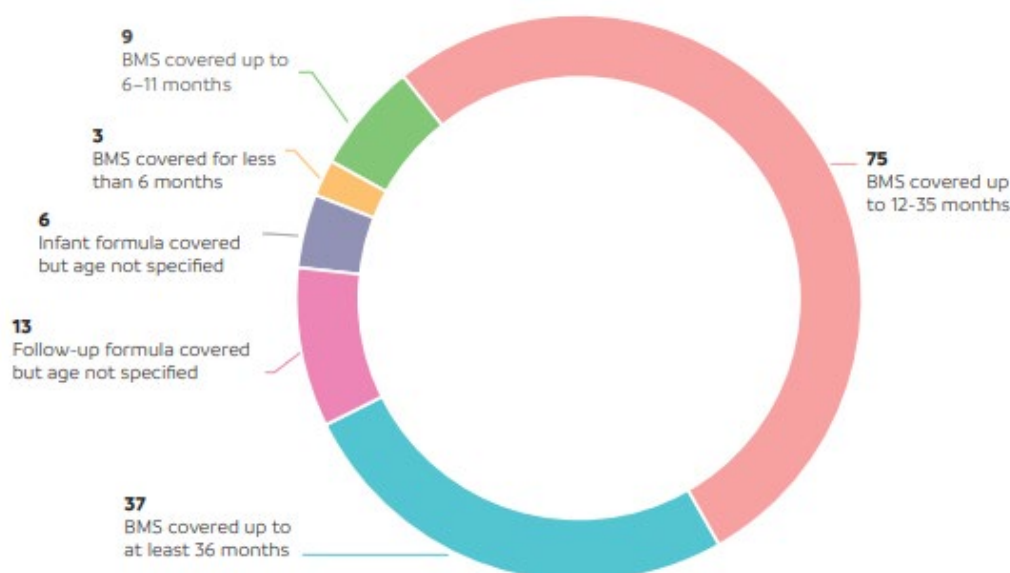
*Breastmilk substitute, including infant formula. This should be understood to include any milks (or products that could be used to replace milk) that are specifically marketed for feeding infants and young children up to the age of 3 years, including follow-up formula and growing-up milks (WHO, 2017).*

A subsequent WHO resolution to end inappropriate promotion of foods for infants and young children clarified that 'follow up formula' is also within the scope of the Code and should not be promoted (WHO, 2017). The WHO Code also prohibits the marketing of other foods and beverages promoted to be suitable for feeding a baby during the first six months of life when exclusive breastfeeding is recommended, including baby teas, juices and waters; and feeding bottles and teats (WHO, 2017).

#### 4.3.1.1 International approaches

The scope of products covered in legal measures by WHO Member States, is outlined in **Figure 7** below. This analysis defines the WHO Code to include all relevant WHA resolutions. Only 37 of 143 countries have legal measures that cover breastmilk substitutes up to at least 36 months, which is considered the full breadth of breastmilk substitutes by the WHO (WHO, 2022). However, 75 countries cover breastmilk substitutes for infants and young children (12 – 35 months), 85 countries also cover complementary foods, while 78 countries include bottles and teats in the scope of their national legislation (WHO, 2022). Only 29 countries have legislation that covers the full scope of the WHO Code, including breastmilk substitutes marketed up to 3 years of age, complementary foods inappropriately marketed as suitable for infants 0-5 months of age, and feeding bottles and teats (WHO, 2022).

**Figure 7: Scope of breastmilk substitute products covered in legal measures by WHO Member States (n=143) (WHO, 2022)**



**Source: World Health Organization, Marketing of breast-milk substitutes: national implementation of the international code, status report 2022**

#### 4.3.1.2 Approach in Australia

Products covered under the MAIF Agreement are narrower in scope than those included in the WHO Code and subsequent WHA resolutions. The MAIF Agreement prohibits manufacturers and importers from advertising 'infant formula', which it defines in clause 3(e) as human milk alternatives *'for the feeding of infants up to the age of 12 months'* (The MAIF Agreement, 1992). It also restricts the promotion of 'breastmilk substitutes' which includes *'any food marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose'* (The MAIF Agreement, 1992). In Australia, products aimed at toddlers over 12 months of age, including toddler milks, baby food, feeding bottles, teats and dummies are not within the scope of the MAIF Agreement.

#### 4.3.1.3 Infant formula policy and marketing environment

In Australia, the Food Standards Code defines and regulates infant formula products and toddler milk (as a formulated supplementary food for young children). During the ACCC's most recent re-authorisation of the MAIF Agreement, industry stakeholders expressed the view that 'toddler milk is not a substitute for breastmilk and should therefore not be regulated within the same framework' given that toddler milk has a different composition and is intended as an alternative non-human milk for children over 12 months of age. This is illustrated by the separate regulation of toddler milk and infant formula in the Food Standards Code (ACCC, 2021).

Research has shown that despite a reduction in infant formula marketing, there has been an increase in toddler milk advertising and brand promotion (Smith, J, Blake, M, 2013). This is mirrored internationally with 2016 data from 16 countries indicating that infant formula sales were static or decreasing, while toddler milk drinks were the fastest growing category of breastmilk substitutes (Collins, N, et al, 2016).

Literature suggests that toddler milks may act as a cross-promotion for advertising infant milk, with companies indirectly promoting their infant formula to circumvent marketing restrictions (Thatcher, F, 2022), (Berry, N, et al, 2010). With strong brand marketing, similar packaging, and shelf placement, it can be difficult to distinguish between the two products. In 2016, a WHO resolution recommended that packaging of non-breastmilk substitute products and promotion of complementary foods should be distinct from those used for breastmilk substitutes to avoid cross-promotion (WHO, 2017).

A study of Australian parents found that most respondents reported having seen an advertisement for infant formula and that consumers fail to distinguish between advertising for infant formula and toddler milk (Berry, N, et al, 2010). Brand crossovers may therefore mislead consumers about the nutrition, health-related, and age-appropriate safe use of products (WHO, 2017). However, industry stakeholders have suggested there is no evidence that toddler milk product marketing is tantamount to the promotion of infant formula, and that it is appropriate for toddler milk to be marketed using stage numbers and similar packaging to infant formula (ACCC, 2021).

#### 4.3.1.4 Regulation of labelling and proxy advertising

FSANZ's review of the regulation of Infant Formula products as detailed in [Section 2.7](#) is addressing areas of regulation relevant to the MAIF Agreement and which have been raised by this Review. These are relevant to both the effectiveness of the MAIF Agreement and to whether the scope of products should be expanded. There are three key areas of potential change under Proposal P1028.

- **Standardise the nutrition information statement.** FSANZ proposes to '*prescribe the content and format of the nutrition information statement or infant formula and follow-on formula*', which will among other benefits '*assist consumer understanding of nutrition information and enable easier comparisons when making product choices.*' Efforts to increase consumer understanding of products, and enhance their ability to make informed decisions, may tangibly address concerns raised during this MAIF Agreement Review.
- **Set requirements around the position of stage labelling on infant formula and follow-on formula labels.** FSANZ proposes to set requirements that, if used, stage numbers ('1' for infant formula and '2' for follow-on formula) '*must appear on the front of the package immediately adjacent to the relevant age statement for that product.*' FSANZ states this requirement is intended to ensure that stage labelling is visible to consumers when they are making purchasing decisions. This measure may help address a concern raised during this Review that current labelling practices result in uncertainty around identifying the correct product for infants.
- **Prohibit the use of proxy advertising.** This Review of the MAIF Agreement has heard concerns about the use of toddler milk advertising as a proxy for advertising of infant formula and resulting calls for advertising restrictions on toddler milk products.

FSANZ is proposing to prohibit information about other products on the labels of infant formula and follow-on formula. The intent is to ensure that infant formula and follow-on formula are distinctly labelled so consumers are not influenced by the presence of information about other products and are able to choose the appropriate product for their infants. Information about other products may suggest to consumers a progression through different age/stage products is necessary. This change is also intended to prevent permitted

claims made about toddler milks appearing on infant formula and follow-on formula labels as a means of influencing purchase decisions.

### 4.3.2 Scope of parties

The WHO Code applies to manufacturers and distributors of breastmilk substitutes. The WHO Code defines 'manufacturers' and 'distributors' as follows:

**Manufacturers:** *A corporation or other entity in the public or private sector engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing a product within the scope of this Code*

and

**Distributor:** *A person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code. A 'primary distributor' is a manufacturer's sales agent, representative, national distributor or broker (WHO, 1981).*

#### Approach in Australia

The MAIF Agreement applies only to its signatories, which are manufacturers and importers of infant milk products. It does not apply to retailers and distributors, and manufacturers and importers who have not signed the MAIF Agreement. The scope of parties subject to the MAIF Agreement has been widely criticised because retailers, such as supermarkets and pharmacies, or other parties, such as social media influencers, remain able to advertise infant milk products.

#### 4.3.2.1 International approaches

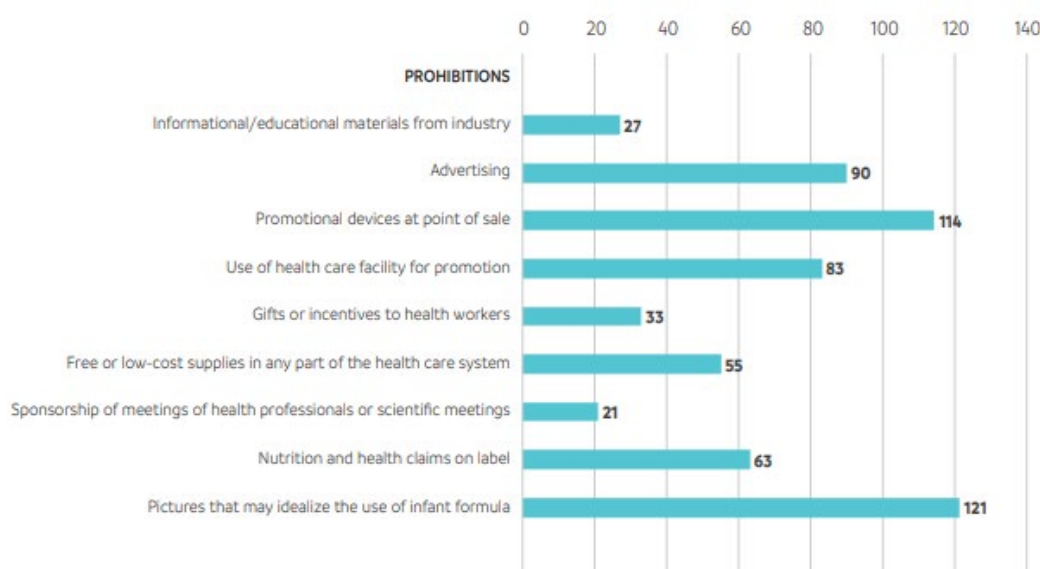
Marketing is becoming increasingly targeted beyond traditional settings such as retail outlets. The rise in, and popularity of, social media channels, internet sites, and online communities dedicated to pregnant women and mothers provide manufacturers and distributors with new and often unregulated points to market their products (WHO, 2017) (UNICEF, 2020).

Article 5.1 of the WHO Code states that '*There should be no advertising or other form of promotion to the general public of products within the scope of the Code.*' This includes any advertising through mass media outlets such as television, magazines, billboards, websites, or social media. The WHO Code further states there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level. Furthermore, no company personnel should seek direct or indirect contact with, or provide advice to, pregnant women or mothers, whether via retail outlets or social media channels (WHO, 2017). The WHO Code also states that labels should inform parents about the correct use of infant formula and the risk of misuse, and require that labels do not discourage breastfeeding.

**Figure 8** outlines countries with key WHO Code provisions enumerated in legal measures, by provision. 121 countries have prohibited pictures that may idealise the use of infant formula, with only 21 countries prohibiting sponsorship of meetings of health professionals or scientific meetings.

The WHO has found significant variation in the implementation of advertising and marketing prohibition measures: 121 countries have prohibitions on advertising, provision of promotional devices at point of sale, and pictures idealising the use of infant formula, 63 countries require health and nutrition claims on labels, and only 27 prohibit the distribution of informational or educational materials from manufacturers or distributors (WHO, 2022).

**Figure 8: Countries with key Code provisions enumerated in legal measures, by provision (WHO, 2022)**



**Source: World Health Organization, Marketing of breast-milk substitutes: national implementation of the international code, status report 2022**

#### 4.3.2.2 Approach in Australia

The scope of the MAIF Agreement only covers infant formula products, thus there are no restrictions on marketing and advertising toddler formula, baby food, and products such as bottles and teats, other than under general consumer law. Entities who are not signatories to the MAIF Agreement, such as retailers, are not subject to marketing restrictions. Furthermore, price promotion of infant formula (such as 'special prices' and discounts) is permitted in Australia.

In Australia, products such as bottles and teats are regulated in the context of product safety. This Review also agrees with the finding in the 2012 Review that restrictions on bottles and teats would be inappropriate as they are also used by breastfeeding parents (e.g., for expressed breastmilk).

#### 4.3.2.3 Current marketing environment

A review of the digital marketing of breastmilk substitutes identified multiple digital channels that are being used to promote breastmilk substitutes (Jones A, et al, 2022), including social media, manufacturer websites, online retailers, blogs, mobile apps, and digital streaming





services. The review noted that data is being ‘mined’ to direct targeted advertising to consumers. Highlighting the importance of online information sources, a 2015 study found that 52% of mothers in Australia reported using the Internet to access information on formula feeding, while 73% accessed it for information on breastfeeding (Newby R, et al, 2015).

Studies suggest that Australian manufacturers of infant formula may be disregarding regulatory prohibitions under the FSANZ Code, relating to the inclusion of health and nutrition content claims in websites advertising their products. A 2017 study of web pages advertising 25 infant formula products purchasable in Australia identified that every advertisement contained at least one health claim. Eighteen products contained at least one nutrition content claim and three web pages advertising brands associated with infant formula products referenced the nutritional content of human milk (Berry, NJ, Gribble, KD, 2017). This has led to one consumer advocate calling for plain packing laws to be introduced (ACCC, 2021).

As discussed in [Section 4.1.1.1](#) however, there are also arguments in favour of increasing the availability of factual information to consumers to support the making of informed decisions about breastfeeding and the use of infant formula.

### 4.3.3 Consultation findings

The Review consultation process sought feedback on the appropriateness of the MAIF Agreement’s scope in the current policy environment. A summary of the consultation findings relevant to this KRQ is provided below. More detailed information is provided in the MAIF Review Consultation Report.

#### 4.3.3.1 There were conflicting views between industry and non-industry stakeholders on the appropriateness of the scope of the MAIF Agreement

Most survey respondents (62.5%) indicated that the MAIF Agreement’s overall scope was not appropriate. Industry stakeholders generally considered the current scope of the MAIF Agreement to be appropriate, while other non-industry stakeholders broadly perceived that the scope was inappropriate. Among consumers and the general public, two-thirds perceived the current scope as inappropriate, while just over a quarter held the view that the current scope was appropriate. Based on qualitative survey responses, focus groups and interviews, the consensus among stakeholders who considered the scope of the MAIF Agreement inadequate was that the MAIF Agreement should:

- Be replaced by legislation of the full WHO Code and subsequent WHA resolutions, i.e., the scope of products should be extended to include toddler milk for children aged 12-36 months, bottles, and teats
- Be expanded to include retailers (supermarkets and pharmacies) and distributors
- More explicitly address social media / online marketing practices
- Have more effective and transparent monitoring alongside enforcement of stronger penalties.

#### **4.3.3.2 The inclusion of toddler milk drinks within the scope of the MAIF Agreement remains a point of contention**

During the consultation process, the Review heard strong feedback about the inclusion of toddler milk drinks within the scope of products under the MAIF Agreement. Many non-industry stakeholders highlighted concerns around:

- The marketing of a wider range of products perceived as breastmilk substitutes via brand recognition, cross-promotion, and line extension as a form of indirect marketing
- Similar packaging of infant formula and toddler milk drinks, leading to difficulty differentiating these products among consumers
- Complementary foods or milks for toddlers being unnecessary for healthy children.

In contrast, industry stakeholders cited the Food Standards Code to suggest that toddler milk drinks are not breastmilk substitutes; and suggested that these products can play a valuable role in addressing nutritional deficiencies (such as iron and vitamin D). Industry stakeholders cited an industry-funded survey (Infant Nutrition Council, 2022) on a proposed ban for marketing of toddler milk drinks, which suggested that only a small percentage of parents (8%) may confuse toddler milk drinks with infant formula.<sup>8</sup>

Further, expanding the product scope to include toddler milk drinks was perceived to negatively impact the competitive landscape and reduce incentives for innovation. Industry stakeholders emphasised that the inclusion of toddler milk drinks would lead to a reduction in innovation, research, and education regarding infant nutrition, and reduce the incentive to invest in these areas. In this regard, during the 2021 re-authorisation process, the ACCC noted the potential public detriment arising from a reduction in rivalry among competitors, including reduced incentives for innovation and increased barriers to entry, if further limitations were imposed on promotional activity (ACCC, 2021).

#### **4.3.3.3 Industry and non-industry stakeholders disagreed on the appropriateness of the scope of parties subject to the MAIF Agreement**

Among stakeholders who considered the current scope of parties to be inappropriate, there was a broad view that the scope should be expanded to include retailers (supermarkets and pharmacies), who were perceived to engage in regular product marketing and advertising through price discounting. Broadly, signatories, representatives of the infant formula and retail industries, and some consumers did not support the view that the scope of parties should be extended to include retailers. Signatories suggested that they held their retailers responsible for complying with the MAIF Agreement by ensuring retailers are aware of restrictions under the MAIF Agreement. In relation to the inclusion of distributors, the Review team heard that they should be included in the regulation of infant formula marketing, though little evidence was provided relating to perceived inappropriate marketing by distributors.

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<sup>8</sup> The Review team notes that this research was funded by the Infant Nutrition Council.





In relation to healthcare providers, some non-industry stakeholders expressed the view that the MAIF Agreement should be broadened to provide further prohibitions on engagement by infant formula companies with healthcare providers. In contrast, industry stakeholders highlighted the risks associated with expanding the scope of the MAIF Agreement to include a full prohibition on engagement with healthcare providers, given perceptions that the MAIF Agreement already limits education and information sharing about infant formula.

#### **4.3.3.4 The MAIF Agreement should be updated to reflect the evolution of electronic marketing practices**

Approximately two-thirds of survey respondents did not consider the scope of advertising and marketing provisions covered by the MAIF Agreement to be appropriate. Consultations revealed a general perception among non-industry stakeholders that the MAIF Agreement has not kept pace with the evolution of marketing practices. Concerns were raised about the growth of 'digital influencers' and the challenges with monitoring targeted advertising and information that is posted on a social media platform '24-hour feed'. Stakeholders suggested that marketing provisions in the MAIF Agreement should be updated to ensure parity and encapsulate all digital media.

While industry representatives acknowledged that digital and social media marketing has evolved since the implementation of the MAIF Agreement, they suggested that the core provisions of the MAIF Agreement are sufficiently broad to cover the wide range of modern advertising and marketing formats. In addition, the MAIF Complaints Committee's [Guidance document for interpretation of the MAIF Agreement – Electronic media](#) provides guidance and helps to guard against inappropriate marketing in this domain. Accordingly, industry representatives perceived that the current marketing provisions are appropriate, with no need for scope expansion.

Further, some consumers/members of the public stated that formula-feeding should be normalised, and more product information should be made available on social media to support more informed decision-making about infant nutrition.

The Review received details of several tools for monitoring online marketing that may be able to be utilised for monitoring the marketing of infant formula in Australia, including:

- NetCode toolkit (WHO UNICEF, 2017), which provides protocols for an ongoing monitoring system for enforcement of the WHO Code (and other related agreements and regulations)
- the Corporate Accountability Tool and Communications Hub developed by the organisation FHI Solutions (FHI Solutions, 2022), which has demonstrated success in monitoring breaches of the WHO Code on digital platforms
- the Virtual Violations Detector (VIVID) (FHI Solutions, 2022), which uses automated artificial intelligence and supervised machine learning to detect advertising violations of the WHO Code on digital platforms.

## 4.4 Are the MAIF Agreement processes appropriate?

This section describes the current MAIF Agreement processes, including the operation of the MAIF Complaints Committee and its membership, the complaints process, and enforcement mechanisms and outcomes.

Regulation of infant formula marketing should be supported by an efficient, transparent, robust complaints mechanism that is able to reach decisions and publish them in a timely manner. Improvements should be made to the accessibility and public awareness of the complaints process, and to the timeliness of complaints management and publication of complaints. Complaints assessment should be managed by a party or parties with the appropriate level and types of technical expertise, and should be independent of industry influence.

### 4.4.1 Background

#### 4.4.1.1 Overview of the MAIF Complaints Committee and complaints process

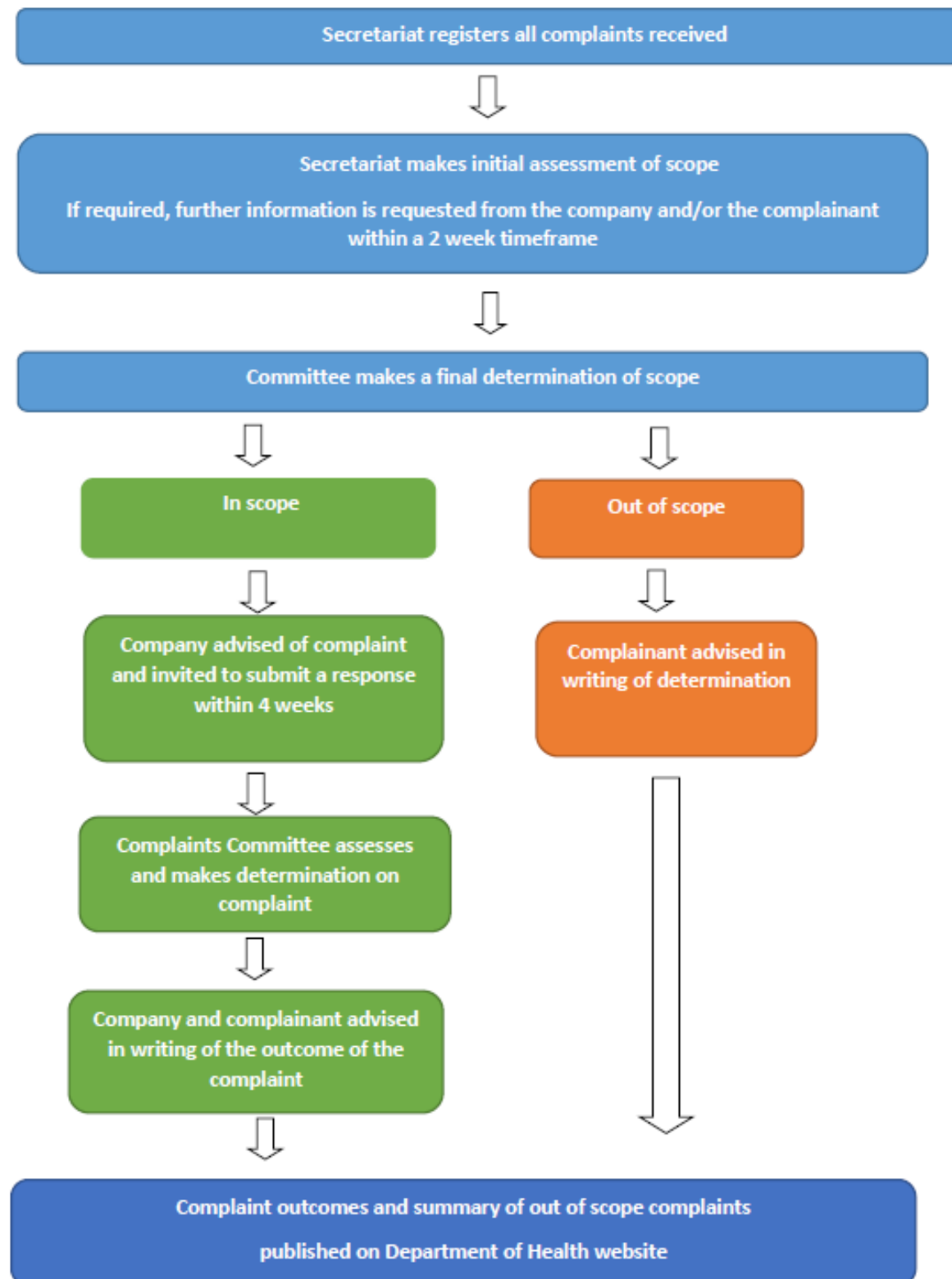
The MAIF Complaints Committee was established in its current form in 2018 and is responsible for receiving and investigating complaints made against organisations who have signed the MAIF Agreement. Previously, complaints were processed by the Department's APMAIF, before being overseen by an independent body, the Ethics Centre, between 2014-2017.

The MAIF Complaints Committee consists of three members, appointed by the Department of Health and Aged Care: an independent representative, a public health representative, and an infant formula industry representative.

Complaints about inappropriate marketing of infant formula can be made by members of the public through a [complaint form](#), downloadable from the Department of Health and Aged Care website, and submitted by email or post to the MAIF Complaints Committee Secretariat.

All complaints are then sent to the MAIF Complaints Committee for review, following the process outlined in **Figure 9** below. If a complaint is in scope, the relevant company will be advised of the complaint and invited to submit a response within four weeks. The MAIF Complaints Committee then determines whether the complaint is in breach of the MAIF Agreement, and the company is advised in writing of the outcome. Complaint outcomes are published on the Department of Health and Aged Care's website and in annual reports.

**Figure 9: MAIF Agreement complaints process (Department of Health and Aged Care, 2022)**

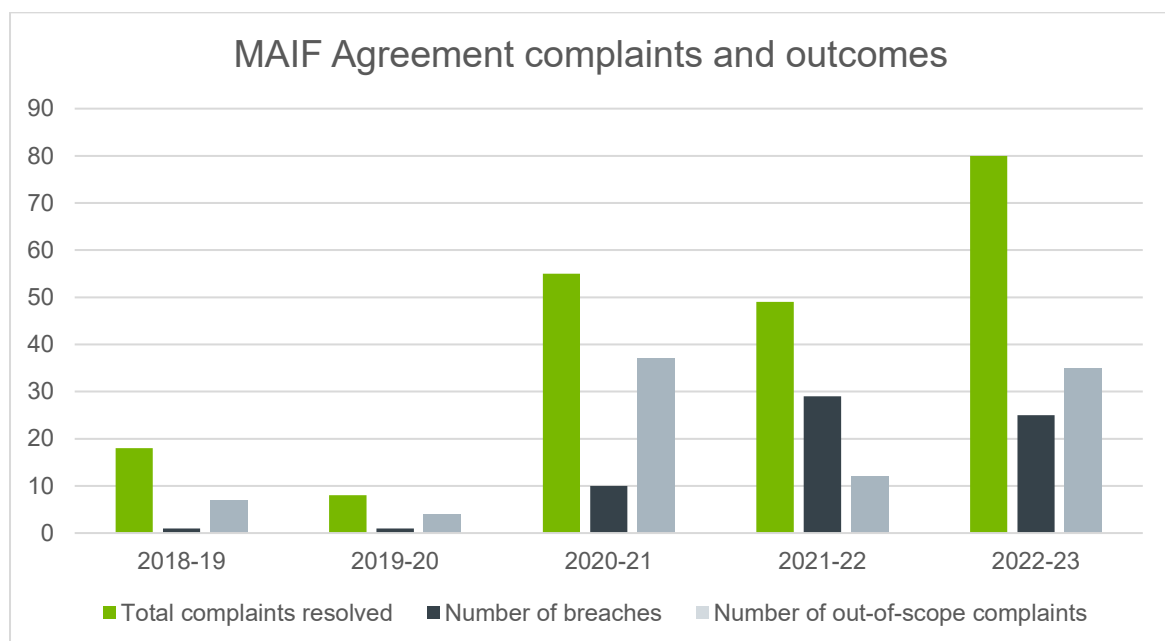


#### 4.4.1.2 Nature of MAIF Agreement complaints and outcomes

As **Figure 10** details, in the 2018-19 and 2019-20 financial years a total of 26 complaints were resolved. Of these, 11 were deemed out of scope and only 2 complaints were found to constitute breaches. The number of complaints resolved has increased significantly from 2020-21 onwards. A total of 104 complaints were resolved during 2020-21 and 2021-22, of which 39 constituted breaches. In 2022-23, 80 complaints were resolved, of which 25 constituted breaches.

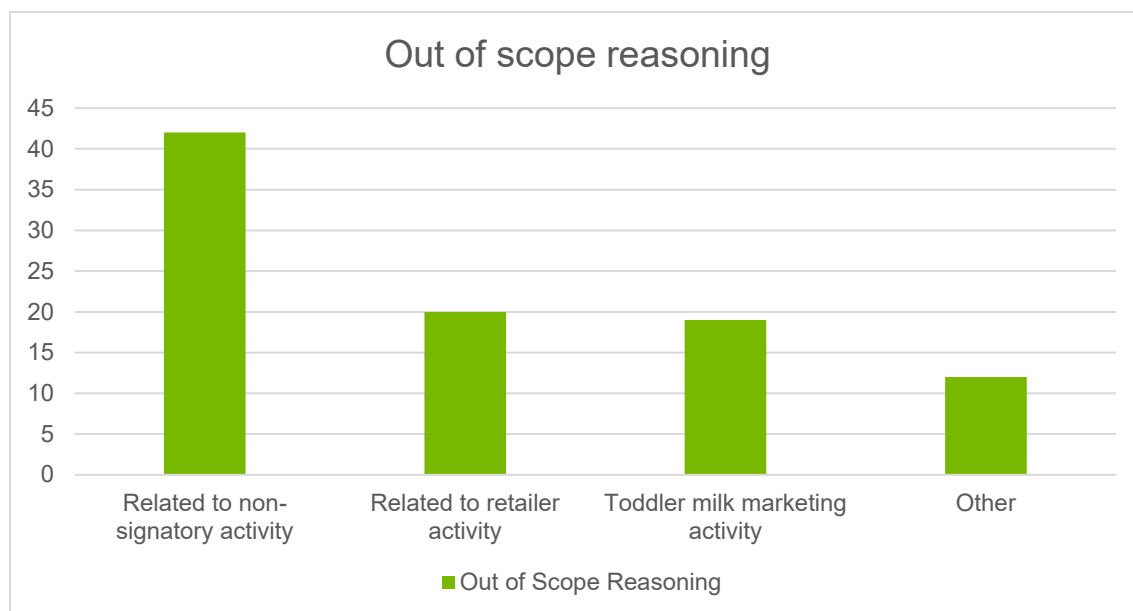
As **Figure 11** and **Figure 12** illustrate, over the period 2018-2019 to 2022-23 a total of 93 complaints were deemed to be out of scope. The primary reasons for complaints being out of scope included that they related to the activities of non-signatories (n=42) or retailers (n=20), or involved the promotion of toddler milks (n=19).<sup>9</sup>

**Figure 10: MAIF Agreement complaints and outcomes 2018-19 – 2022-23**

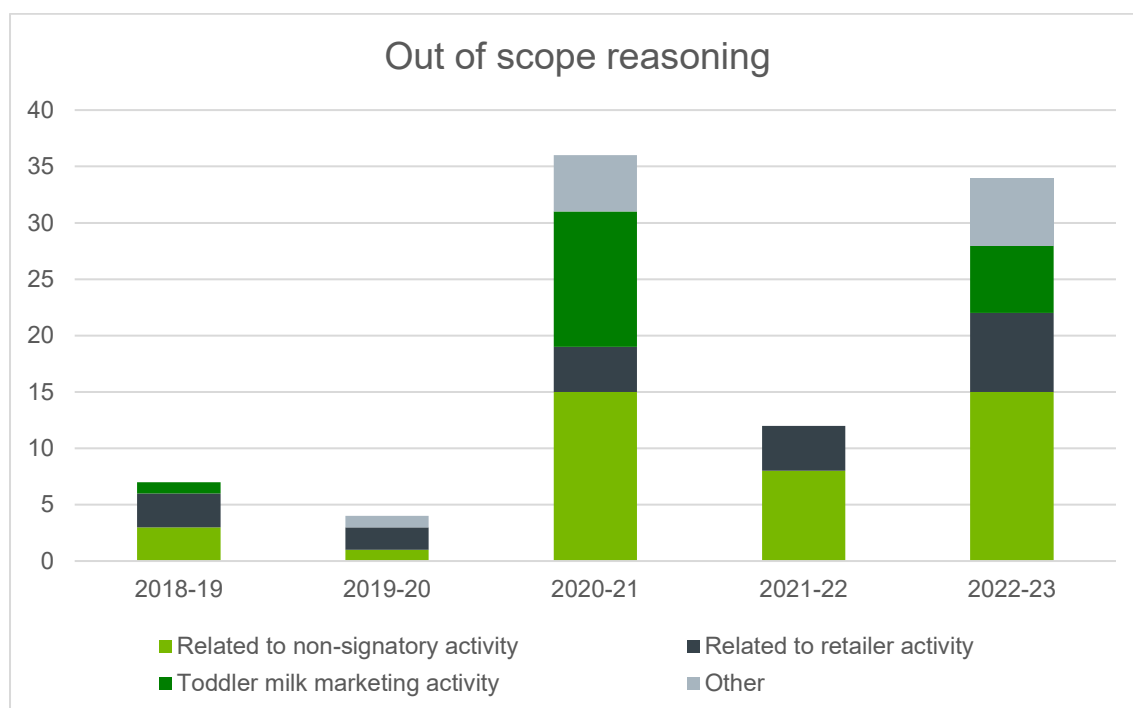


<sup>9</sup> This section is based on published MAIF Agreement Complaints Committee Annual Reports for 2018-19, 2019-20, and 2020-21, and unpublished complaints data for 2021-2022 and 2022-23 provided to Allen + Clarke by the Department of Health and Aged Care.

**Figure 11: Out of scope MAIF Agreement complaints by reason (2018-19 – 2022-23)**



**Figure 12: Out of scope MAIF Agreement complaints by year (2018-19 – 2022-23)**



#### 4.4.2 Concerns with the complaints process

There are significant deficiencies in the processes supporting implementation of the MAIF Agreement, particularly in relation to the management of complaints. These deficiencies have been consistently raised in previous reviews and by stakeholders, and little appears to have been done to improve these processes. Given the deficiencies detailed below in the current complaints process and the likelihood that the number of complaints does not equate to the total number of instances of marketing of infant formula, complaints data are also not a reliable guide to the extent of breaches to the MAIF Agreement and the effectiveness of the regulation.

Whether the MAIF Agreement continues as a voluntary self-regulated instrument, or a stronger regulatory model is adopted, significant improvements are needed to the complaints management process to achieve an efficient and effective regulatory environment that has broad public support and confidence.

#### 4.4.2.1 Independence and representativeness

The INC currently holds one of the three positions on the MAIF Complaints Committee. This has drawn criticism (from non-industry stakeholders) and support (from MAIF signatories and industry representatives).

Recommendation 6 of the WHO guidance on ending the inappropriate promotion of foods for infants and young children is ‘avoidance of conflict of interest’ (WHO, 2022). In its re-authorisation of the MAIF Agreement, the ACCC noted that in relation to the effectiveness of voluntary industry codes, it is important to have a review process which is independent of industry interests (ACCC, 2021). The ACCC presented data suggesting that:

*during the period when there was no industry representative on the complaints panel (that is, while the Tribunal was operated by the Ethics Centre 2014–2017) there was a significantly higher percentage of complaints found to be breaches compared to the years before and immediately after that period (ACCC, 2021, p. 28).*

The ACCC concluded that while having two independent members on the panel reduces the risk of industry involvement in decision making, it also reduces the robustness of the complaints processes, and the risk would be lower if all members were independent. The ACCC also commented that if industry expertise was required by the Committee, the Committee could seek further advice. *‘It is not necessary for one of the decision makers on the Committee to be an industry representative’* (ACCC, 2021).

On the other hand, industry representatives and MAIF signatories have suggested that it is important to have an industry representative on the Committee who has a practical understanding of the infant formula market. Furthermore, the established processes of having members declare their potential conflicts of interest on the Department website, and having two other Committee members who are not industry representatives serve to reduce the risk of undue industry involvement in decision making.

#### 4.4.2.2 Transparency and timeliness

Since the MAIF Agreement complaints process relies primarily on complaints being made by members of the public, and the consequences of any breaches being the risk of reputational damage for infant formula companies, transparency and timeliness are important elements of an appropriate and effective complaints process.

*In this context, it is important that breach findings are publicised in a timely and effective manner, that the process of the Committee in assessing complaints is robust, impartial, and transparent, and that the public is aware of and easily able to access and contribute to the complaints process. (ACCC, 2021)*

Concerns around transparency and timely reporting of complaints process outcomes and identified breaches of the MAIF Agreement were raised as part of the 2017 Complaints Handling Process Review (Nous Group, 2018), and again in the ACCC re-authorisation of the MAIF Agreement (ACCC, 2021). In its re-authorisation determination, the ACCC



expressed concern about the timeliness of the publication of complaints stating, '*publication does not appear to happen shortly after decisions are finalised but rather some months afterwards...decisions are not published until more than 12 months after the initial complaint is lodged*' (ACCC, 2021).

#### 4.4.2.3 Consequences for breaching the MAIF Agreement

The 2017 Complaints Handling Process Review identified that the potential for reputational damage was the only external consequence for breach of the MAIF Agreement (Nous Group, 2018, p. 23). The limited level of consequences faced with potential breaches of the MAIF Agreement remains one of its key criticisms (Thatcher, F, 2022), with the MAIF Agreement being called a 'Toothless Tiger' (Daniel, D, 2022).

### 4.4.3 Consultation findings

The current Review's consultation process sought feedback on whether the MAIF Agreement processes are appropriate, and further explored the issues of independence, transparency, and timeliness. A summary of the consultation findings in relation to this KRQ is provided below. For more detailed information please refer to the MAIF Review Consultation Report.

#### 4.4.3.1 Non-industry and industry stakeholders hold divergent views on whether current MAIF Agreement processes are appropriate, but both agree that the processes could be improved

In stakeholder interviews and focus groups, views expressed about the appropriateness of MAIF processes were predominantly negative, with a widespread perception that the current processes require improvement. Furthermore, the consultation survey showed that at least a third (34%) of the 443 survey respondents (most of whom were non-industry stakeholders) disagreed or strongly disagreed that the MAIF Agreement complaints processes are appropriate.

The key reasons given for this response were:

- a lack of enforcement and consequences
- a lack of visibility and transparency
- a lack of independence and adequate representation on the committee
- many of the complaints are considered out of scope
- the complaints process is too complex and onerous
- the complaints process is too slow.

In contrast, among the 23 industry stakeholders who completed the survey, 60% agreed or strongly agreed that the MAIF Agreement complaints processes are appropriate. In their supporting comments, a major theme was that there is a high level of compliance amongst signatories, which demonstrates the overall effectiveness of the MAIF Agreement and its processes. Some industry stakeholders expressed a view that it is newer or smaller



organisations and those who are not members of the INC who demonstrate more frequent non-compliance, and it was suggested that there is a need for more education and guidance for newer market entrants. Furthermore, industry stakeholders reported that compliance with the MAIF Agreement is often achieved through other mechanisms, including internal compliance audits and INC-led complaints investigations.

There was also a general view among industry stakeholders that there is room for improvement in relation to timeliness, transparency of processes and decision-making, and communication of outcomes.

#### **4.4.3.2 The complaints process is not administered in a timely manner**

Stakeholders expressed concerns about the timeliness of the complaints process, including decision-making and reporting of outcomes by the MAIF Complaints Committee.

Among survey respondents, 20.3% disagreed or strongly disagreed that the complaints process is administered in a timely manner. In general, stakeholder feedback indicated that the complaints process can take several months (and up to a year in some cases) from when a complaint is made, to when a determination is reached and the outcome reported, with many describing it as 'inadequate and unacceptable'.

Interview and focus group discussions identified several factors that contribute to delays in complaints management. These included that the MAIF Complaints Committee is reliant on volunteers rather than full time staff, only meets once every three months, and is impacted by turnover of staff in the secretariat at the Department of Health and Aged Care. There was concern that fatigue and a lack of confidence in the process may lead to members of the public deciding not to make complaints.

#### **4.4.3.3 Visibility, accessibility and transparency of the complaints process could be improved**

Only a small proportion of survey respondents (13.8%) agreed or strongly agreed that the complaints process is adequately transparent.

Non-industry stakeholder feedback indicated that concerns around the lack of transparency included that the process is too industry-focused and not sufficiently visible or accessible to the general public, despite being reliant on public engagement to be effective. Furthermore, there is an absence of sufficient information communicated to complainants and the companies against whom a complaint is made, with regards to how the MAIF Complaints Committee's decision was made, and who was involved. Finally, it was felt that there is also an absence of sufficient information in reporting of complaints outcomes and any actions taken.

In contrast, many industry stakeholders were of the opinion that the complaints process is sufficiently transparent, given that all of the necessary information is made available on the Department of Health and Aged Care's website. However, several suggestions for improvements were made, including greater transparency on:

- the nature and origin of complaints made



- the process for decision-making, including interpretation, who was involved, and any expert advice considered
- complaints that were received but determined to be out of scope
- the information accessible to the public on the nature of breaches, as well as the penalties and outcomes of such breaches.

#### **4.4.3.4 The size and composition of the MAIF Complaints Committee should be changed to ensure effectiveness and impartiality**

Only 15.1% of survey respondents agreed or strongly agreed that the complaints process is sufficiently independent. Survey responses indicated that having an industry representative on the MAIF Complaints Committee represents a clear conflict of interest, and that industry has too much involvement and influence overall for the process to be truly independent. Furthermore, the size and make-up of the committee, as well as the lack of transparency of the MAIF Complaints Committee and processes, limit the degree to which independence is possible.

In general, industry representatives and MAIF signatories felt that the current structure of three independent committee members representing different voices is well-balanced and effective. However, some also suggested that broader representation of stakeholder groups and expertise on the MAIF Complaints Committee would enhance its independence and effectiveness. Some stakeholders expressed the view that the MAIF Complaints Committee should be expanded to include additional members (up to a total of five) who would represent all groups (e.g., industry, public health, advocacy groups, and consumers) or bring particular expertise to the committee (e.g., legal, marketing, and communications).

#### **4.4.3.5 Enforcement mechanisms and consequences for breaches are considered to be too weak by many stakeholders, resulting in reduced compliance**

The question of whether publication of breaches of the MAIF Agreement is an appropriate enforcement mechanism received a mixed response from stakeholders. Many considered the current consequences to be too weak and that stronger penalties are needed.

The survey results in response to this question were mixed, with one quarter (25.7%) of respondents agreeing and just over one-third (35%) disagreeing that the publication of breaches of the MAIF Agreement is an appropriate enforcement mechanism.

In interviews and focus groups, industry stakeholders generally felt that the approach of publishing breaches is appropriate as it has several flow-on effects for companies within the industry that reinforce its strength as a deterrent including negative media attention, reputational damage, impact on sales, and customer base.

In contrast, a broad group of stakeholders including State and Territory Health Department representatives, health sector agencies, and breastfeeding advocates called for stronger penalties to be introduced. This was reiterated by members of the MAIF Complaints



Committee itself who felt that the enforcement powers could be strengthened by adding fines for companies who have repeated breaches.

## 4.5 What are the benefits, costs, and any limitations of changes and expansion of the MAIF Agreement scope, alternative regulatory models and MAIF Agreement processes?

### 4.5.1 Background

Changes in the MAIF Agreement's scope, processes, or regulatory model would be accompanied by both costs and benefits. The relative weighting of these costs and benefits is an important consideration in determining whether action should be taken to enhance the MAIF Agreement and regulatory environment.

Increases in the MAIF Agreement's scope or included parties would be accompanied by increased regulatory burden. The desired regulatory outcomes of the changes to the MAIF Agreement would need to be balanced against the potential regulatory costs imposed on businesses, community organisations, and individuals. The following types of regulatory costs would need to be considered in applying the Regulatory Burden Measurement Framework (Office of Best Practice Regulation, 2020):

- Compliance costs, including:
  - administrative costs incurred by regulated entities primarily to demonstrate compliance with the regulation (including record keeping and reporting costs)
  - substantive compliance costs including costs incurred to deliver the regulated outcomes being sought.
- Application and approval delay costs, including expenses and loss of income incurred by a regulated entity

The following costs are excluded from the Regulatory Burden Measurement framework and do not need to be considered when quantifying regulatory burden. However, depending on the significance of the impacts, they can be analysed in a regulatory impact assessment so the decision maker can understand the impacts:

- Opportunity costs that cannot be realised because of the changes to the regulation
- Non-compliance and enforcement costs. This could include costs such as fines for failing to comply with a regulation, or costs incurred by businesses that fail to comply with government requirements and action is required by the business to ensure compliance
- Regulatory impacts associated with the administration of court and tribunals
- Indirect costs, including changes to market structure and competition impacts
- Direct financial costs (Department of Health and Aged Care, 2020).

In re-authorising the MAIF Agreement in 2021, the ACCC outlined costs and limitations associated with the MAIF Agreement as it currently stands. These included increased anti-competitiveness, including market entry barriers arising from companies not being able to market their products, increased costs of products, and stifling product innovation/improvement (ACCC, 2021). A consideration in potential changes to the MAIF Agreement or adoption of other regulatory models will be the extent to which the changes exacerbate these existing costs. The ACCC noted that with uncertainty around what the regulatory alternatives to the MAIF Agreement are, it is unclear whether the MAIF Agreement is likely to result in public benefit in the form of reduced compliance costs' when compared with other potential regulatory regimes (ACCC, 2021).

The rest of this section of this Review outlines a variety of costs, benefits and limitations that would be associated with changes to the scope and processes of the MAIF Agreement, and establishment of alternative models. On balance, this Review finds that the benefits of recommended changes would outweigh the costs involved.

## 4.5.2 Breastfeeding rates and marketing of infant formula in Australia

One of the primary aims of the MAIF Agreement is to encourage breastfeeding as the first option for babies. Due to the many social, economic and health factors that influence breastfeeding rates, it is not possible to directly attribute the effectiveness of the MAIF Agreement to breastfeeding rates, or to draw categorical conclusions about the benefits to breastfeeding rates that would be achieved by changes to the regulatory framework.

This Review found that in Australia there is a lack of robust large-scale data relating to breastfeeding rates at the national level. Data from five studies undertaken since 2010 are summarised in [Appendix C](#). National Health Survey data shows breastfeeding rates remained somewhat consistent over the period 2014-2018, with a slight increase in 2020-2021. The recent Australian OzFits study<sup>10</sup> (Netting MJ, et al., 2022) (n=1,140 participants) indicated that 39% of infants exclusively received breastmilk to four months, seemingly an increase from the 27% reported in the Australian Institute for Health and Wellbeing's 2010 Australian National Infant Feeding Survey (ANIFS) (Australian Institute of Health and Welfare, 2011)

Literature suggests that marketing may subtly influence choices '*by shaping perceived social norms concerning alternatives to breastfeeding and creating a distorted view of what is the most 'scientific' or 'optimal food for infants'*' (Thorley, V, 2003), and that '*marketing might take advantage of normal neurological processes to increase the likelihood of consumer 'mistakes'*' (Fehr, E, Rangel, A, 2011). Ultimately, however, the effect of commercial marketing on breastfeeding is difficult to isolate (Berry, 2011).

A 2022 WHO-commissioned multi-country study assessed exposure and experience of formula marketing among women in eight countries (Bangladesh, China, Mexico, Morocco, Nigeria, South Africa, the United Kingdom, and Vietnam). This study indicated that women's

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<sup>10</sup> The Ozfits study was conducted by the South Australian Health and Medical Research Institute, with some funding provided by Nestle Nutrition Institute. Despite partial industry funding, its conflict-of-interest statement says 'Nestlé Nutrition Institute had no role in the design of this study nor in its execution, analyses, interpretation, or decision to submit results'.



exposure to marketing correlated with positive attitudes towards formula milk and negatively impacted breastfeeding practices. The study found that 51% of the 8,528 pregnant and postnatal women surveyed reported seeing or hearing formula milk marketing in the preceding year, and women who reported being exposed to marketing were more likely to think that infant formula was a more nutritious alternative to breastmilk (WHO, 2022).

Three Australian studies undertaken since 2010, and infant formula customer feedback provided to the Review by a MAIF signatory, were reviewed to understand factors that contribute to the cessation of breastfeeding and/or use of infant formula. Findings from these sources are summarised in [Appendix D](#).<sup>11</sup>

In re-authorising the MAIF Agreement in 2021, the ACCC noted that:

- Relying on Australian breastfeeding rates data was unlikely to be useful in its assessment of whether the MAIF Agreement results in public benefit *‘because of the multifactorial influences on breastfeeding rates and individual decisions to start or cease breastfeeding, and the complexity of measuring these within a population’*, and
- It *‘considers the restrictions in the MAIF Agreement are likely to protect and promote breastfeeding to the extent that they effectively limit the marketing of breastmilk substitutes.’* (ACCC, 2021).

### 4.5.3 Stakeholder views on benefits of changes

#### 4.5.3.1 Public health benefits

Literature and advice provided by non-industry stakeholders during consultation for this Review suggests that changes to the MAIF Agreement's scope, processes and regulatory model would result in increased levels of breastfeeding and a broad range of benefits.

As outlined in [Section 2.1.1](#), breastfeeding has many health benefits for babies and mothers. During consultation, stakeholders suggested that increased rates of breastfeeding would have a broad range of public health benefits across the lifespan. Some survey respondents identified short, medium, and long-term health benefits, and detailed a range of health conditions that changes to the MAIF Agreement would directly address.<sup>12</sup> Stakeholders, particularly breastfeeding advocates, commented on the important role of breastfeeding in the food security of infants and young children in the face of natural disasters, emergencies, and climate change.

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<sup>11</sup> This data analysis contained several limitations. While marketing of products was not explicitly mentioned as a factor contributing to altered breastfeeding practices, this may have been due to this not being an option provided in the surveys, and marketing may play a role in other reasons given, including around positive views of infant formula. Questions were not fully standardised across the four studies, and the studies were based on small sample sizes.

<sup>12</sup> Including, *inter alia*, ‘increased IQ’, infections, malocclusions, obesity/overweight, various cancers, cardiovascular diseases, osteoporosis, type 2 diabetes.



#### 4.5.3.2 Economic and financial benefits

Alongside health benefits, breastfeeding has significant economic and wellbeing benefits. According to the Institute for Health Metrics and Evaluation's Global Burden of Disease tool (Institute for Health Metrics and Evaluation, 2019), nutritional deficiencies for infants cost 87.6 disability adjusted life year (DALYs) per 100,000 people. A UK study found that increasing the percentage of mothers who exclusively breastfeed until their infant is four months old could reduce the incidence of gastrointestinal infection, lower respiratory tract infection and acute otitis media in infants and save at least £11 million annually (Pokhrel, 2015).

Stakeholders highlighted a range of economic and financial benefits that would arise from strengthening the regulation of infant formula. Several stakeholders cited estimates that \$US341.3 billion is lost globally per year from unrealised benefits to health and human development because of inadequate investment in protecting, promoting, and supporting breastfeeding (Walters et al, 2019). Stakeholders highlighted the benefits that would arise from reduced burden on Australia's health system.

Stakeholders described the monitoring and enforcement costs currently borne by non-government organisations (NGOs) and members of the public, and described that these costs sit overwhelmingly with women. *'The cost burden of monitoring is highly gendered'*. One academic stakeholder described that *'If public regulation were put in place, it would massively reduce the monitoring and enforcement costs of NGOs and members of the public, and put these costs where they belong, on industry and on government.'*

Some stakeholders outlined the benefit families would receive from purchasing less infant formula, with one breastfeeding advocate highlighting the benefit of *'parents not wasting money on all the different formulas.'*

#### 4.5.3.3 Support achievement of Australian Government priorities

Stakeholders stated that strengthening the regulation of marketing of infant formula would support delivery of key national policies and strategies, including the Australian National Breastfeeding Strategy: 2019 and Beyond, the Infant Feeding Guidelines, National Obesity Strategy (2022 – 2032), and the Early Years Strategy.

#### 4.5.3.4 Promoting and protecting the rights of women and children

Over 20 survey respondents highlighted that by strengthening the MAIF Agreement, Australia would more effectively protect the rights of women and children, and uphold obligations under international law. Stakeholders highlighted Australia's obligations as a signatory to the United Nations Convention on the Rights of the Child. These obligations are further discussed in [Section 2.2](#).

#### 4.5.3.5 Improved industry-wide compliance

As outlined in [Section 4.2.2](#), stakeholders indicated that a benefit of strengthening the regulation of infant formula marketing would be creating a 'level playing field' among infant formulas manufacturers. Some MAIF Agreement signatories suggested they did not oppose making the MAIF Agreement mandatory for all infant formula manufacturers – they expressed support for the MAIF Agreement and that they have effective internal monitoring and compliance measures, and that they would welcome a more level playing field in relation to marketing restrictions.

#### 4.5.3.6 Environmental benefits

Advocates and academic stakeholders described that the manufacture of infant formula may have negative impacts on the environment, and that reducing the use of infant formula in Australia through further restrictions on marketing would likely provide benefits to the environment. Potential benefits cited included reduced electricity use, water use, CO<sub>2</sub> emissions, and waste associated with packaging. Stakeholders cited published materials in relation to the environmental impacts of infant formula, including an Editorial from the British Medical Journal in 2019 which suggested that 'The production of unnecessary infant and toddler formulas exacerbates environmental damage and should be a matter of increasing global concern.' (Shenker, N, 2019).

#### 4.5.3.7 Consumer benefits

A common theme during consultations was the need for better information to be available for consumers about infant formula products. Changes to labelling, and enhanced availability of information to medical professionals and consumers through other mechanisms, would support the ability of consumers to make more informed decisions, and would increase consumer confidence in the regulation of infant formula products.

There was a strong view among some survey respondents that an approach to labelling and marketing requirements should be adopted to provide a more nuanced view around the important role infant formula plays for some children and families. A more nuanced approach to messaging would provide benefit to consumers including reducing anxiety around breastfeeding and infant formula use and reducing perceived social stigma.

Several survey respondents and interview participants outlined challenges experienced by multiple birth families, and benefits they would experience if changes were made to the MAIF Agreement which enhanced access to information relating to products and pricing. Survey respondents highlighted that multiple birth families can experience challenges with breastfeeding multiple infants, and the need for infant formula to supplement or take the place of breastfeeding. Survey respondents also highlighted the burden of increased costs associated with having multiple birth children, and that better access to information about price discounting and donations of infant formula products would be beneficial for multiple birth families.

### 4.5.4 Costs

A diverse range of views were heard during consultation around costs that would be associated with changes to the MAIF Agreement scope, processes, and regulatory model. Costs would be incurred by the Australian Government, by the infant formula industry, and by consumers.

#### 4.5.4.1 Costs to government

Stakeholders consistently cited the costs to government that would be associated with changes to the MAIF Agreement or the regulatory model. Stakeholders also stated that changes to the MAIF Agreement or regulatory environment would likely also generate monitoring costs for Government. Several stakeholders suggested that the benefits of changes would significantly outweigh the cost of changes. Financial costs are estimated in [Section 4.5.6](#) below.



Stakeholders suggested that the Australian Government should consider cost recovery mechanisms for costs associated with changes to the MAIF Agreement.

*We need mechanisms for it to pay for itself. Whether that is increasing fines or licensing fees or something. How can we make this a cost-effective strategy?*

- State/Territory Health Department representative, focus group participant

#### 4.5.4.2 Costs to industry

The consultation process heard a range of views about the costs to industry of changes to the MAIF Agreement or the regulatory model. Several signatories suggested there would be minimal cost to them if the MAIF Agreement was made mandatory, assuming this was not accompanied by changes to scope of products. The Review team was informed that the larger companies have existing internal policies and processes that 'go beyond' the requirements on the MAIF Agreement. A non-signatory suggested though that the burden of increased regulation would fall more strongly on smaller companies.

If changes needed to be made to product labelling, there may be significant costs associated. One signatory suggested that if there were changes to labelling *'that would be a nightmare. There needs to be a grace period. The impact on cost of packaging etc.'* Another suggested that *'any label change is expensive. Lead times, running out existing products etc is expensive.'*

#### 4.5.4.3 Costs to consumers

A number of industry stakeholders suggested that extra costs borne by manufacturers arising from regulatory changes would lead to increased costs being passed on to infant formula consumers. One signatory suggested that *'Formulas also have complex ingredients and are getting more expensive anyway so to add costs to that would impact families'* while another indicated that increased regulation *'will drive costs into these products. It won't deter people from using them. Adding on a layer of cost to this category has a wide impact on families.'*

Several industry stakeholders expressed concerns that changes to the scope or processes of the MAIF Agreement may result in reduced research, innovation, and competition within the infant formula industry, and that this would be detrimental to consumers. The Review heard that if regulatory changes reduced the ability of manufacturers to communicate with the Australian public about the features and benefits of their products, there would be reduced incentive for developing innovative products.

This was particularly the case in relation to potentially including toddler milk drinks within the scope of the MAIF Agreement, and to tightening restrictions on communication with healthcare practitioners in the MAIF Agreement. Signatories described that *'we cannot communicate about toddler milks, there will be reduction in investment we do in research and education, as a consequence, innovation will be very limited'* and suggested that *'there would be limitations to the right to good nutrition for infants and carers who cannot use breastmilk as their sole source of nutrition.'*

Several industry stakeholders and consumers/members of the public highlighted costs associated with further reducing available information about infant formula products, including the importance of consumers being able to make an informed choice and the potential *'influx of misinformation.'*



#### 4.5.4.4 Costs versus benefits

Many non-industry stakeholders expressed the view that the benefits (and particularly the public health benefits) of changes to the MAIF Agreement or the regulatory framework would far outweigh the costs involved. One academic stakeholder suggested that the costs of implementing stronger regulation would be outweighed by the benefits such changes would generate, and that *'In considering costs of regulation, the lifetime health costs of not regulating must be considered.'*

On the other hand, several industry and non-industry stakeholders suggested that the costs of changes would be better spent on other investments to support improvements in breastfeeding rates or to support the mental health of parents.

#### 4.5.5 Summary of costs and benefits by regulatory option

**Table 7** summarises the benefits and costs for each regulatory option, having regard to the Office of Impact Analysis' five impact considerations - social, competition, environmental, distributional and regulatory (The Office of Impact Analysis, 2023).

**Table 7: Benefits and costs of regulatory alternatives**

Regulatory model	Benefits	Costs
Option 1 – Status quo	<ul style="list-style-type: none"> <li>No costs associated with development of new regulatory model</li> <li>No increase to regulatory compliance costs</li> <li>Provides industry certainty</li> <li>Industry confidence in the MAIF Agreement is high</li> <li>Still ensures appropriate information is available for caregivers to make an informed choice</li> </ul>	<ul style="list-style-type: none"> <li>Does not include all suppliers</li> <li>Confidence of non-industry stakeholders is low</li> <li>Potential health impacts for babies if inappropriate marketing impacts breastfeeding</li> <li>Anti-competitive</li> </ul>
Option 2 – MAIF Agreement, with enhancements (quasi-regulation)	<ul style="list-style-type: none"> <li>More efficient and effective complaints handling</li> <li>Improved transparency and some improvements to stakeholder confidence</li> <li>Still ensures appropriate information is available for caregivers to make an informed choice</li> </ul>	<ul style="list-style-type: none"> <li>Increases administration costs</li> <li>Does not include all manufacturers and importers</li> <li>Potential health impacts for babies if inappropriate marketing impacts breastfeeding</li> <li>Anti-competitive</li> </ul>
Option 3 – Prescribed voluntary code (co-regulation)	<ul style="list-style-type: none"> <li>Enforced by government</li> </ul>	<ul style="list-style-type: none"> <li>Increased administration costs</li> </ul>

Regulatory model	Benefits	Costs
	Enhance deterrence of non-compliance through more enforcement options Improved stakeholder confidence Improved transparency	Increased industry regulatory costs, potentially leading to higher infant formula prices At least two years to develop More anti-competitive Does not include all manufacturers and importers Potential health impacts if marketing impacts breastfeeding
Option 4 – Prescribed mandatory code (statutory regulation)	All manufacturers and importers regulated (and potentially expand to other marketers including retailers) Enforced by government Improved non-industry stakeholder confidence Potentially improved health outcomes	Increases administration costs. At least two years to develop Raises industry regulatory costs, potentially leading to high infant formula prices Anti-competitive

## 4.5.6 Economic analysis

### 4.5.6.1 Overview

This section provides an overview of cost effectiveness analysis of three levels of potential policy changes: changes to the MAIF Complaints Committee processes and membership; expanding the scope of regulated parties and products; and developing regulation. This section also provides a description of the cost estimation method and key assumptions, Monte Carlo risk analysis, and cost effectiveness analysis which estimates the scale of impact required to justify the scale of costs estimated here. The complete economic analysis is provided in [Appendix E](#).

The three options are outlined below.

#### 1. Changes to MAIF Complaints Committee processes and membership

- Expanding the MAIF Complaints Committee from three to five members.
- Increasing the number of MAIF Complaints Committee meetings from four to six meetings per year.
- Increasing MAIF Complaints Committee secretariat capabilities at the Department of Health and Aged Care.
- Establishing a function for monitoring regulatory breaches at the Department of Health and Aged Care.

- Further development of the MAIF Agreement website to enhance publication of MAIF Complaints Committee activities and findings.

## 2. Expand the scope of regulated parties and products

- Extend the scope of regulation (whether under the existing voluntary arrangements, or in a future mandatory regulatory model) to include toddler milk drinks.
- Extend the scope of parties to include retailers, including supermarkets and pharmacies.

## 3. Develop a stronger regulatory framework

- Develop a mandatory regulatory model backed by legislation, monitoring and sanctions for breaches

### 4.5.6.2 Analysis

The summary results of cost estimates are presented in **Table 8**, which indicates that implementation and maintenance costs are expected to increase as one moves from process to scope and then to regulatory options.

Estimates provided in **Tables 8** and **9** reflect the anticipated direct incidence of costs. The key purpose of these policy costing exercises is to estimate the expected costs from a national perspective. Which entity would ultimately bear the costs would depend on a multitude of policy and implementation considerations.

The breakdown of costs outlined in **Tables 8** and **9** is estimated as follows:

- Option 1 (process enhancements) – 100% of costs borne by Government
- Option 2 (scope expansion) – 97% of costs borne by industry, 3% of costs borne by Government
- Option 3 (regulatory change) – 20% of cost borne by Government, 80% of cost borne by industry

**Table 8: Central estimates of costs associated with adjustments to Infant formula marketing regulations, \$ million**

Option	Set up costs	Ongoing costs	10-year present value
<b>Changes to Complaints Committee processes and membership</b>	0.8	0.6	4.9
<b>Expand scope of regulated parties and products</b>			
Extend to toddler milk drinks	6.3	2.1	21.8
Increase scope of regulated parties	8.6	4.3	39.5
Combined	14.9	6.4	61.3
<b>Develop stronger regulation</b>	40.8	10.4	115.5

Given the inevitable uncertainties around the estimates presented in this report, this Review supplements analysis using Monte Carlo risk-analysis techniques to provide information about the potential range of costs associated with each option. The summary results from the Monte Carlo analysis are presented in **Table 9**.

**Table 9: 95% confidence range of 10-year net present value estimates resulting from Monte Carlo analysis, \$ million<sup>13</sup>**

Option	Central	Low	High
<b>Changes to Complaints Committee processes and membership</b>	4.9	2.4	8.7
<b>Expand scope of regulated parties and products</b>			
Extend to toddler milk drinks	21.8	8.5	45.6
Increase scope of regulated parties	39.5	13.3	86.7
Combined	61.3	27.7	114.8

<sup>13</sup> For Table 8 and subsequent estimates of 'low', 'central' and 'high' the following definitions apply. 'Low' and 'high' present the lower and upper bounds of the 95% confidence range of the Monte Carlo analysis. The 'central' estimates are the results of calculations based on the central assumptions, as presented in the column headed Central assumptions in Table E1: Assumptions underpinning the calculations included in the Monte Carlo Analysis.



Option	Central	Low	High
<b>Develop stronger regulation</b>	115.6	58.1	211.0

The analysis does not attempt to attribute an improvement in breastfeeding rates expected from any of the policy options costed. This reflects two factors:

- The impact of any policy will depend on specific design factors that have not been yet considered.
- Uncertainties relating to the role of marketing of infant formula on breastfeeding rates.

However, the cost effectiveness analysis presents estimates of the scale of increase in breast feeding rates that would be required to justify the estimated costs for each option. These estimates are based on reduced impacts associated with a narrow range of public health benefits, and not the whole range of benefits that would be associated with increases in breastfeeding. Accordingly, the scale of breastfeeding rate improvements identified as necessary to justify the estimated costs is likely to be only a portion of the actual benefits that would arise.

These estimates range from:

- A 0.3 percentage point required increase in breastfeeding rates for the improvements to complaints management processes in Option 1 (with a low/high range from 0.1 to 0.5 percentage points)
- 3.7 (1.6 to 7.1) percentage points for changes to the regulatory scope
- 7.0 (3.4 to 13.1) percentage points for enhanced regulation.

## 5.0 CONCLUSION

This Review provides recommendations which, if implemented, would strengthen the regulation of infant formula marketing in Australia and would be expected to generate significant public health and economic benefits.

The Australian Government should develop a stronger regulatory framework to restrict the inappropriate marketing of infant formula in Australia. The policy and marketing environment in Australia has changed significantly since the MAIF Agreement was established in 1992. The voluntary, self-regulatory nature of the MAIF Agreement is no longer an appropriate response to address the marketing of infant formula in Australia, given the evolution of digital marketing practices and the need to improve breastfeeding rates. This Review has also heard views from some MAIF Agreement signatories supporting the development of mandatory regulation that applies across the whole industry – not just to companies that voluntarily sign the MAIF Agreement.

This Review has identified significant weaknesses in the MAIF Agreement's processes. These undermine the effectiveness of, and public confidence in, the regulation of infant formula marketing. Placing the burden of monitoring on civil society and members of the public is not fit-for-purpose, and this model should be revised to support strengthened regulation. This Review also found that the complaints management system does not adequately contribute to an efficient and effective regulatory environment that has broad stakeholder support, and that significant changes are needed to the model.

This Review has not found a compelling rationale for increasing the scope of regulated parties at this point. There remains insufficient evidence regarding the scope and impact of marketing of infant formula by retailers to warrant their inclusion within the scope of regulation. Instead, this Review has found that efforts should be made to increase awareness within the retail industry of the aims of regulation of the marketing of infant formula, and further review should be undertaken into whether the extent and impacts of marketing in retail environments warrant expanding the scope of regulated parties in this space.

This Review has also not found evidence that the potential benefits of expanding the scope of regulated products would justify the costs. The current review being undertaken by FSANZ relating to infant formula regulation may help to address concerns relating to the marketing of toddler milk drinks, and the Department of Health and Aged Care should continue to monitor and respond as needed to these reforms.

## 6.0 APPENDICES

### Appendix A: MAIF Agreement

#### Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement

##### Preamble

This document sets out the obligations of manufacturers in and importers to, Australia of infant formulas and gives effect in Australia to the principles of the *World Health Organization's International Code of Marketing of Breastmilk Substitutes* (WHO Code).<sup>1</sup>

##### Clause 1: Aim

The aim is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breastmilk substitutes, when they are necessary,<sup>2</sup> on the basis of adequate information and through appropriate marketing and distribution. (WHO Code Article 1)

##### Clause 2: Scope

This document applies to the marketing in Australia of infant formulas when such products are marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk. It also applies to their quality and availability, and to information concerning their use. (WHO Code Article 2)

##### Clause 3: Definitions

- (a) 'Breastmilk substitute' - any food marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.
- (b) 'Container' - any form of packaging of infant formulas for sale as a normal retail unit, including wrappers.
- (c) 'Health care system' - governmental, non-governmental or private institutions engaged, directly or indirectly, in health care for mothers, infants and pregnant women and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this document, the health care system does not include pharmacies or other retail outlets.
- (d) 'Health care professional' - a professional or other appropriately trained person working in a component of the health care system, including pharmacists and voluntary workers.
- (e) 'Infant formula' - any food described or sold as an alternative for human milk for the feeding of infants up to the age of twelve months and formulated in accordance with all relevant clauses of the Australia New Zealand Food Standards Code, including Infant Formula Products Standard 2.9.1.

<sup>1</sup> Where applicable, clauses in this document are cross-referenced to the relevant articles from the World Health Organization (1981) *International Code of Marketing of Breast-milk substitutes, Geneva (WHO Code)*.





- (f) 'Label' - any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of infant formulas.
- (g) 'Marketing' - includes the promotion, distribution, selling, advertising, public relations and information services related to infant formulas.
- (h) 'Marketing personnel' - any persons whose functions include the marketing of infant formulas.
- (i) 'Samples' - single or small quantities of an infant formula provided without cost. (WHO Code Article 3)

#### **Clause 4: Information and Education**

- (a) Manufacturers and importers of infant formulas in Australia agree that informational and educational materials, whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women and parents of infants and young children, should always include clear information on all the following points:
  - (i) the benefits and superiority of breastfeeding;
  - (ii) maternal nutrition, and the preparation for and maintenance of breastfeeding;
  - (iii) the negative effect on breastfeeding of introducing partial bottle-feeding;
  - (iv) the difficulty of reversing the decision not to breastfeed; and
  - (v) where needed, the proper use of infant formula, whether manufactured industrially or home prepared. (WHO Code Article 4.2)
- (b) When such materials contain information about the use of infant formulas, they should include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods and, in particular, the health hazards of unnecessary or improper use of infant formulas. Such materials should not use any pictures or text which may idealise the use of infant formulas. (WHO Code Article 4.2)
- (c) Manufacturers and importers of infant formulas should not donate informational or educational equipment or materials unless it is at the request of, and with the written approval of, the appropriate government authority or within guidelines given by the Commonwealth, State or Territory Governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary infant formula, and should be distributed only through the health care system. (WHO Code Article 4d.3)



## **Clause 5: The general public and mothers**

- (a) Manufacturers and importers of infant formulas should not advertise or in any other way promote infant formulas to the general public. (WHO Code Article 5.1)
- (b) Manufacturers and importers of infant formulas should not provide samples of infant formulas to the general public, pregnant women, parents or members of their families. (WHO Code Article 5.2)
- (c) Manufacturers and importers of infant formulas should not distribute to pregnant women, or parents of infants and young children, any gifts of articles or utensils which may promote the use of breastmilk substitutes or bottle-feeding. (WHO Code Article 5.4)
- (d) Marketing personnel, in their business capacity, should not seek direct or indirect contact with pregnant women or with parents of infants and young children. This does not prevent appropriately qualified personnel from responding to complaints or unsolicited requests for information. For these requests, parents should be referred to a health care professional whenever health advice is required. (WHO Code Article 5.5)

## **Clause 6: Health care system**

- (a) Manufacturers and importers of infant formulas should not use any facility of the health care system for the purpose of promoting infant formulas. This does not, however, preclude the dissemination of information to health care professionals as provided in clause 7(a). (WHO Code Article 6.2)
- (b) Manufacturers and importers of infant formulas should be aware that facilities of health care systems should not be used for the display of products within the scope of this document, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in clause 4(c) above. (WHO Code Article 6.3)
- (c) The use by the health care system of pharmacies or retail outlets, 'professional service representatives', 'mothercraft nurses', or similar personnel, provided or paid for by manufacturers or importers of infant formulas is not permitted. (WHO Code Article 6.4)
- (d) Manufacturers and importers of infant formulas should be aware that feeding with infant formulas, whether manufactured or home prepared, should be demonstrated only by health care professionals. Such demonstrations should be made only to the parents or other persons who need to use it, and the information given should include a clear explanation of the hazards of improper use. (WHO Code Article 6.5)
- (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 breastmilk 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. (WHO Code Article 6.6)

- (f) Manufacturers and importers of infant formulas should note that, where donated infant formulas are distributed outside an institution, the institution or organisation should take steps to ensure that these provisions can be continued as long as the infants concerned need them. Donors, as well as the institutions or organisations concerned should bear in mind this responsibility. (WHO Code Article 6.7)
- (g) Equipment and materials, in addition to those referred to in clause 4(c), donated to a health care system may bear a company's name or logo, but should not refer to any proprietary infant formulas. (WHO Code Article 6.8)

## **Clause 7: Health Care Professionals**

- (a) Manufacturers and importers of infant formulas providing information about the formulas to health care professionals should restrict the information to scientific and factual matters. Such information should not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. It should also include the information specified in clause 4(a) above. (WHO Code Article 7.2)
- (b) Manufacturers and importers of infant formulas should provide members of the medical profession and related health care professionals with information about the products, and this information should accurately reflect current knowledge and responsible opinion. Such material should be clearly identified with the name of the manufacturer or importer, the brand names of the infant formulas, and the date of publication.
- (c) Manufacturers and importers of infant formulas should not offer any financial or material inducement to health care professionals or members of their families to promote infant formulas, nor should such inducements be accepted by health care professionals or members of their families. (WHO Code Article 7.3)
- (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. (WHO Code Article 7.4)
- (e) Manufacturers and importers of infant formulas should disclose to institutions, to which a recipient health care professional is affiliated, any contribution made to him/her, or on his/her behalf, for fellowships, study tours, research grants, attendance at professional conferences, or the like. (WHO Code Article 7.5)

**Clause 8: Persons employed by manufacturers and importers**

- (a) In systems of sales incentives for marketing personnel, the volume of sales of infant formulas should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it. (WHO Code Article 8.1)
- (b) Personnel employed in marketing infant formulas should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or parents of infants and young children. This does not prevent such personnel from being used for other functions by the health care system. (WHO Code Article 8.2)

**Clause 9: Quality and Labelling**

- (a) Manufacturers and importers of infant formulas must ensure that infant formulas sold in Australia conform to all relevant clauses of the Australia New Zealand Food Standards Code, including Infant Formula Products Standard 2.9.1. (WHO Code Articles 9.2, 9.4, 10.1 and 10.2)
- (b) Manufacturers and importers of infant formulas must ensure that labels provide the information required to be provided by the Australia New Zealand Food Standards Code Part 1.2 and Infant Formula Products Standard 2.9.1., and also provide the necessary information about the appropriate use of infant formula and should not discourage breastfeeding. (WHO Code Article 9.1)

**Clause 10: Implementation and monitoring**

- (a) Independently of any other measures taken to implement their obligations under this document, each manufacturer and importer of infant formulas should regard itself as responsible for monitoring its marketing practices according to the principles and aim of this document, and for taking steps to ensure that its conduct at every level conforms to those principles and aims. (WHO Code Article 11.3)
- (b) Each manufacturer and importer of infant formulas should apprise its personnel of the existence of this document and of their responsibilities under it.



## Appendix B: List of companies who have signed the MAIF Agreement

- Abbott Australasia Pty Ltd
- Aspen Pharmacare Pty Ltd
- Australian Dairy Nutritionals Limited
- Australian Dairy Park Pty Ltd
- Bellamy's Organic
- H & H Group
- Bega Nutritionals
- The Infant Food Co. Pty Limited
- The LittleOak Company
- Max Biocare
- Nature One Dairy Pty Ltd
- Nestlé Australia Ltd
- Nuchev Limited
- Nutricia Australia Pty Ltd
- Sanulac Nutritionals Australia Pty Ltd
- Spring Sheep Milk Co.
- Sprout Organic
- The a2 Milk Company Ltd



## Appendix C: Data from selected studies on breastfeeding in Australia

Data source	Initiation	Breastfeeding type	At 2 months	At 4 months	At 6 months	At 12 months
<b>ANIFS 2010</b> (Australian Institute of Health and Welfare, 2011)	96%	Any	72.7%	70%	60%	42%
		Exclusive	48%	27%	2%	-
<b>2014-15 NHS</b> (Australian Bureau of Statistics, 2017)	92.1%	Any	Not reported	Not reported	59.4%	46.8%
		Exclusive	72.6%	61.6%	24.7%	-
<b>2017-18 NHS</b> (Australian Bureau of Statistics, 2018)	91.7%	Any	83%	73%	66%	40.8%
		Exclusive	73.8%	61%	29%	-
<b>2020-21 NHS</b> (Australian Bureau of Statistics, 2022)	95.9%	Any	88.6%	79.5%	73.8%	51.1%
		Exclusive	74.8%	66%	35.4%	-
<b>OzFits 2021</b> (Netting MJ, et al., 2022)	98%	Any	91%	87%	68%	44%
		Exclusive	54%	39%	1%	-

## Appendix D: Factors contributing to cessation of breastfeeding and/or introduction of infant formula in the first six months

Data source	Insufficient breastmilk	Baby unsettled, not attaching	Baby lost interest in breastfeeding	Breastfeeding painful	Breastfeeding previously not successful	Baby not gaining enough weight	Top up / back up	Return to work	Shared feeding with partner	Perception infant formula is as good as breastfeeding
2010 ANIFS (Australian Institute of Health and Welfare, 2011) (n = 28,436)	X	X	X	X	X			X	X	X
(Newby, RM; Davis, PS, 2016) (n= 290)	X	X	X	X		X				
2020/21 NHS (Australian Bureau of Statistics, 2022) (n = 826)	X	X	X	X				X		
Customer feedback (Danone) (n= 89)	X					X	X	X		



## Appendix E: Economic analysis of options

### Overview

This appendix presents cost effectiveness analysis of three levels of potential policy changes: enhancing processes, expanding scope, and adopting a stronger regulatory approach. This appendix includes a description of the cost estimation method and key assumptions, Monte Carlo risk analysis, and cost effectiveness analysis which estimates the scale of impact required to justify the scale of costs estimated here. The summary results of cost estimates are presented in **Table E1**.

The three options are outlined below.

#### 1. Changes to MAIF Agreement Complaints Committee processes and membership

- Expanding the Committee from three to five members
- Increasing the number of Committee meetings from four to six meetings per year
- Increasing MAIF Complaints Committee secretariat capabilities at the Department of Health and Aged Care
- Establishing a function for monitoring regulatory Agreement breaches at the Department of Health and Aged Care
- Further development of the MAIF Agreement website to enhance publication of MAIF Complaints Committee activities and findings.

#### 2. Expand the scope of regulated parties and products

- Extend the regulation (whether under the existing voluntary arrangements, or in a future mandatory regulatory model) to include toddler milk drinks
- Extend MAIF membership to include retailers, including supermarkets and pharmacies.

#### 3. Develop a stronger regulatory framework

- Develop new legislation and/or regulation
- Increased monitoring and enforcement
- Compliance costs.

**Table E1: Central estimates of costs associated with adjustments to Infant formula marketing regulations (\$ million)**

Option	Set up costs	Ongoing costs	10-year present value
<b>Committee processes and membership</b>	0.8	0.6	4.9
<b>Scope of regulated parties and products</b>			
Extend to toddler milk drinks	6.3	2.1	21.8
Increase scope of parties	8.6	4.3	39.5
Combined	14.9	6.4	61.3
<b>Stronger regulatory framework</b>	40.8	10.4	115.6

The following analysis does not seek to attribute improvements in breastfeeding rates expected from the policy options costed. Reasons for this include:

- The impact of any policy will depend on specific design factors that have not been yet considered
- There are a multitude of factors that influence breastfeeding rates, and the impact that infant formula marketing has on breastfeeding rates is complex and not possible to quantify.

However, the cost effectiveness analysis presents estimates of the scale of increase in breast feeding rates that would be required to justify the estimated costs for each option. These estimates are based on a narrow band of indicative improvements to health, and do not purport to encompass all possible improvements. These estimates are based on sustained improvements in breastfeeding rates over a 10-year period, and range from:

- A 0.3 percentage point required increase in breastfeeding rates for 'process' changes in option1 (with a low/high range from 0.1 to 0.5 percentage points)
- 3.7 (1.6 to 7.1) percentage points for expansion of scope
- 7.0 (3.4 to 13.1) percentage points for a change in the underlying regulatory model.

## Central estimates

### General assumptions

All cost calculations are done on a marginal basis – that is, the costs presented are increases compared with existing costs to both administer and comply with the existing MAIF Agreement. However, it is presumed that any increases in administration costs borne by government agencies will come from within existing department budgets. Although an increase in costs might constitute a reprioritisation in department activities, it does not require an increase in the budget. As such, no allowance has been made for any potential deadweight tax costs associated with any administration cost increases.

Costs are estimated over a 10-year period, with any set up costs presumed to occur entirely in year 0. Cost estimates are presented in present value terms with central estimates using a 7% discount rate. This assumption is relaxed to range between 3% and 10% in the Monte Carlo analysis.

Administration full time equivalent (FTE) labour costs are assumed to have an annual value of \$260,000. Due to the lack of publicly available information on public sector costs in Australia, a New Zealand study has been used to benchmark public sector costs. The cost of public sector time is benchmarked on a 2015 comprehensive investigation into the cost of policy advice in New Zealand, which has been adjusted for inflation to 2023 prices by subsequent increases in public sector wages (New Zealand Treasury, 2015). Australian values account for the New Zealand/Australian exchange rate as well as the premium that Australian public sector workers have over New Zealand public sector workers.

While these values may seem large, they incorporate an extensive amount of overhead support provided to staff. This includes management overheads and support staff providing ancillary activities such as accounts, information technology and human resources. Accordingly, while staff engaged in activities related to MAIF activities will earn significantly less than the amounts detailed in the tables and graphs below, the calculations account for the higher comprehensive cost to society represented by these higher cost figures.

A higher FTE rate of \$420,000 is assumed for private sector compliance costs. This incorporates similar overhead considerations to those described above, but also assumes that MAIF compliance will involve relatively senior executives of private sector organisations.<sup>14</sup>

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<sup>14</sup> These costs are estimates and have not been tested with industry.

## Option 1: Changes to MAIF Agreement Complaints Committee processes and membership

It has been assumed that a package of enhancements to monitoring, enforcement and MAIF Complaints Committee processes would include:

- Expanding the MAIF Complaints Committee from three to five members
- Increasing the number of MAIF Complaints Committee meetings to six meetings a year
- Increasing secretariat capacity at the Department of Health and Aged Care
- Active participation by the Department of Health and Aged Care, and State/Territory Departments of Health, in monitoring infant formula marketing activities (supplementing or replacing existing monitoring performed by advocacy organisations and members of the public)
- The enhancement of a website (or some other platform) to enhance publication and awareness of the MAIF Agreement, MAIF Complaints Committee activities and findings, and related materials.

Meeting costs are based on current payment arrangements for the MAIF Complaints Committee (based on information provided for this Review by the Department of Health and Aged Care). The central assumption is that additional secretariat and monitoring activities will each require additional ongoing resources equivalent to one FTE per year. The website improvements will require a one-off set up resource cost equivalent to one FTE per year. It is presumed that any ongoing enhancement of communication and publication activities will be part of the expanded secretariat responsibilities.

All costs associated with Option 1 are likely to be administration costs (i.e., borne by government).

**Table E2: Central cost estimates for Option 1 (\$ million)**

Option 1 Process enhancements	Set up costs	Ongoing costs	10-year present value
Committee	0.1	0.1	0.5
Secretariat	0.2	0.2	2.1
Monitoring	0.2	0.2	2.1
Publication platform	0.2	0.0	0.2
<b>Total - process enhancements</b>	<b>0.7</b>	<b>0.5</b>	<b>4.9</b>

## Option 2: Expand the scope of regulated parties and products

Option 2 consists of expansion of the scope of the MAIF Agreement to:

- include restrictions of marketing of toddler milk drinks
- broaden scope of parties to include retail distributors (supermarkets and pharmacies).

Costs involved in this option would largely consist of compliance costs borne by industry. The estimated administration costs are comparatively low, incorporating an allowance for one department FTE in the setup phase in each sub-option, with minor ongoing administration resource requirements. These costs are based on scope expansion of the current Agreement, not scope expansion that might take place under a new regulatory framework.

### Toddler milk drinks

Compliance cost estimates allow for each member to devote 0.5 FTE of executive time during the introduction of the extension and to require an ongoing 0.25 FTE resource input. The estimates are based around an assumption of 20 MAIF members. The cost estimates also allow for members to relabel their products in response to the inclusion of toddler milk drinks. Based on analysis from the Food Standards Australia New Zealand (**Food Standards Australia New Zealand, 2023**). Our cost estimates incorporate a one-off relabelling of 120 product lines at a relabelling cost of \$16,000 per product line.

### MAIF signatories

It is assumed that any expansion of the scope of parties to the MAIF Agreement to include retail and pharmacy organisations would be limited to major, primarily national organisations. However, there remains considerable uncertainty about the scope and application of this policy option. Our costings assume an additional 20 retail parties to the MAIF Agreement or other strengthened regulatory model, with a set up cost equivalent to one executive FTE, and an ongoing cost of 0.5 FTE per year for each new member.

**Table E3: Central cost estimates for Option 2 (\$ million)**

Option 2 Scope expansion	Set up costs	Ongoing costs	10-year present value
<b>Expand scope to toddler milk</b>	<b>6.3</b>	<b>2.1</b>	<b>21.8</b>
Administration	0.3	0.1	0.7
Compliance	4.2	2.1	19.1
Re-labelling	1.9	0.0	1.9



Option 2 Scope expansion	Set up costs	Ongoing costs	10-year present value
<b>Expand scope of parties</b>	<b>8.6</b>	<b>4.3</b>	<b>39.5</b>
Administration	0.3	0.1	1.2
Compliance	8.3	4.2	38.3
<b>Total</b>	<b>14.9</b>	<b>6.4</b>	<b>61.3</b>

## Option 3: Develop a stronger regulatory model

The cost estimates involve:

- Legislation costs of \$4.9 million (based on a 2012 New Zealand estimate of the cost of new public health legislation, adjusted into 2023 Australian prices (Wilson, N, Nghiem, N, Foster, R, Cobiack, L, Blakely, T, 2012)).
- Increased government monitoring and enforcement activities, involving 8 FTE on an ongoing basis (one for each state/territory jurisdiction) plus an additional 2 FTE during the set-up phase.

Compliance impacts on 40 national organisations (i.e., also involving those retailers who may have become parties to an expanded MAIF Agreement). The setup compliance cost is assumed to be 2 FTE per organisation. Ongoing reporting requirements are assumed to have a 0.5 FTE annual resource requirement.

**Table E4: Central cost estimates for Option 3, \$ million**

Option 3 Regulate infant formula marketing	Set up costs	Ongoing costs	10-year present value
Legislation	4.9	0.0	4.9
Monitoring and enforcement	2.6	2.1	17.5
Compliance	33.3	8.3	93.1
Total	40.8	10.4	115.6



## Risk analysis

Given the uncertainties around the estimates presented in this report, this Review has supplemented analysis using Monte Carlo risk-analysis techniques to provide information about the potential range of costs associated with each option.

Monte Carlo simulation techniques provide a method for investigating the interactions between multiple areas of uncertainty. A Monte Carlo simulation uses statistical sampling and probability distributions to simulate the effects of uncertain variables on model outcomes. It provides a systematic assessment of the combined effects of multiple sources of risk.

The approach adopted here is to simulate 20,000 observations for each varied component, assuming random inputs into a Beta distribution.<sup>15</sup> The assumed distribution takes into account prior information about the potential distribution and can also constrain the distribution to avoid impossible outcomes, such as negative costs.

The strength of the Monte Carlo simulation is that it allows a wide range of combinations between the different components (for example, one simulation could effectively assume that some costs are low, but others are high). Twenty thousand simulations are found to be sufficient to ensure that results were stable between different samplings.

Monte Carlo analysis also allows us to present a graphical presentation of the distribution of cost estimates and to provide 95% confidence intervals for the cost estimates.

The key assumptions underpinning the Monte Carlo analysis undertaken here are presented in **Table E5** below. The central values used are the same as those used in the central analysis presented above. The Beta value summarises the skewness of distribution assumed, with a higher Beta value signifying more room provided for values above the central assumption.

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<sup>15</sup> A Beta distribution is selected as it provides scope to constrain the distribution outcomes within plausible bounds (established by the A and B terms) and to allow skewed distributions (established by the relative size of the  $\alpha$  and  $\beta$  terms).

In practice each alpha term has been set to 1 and then the beta value (which sets the distribution skewness) is adjusted to ensure that the resulting distribution mean matches the values used in the central calculations. The resulting distributions are bound by plausible constraints but also utilise available information about the likely distribution.

For example, if the average price of a milkshake is \$10, prices below zero and over \$50 may be excluded as impossible or implausible. But as the average price is \$10, observations of \$8 to \$12 would be expected to be more likely than observations of \$38-\$42. So, in this example, A would be set to 0, B to 50, and with  $\alpha$  set to 1, a value of 5 would be chosen for  $\beta$ , as this is the value that will generate a sample average of 10.

For the Monte Carlo analysis of the cost estimates of the proposed EPA amendments, the following assumptions have been made:

- $\alpha = 1$ .
- $\beta$  = adjusted to ensure that the distribution average equals the central estimate.
- A = lower bound of distribution (if not constrained by a zero lower bound, assumed to be lower than the low sensitivity test value by a proportion that is 25% of the gap between the sensitivity low value and the central estimate).
- B = upper bound (typically assumed to be greater than the high sensitivity test value by a proportion that is 25% of the gap between the sensitivity high value and the central estimate).



**Table E5: Assumptions underpinning the calculations including the Monte Carlo Analysis**

Variable	Unit	Low	Central	High	Beta (skewness)
<b>General</b>					
Value of government FTE	\$m	0.21	0.26	0.32	1.20
Value of private executive FTE	\$m	0.31	0.42	0.46	0.40
Discount rate	%	3%	7%	10%	0.75
<b>Option 1</b>					
Addition to annual Committee meeting costs	\$m	0.023	0.051	0.084	1.17
<b>Additional FTE requirements</b>					
Secretariat	FTE	0.5	1.0	2.0	2.00
Monitoring	FTE	0.5	1.0	2.0	2.00
Web/publication development	FTE	0.5	1.0	2.0	2.0
<b>Option 2</b>					
<b>Expand to include toddler milk drinks</b>					
Administration FTE requirements					
Set up	FTE	0.50	1.00	2.00	2.00
Ongoing	FTE	0.10	0.25	0.50	1.67
Compliance FTE requirements (per affected member)					
Set-up	FTE	0.25	0.50	1.00	2.00
Ongoing	FTE	0.10	0.25	0.50	1.67
MAIF membership	Count	15	20	30	2.00

Variable	Unit	Low	Central	High	Beta (skewness)
Relabeling costs					
Product lines impacted	Count	90	120	155	1.17
Relabeling cost per product line	\$	\$14,500	\$16,000	\$22,500	4.33
Expand scope of regulated parties					
Additional members	Count	15	20	30	2.0
Administration FTE requirements					
Set up	FTE	0.50	1.00	2.00	2.00
Ongoing	FTE	0.20	0.50	1.00	1.67
Compliance FTE requirements (per affected member)					
Set up	FTE	0.50	1.00	2.00	2.00
Ongoing	FTE	0.20	0.50	1.00	1.67
Option 3					
Legislation costs	\$m	4.5	4.9	6.0	2.75
Administration FTE requirements					
Set up	FTE	7	10	20	3.33
Ongoing	FTE	6	8	16	4.00
Compliance FTE requirements (per affected business)					
Set up	FTE	1.00	2.00	4.00	2.00
Ongoing	FTE	0.25	0.5	1.00	2.00
Affected businesses	Count	30	40	50	1.00

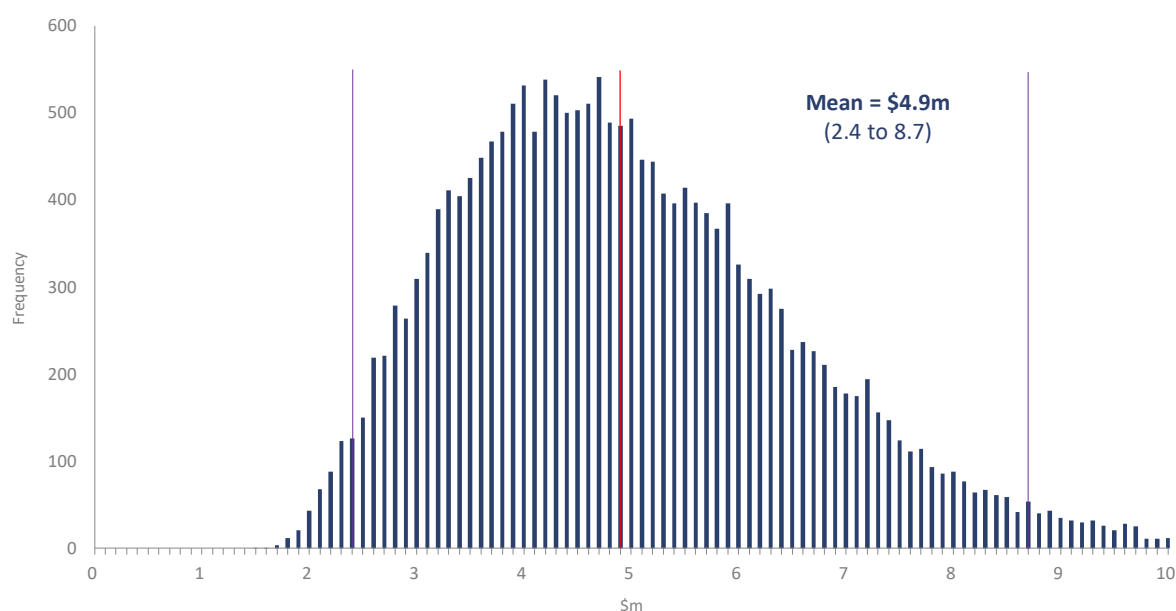
The summary results from the Monte Carlo analysis are presented in **Table E6**, with graphical presentation (histograms) of the distribution of estimated outcomes for each option presented in **Figure E1** to **Figure E5**.

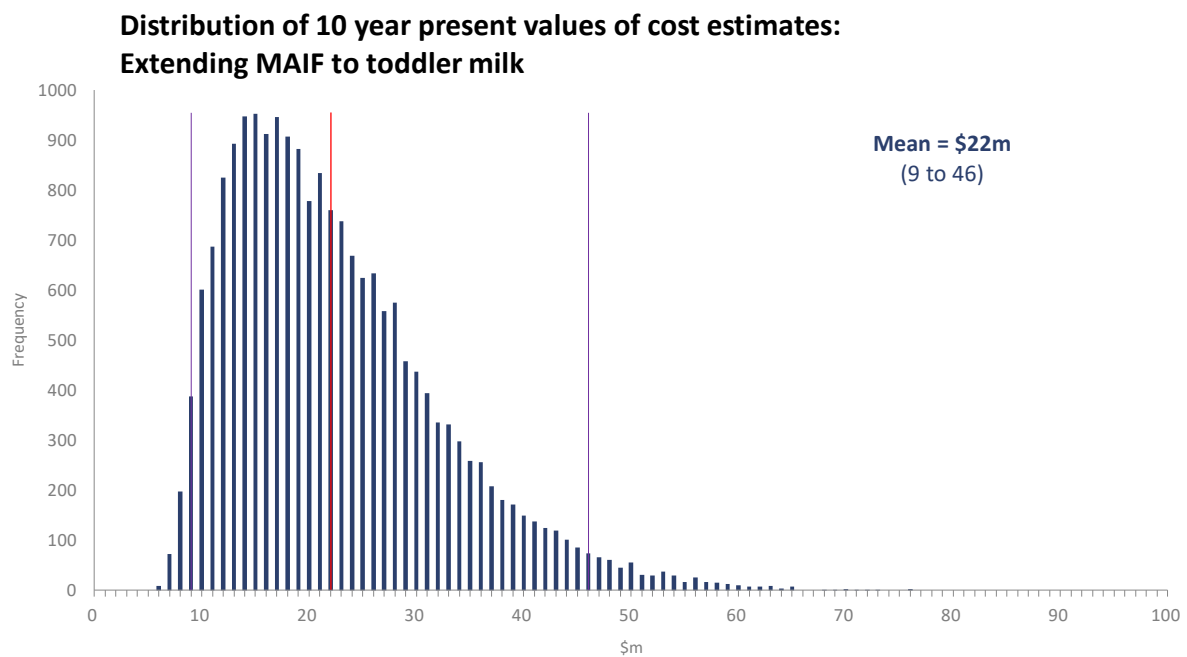
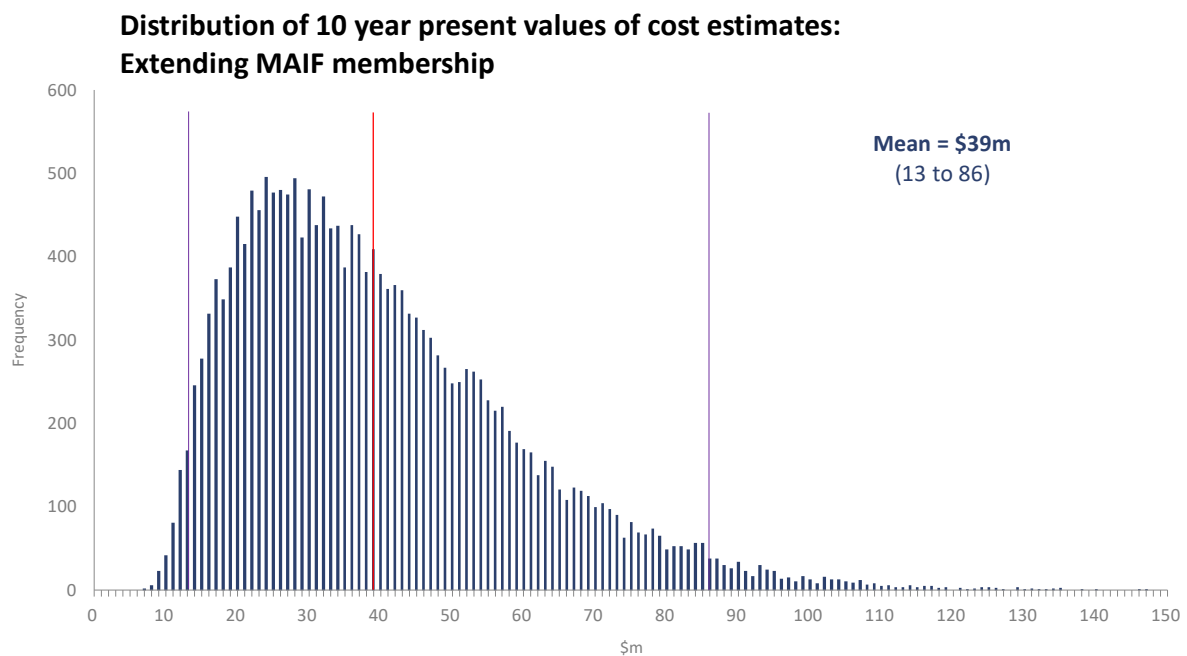
**Table E6: 95% confidence range of 10-year net present value estimates resulting from Monte Carlo analysis (\$ million)**

Option	Central	Low	High
<b>1 process enhancement</b>	4.9	2.4	8.7
<b>2 scope enhancements</b>			
Extend to toddler milk drinks	21.8	8.5	45.6
Extend scope of regulated parties	39.5	13.3	86.7
Combined	61.3	27.7	114.8
<b>3 Strengthen the regulatory approach</b>	115.6	58.1	211.0

**Figure E1**

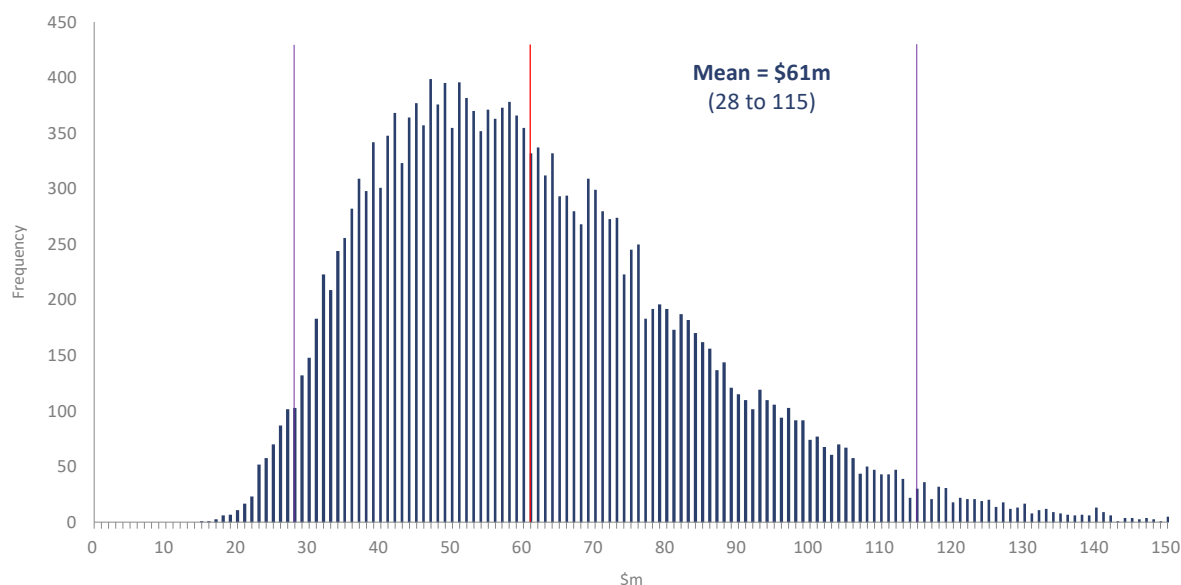
**Distribution of 10 year present values of cost estimates: Option 1**



**Figure E2****Figure E3**

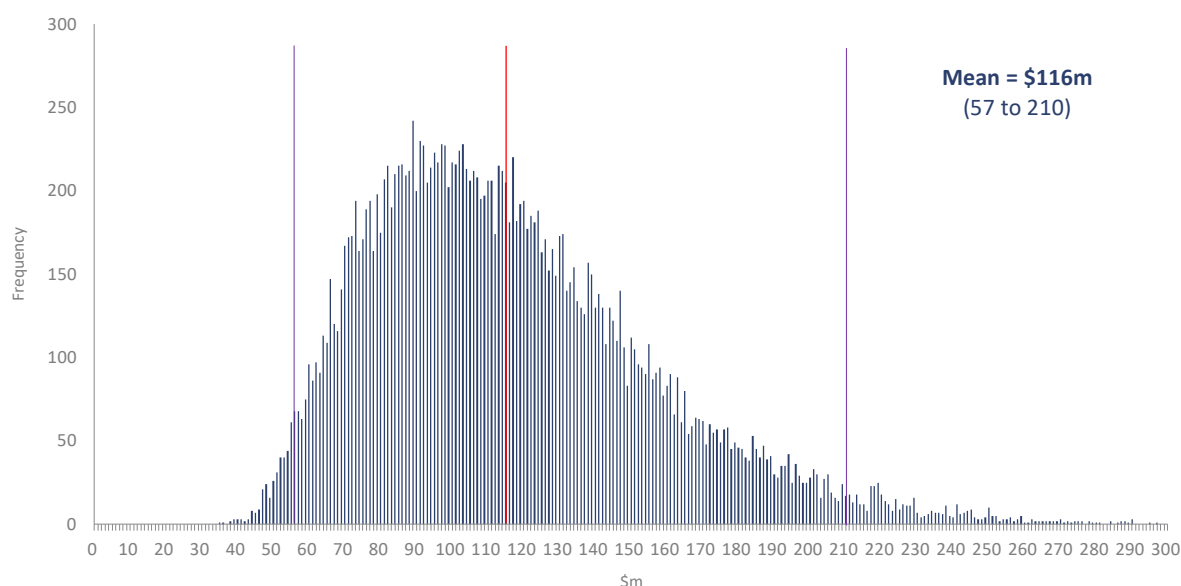
**Figure E4**

**Distribution of 10 year present values of cost estimates: Option 2**



**Figure E5**

**Distribution of 10 year present values of cost estimates: Option 3**



## Cost effectiveness analysis

With respect to whether the MAIF Agreement is effective, and whether a stronger alternative regulatory approach should be adopted, the primary public policy interest concerns the health benefits that may accrue from increased levels of breastfeeding. While there is a lack of quality data and certainty regarding breastfeeding rates in Australia, for the purposes of this analysis figures provided in the 2020-21 National Health Survey have been drawn upon as key assumptions underpinning the economic analysis (Australian Bureau of Statistics, 2022).



The National Health Survey found that:

- 88.6% of Australian babies were receiving breastmilk at two months (74.8% exclusively breastfed)
- 79.5% at four months (66.0% exclusively)
- 73.8% at six months (35.4% exclusively)

As outlined elsewhere in this Report, breastfeeding has significant health benefits for both children and mothers. In this discussion, cost effectiveness has been undertaken with reference to a narrow selection of health benefits as used in Victora, et al., 2016. Victoria et al found that breastfeeding was associated with significant risk reductions for children from:

- Diarrhoea, with babies breastfed up to the age of six months associated with a risk of prevalence and hospitalisation of between 10 to 75% that of non-breastfed children
- Respiratory illnesses, with equivalent risk ratios of 22 to 95%
- Acute otitis media, with a risk of 57% compared with non-breastfed.

For mothers, breastfeeding is associated with reduced risks of breast cancer (93% compared with non-breast feeders) and ovarian cancer (83%).

According to the Institute for Health Metrics and Evaluation (Institute for Health Metrics and Evaluation, 2019) in 2019 diarrhoea caused health impacts equivalent to 128.6 disability adjusted life years (DALYs) for every 100,000 Australians aged under five years (with a 95% confidence interval of 89.6 to 184.6). Similarly, respiratory illnesses were associated with 154.3 DALYs (95% CI: 89.9 – 250.5), and otitis media with 36.8 DALYs (18.5 – 68.5). Breast cancer is estimated to have been associated with 742.9 DALYs for every 100,000 women (95% CI: 679.6 – 816.4), and ovarian cancer with 195.0 DALYs (167.8 – 228.0).

To estimate the health benefit that might result from an increase in breastfeeding rates, this Review estimates the differential in health risks for these diseases between infants who are breastfed, and those who are fed infant formula. The difference in risks is taken as the mid-point in the risk ratios or odds ratios reported in Victoria et al (2016). The proportion of infants who are breastfed is taken as the proportion of breastfed infants at six months in the 2020-21 National Health survey (73.8% breastfed infants and 26.2% non-breastfed infants). The health risk faced by infants who are not breastfed (measured in DALYs per 100,000) is therefore estimated as:

$$DALY_{NB} = \frac{DALY_{Pop}}{(\%_{BF} \cdot RR_{BF} + (1 - \%_{BF}))}$$

To illustrate, with use of diarrhoea statistics, the DALY rate for 100,000 non- breastfed children under the age of five would be:

$128.6 / (0.738 \times 0.425 + 0.262) = 223.4$  DALYs per 100,000 children aged under the age of five.

The equivalent DALY for children who received breastmilk would be 42.5% of this, i.e. 94.9. The calculations presented below are effectively based on a simple (and generous) assumption that the risk of diarrhoea is typically 42.5% lower for children who receive breastmilk (to 6 months) compared to those who never received breastmilk or who stopped

receiving breastmilk before 6 months of age. **Table E7** presents the differential in DALY consequences of an increase in breastfeeding rates that underpin the central social benefit calculations.

**Table E7: Differential in DALYs per 100,000 underpinning calculations of social benefit from increasing breastfeeding rates<sup>16</sup>**

Condition	Breast fed	Non-breast fed	Population
<b>Children</b>			
Diarrhoea	94.9	223.4	128.6
Respiratory disease	130.1	222.4	154.3
Otitis media	30.8	54.0	36.8
<b>Mothers</b>			
Condition	Breastfeeding	Non-breastfeeding	Population
Breast cancer	728.5	783.4	742.9
Ovarian cancer	185.1	223.0	195.0

<sup>16</sup> Figures provided in Table E7 are drawn from the Institute of Health Metrics and Evaluation's GBD Compare tool. <https://vizhub.healthdata.org/gbd-compare/>. For example, the 128.6 DALY per 100,000 for children with diarrhoea was determined using the following settings:

Cause: A.3.1 Diarrheal diseases

Measure: DALYs

Country: Australia

Age: <5

Sex: Both

Unit: Rates

Year: 2019

This analysis does not attempt to attribute an improvement in breastfeeding rates expected from any of the policy options costed. Instead, our approach is to:

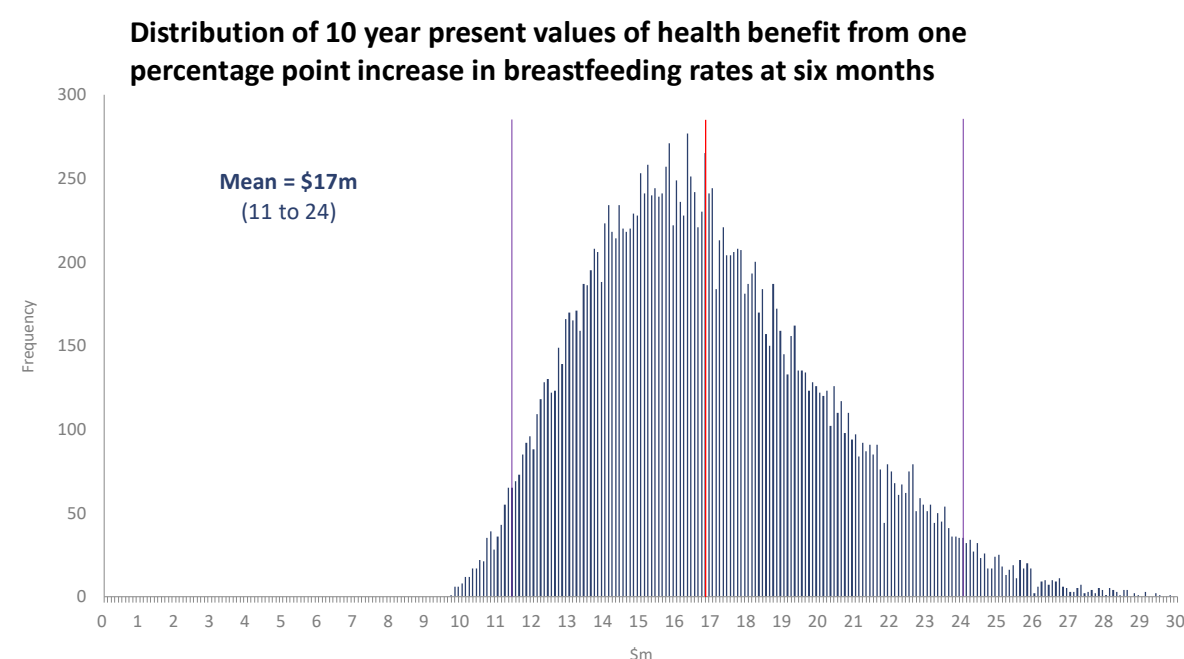
- Estimate the value of the social benefit expected from a one percentage point increase in exclusive breastfeeding rates at six months (i.e., an increase in the six-month breast feeding rate from 73.8% to 74.8%)
- Calculate the minimum increase in exclusive breastfeeding rates that would be required to justify the policy options costed above.

### **The value of the social benefit from a one percentage point increase in breastfeeding rates**

The Australian Bureau of Statistics estimated that there were 305,434 children in Australia as at 30 June 2022. This Review uses 1% of this figure (i.e. 3,054) as the basis of what constitutes a one percentage point increase in breastfeeding rates. Using diarrhoea as an example to illustrate the calculations. An increase in breastfeeding rates is assumed to reduce the DALY impact from 223.4 per 100,000 to 94.9. Applying these rates to 1% of children under one year of age (3,054), implies that such an increase in the prevalence of breastfeeding would be expected to reduce the health burden from infant diarrhoea by 3.9 DALYs  $((223.4 - 94.9)/100,000 \times 3,054)$ . The sum of the DALY impact from the five conditions listed in **Table E7** is an expected reduction in disease burden equivalent to 10.3 DALYs.

Valuing each of these DALYs at \$227,000, as per guidance in the Best Practice Regulation Guidance Note (Office of Best Practice Regulation, 2022), implies a central annual estimate of the value of the annual health benefit expected from a one percentage point increase in breastfeeding rates at \$2.33 million (with low/high estimates of \$1.65 million and \$3.34 million). Assuming this improvement is sustained over a ten-year period implies a ten-year present value of \$16.8 million (with a 95% confidence interval from \$11 million to \$24 million, see **Figure E6** for an illustration of the Monte Carlo analysis results).

**Figure E6**



### Minimum required impact from options

The consequent implied minimum increase in breastfeeding required to justify the expense of the policy options costed are presented in **Table E8**, with illustrations of the Monte Carlo results presented in **Figure E7** to **Figure E11**.

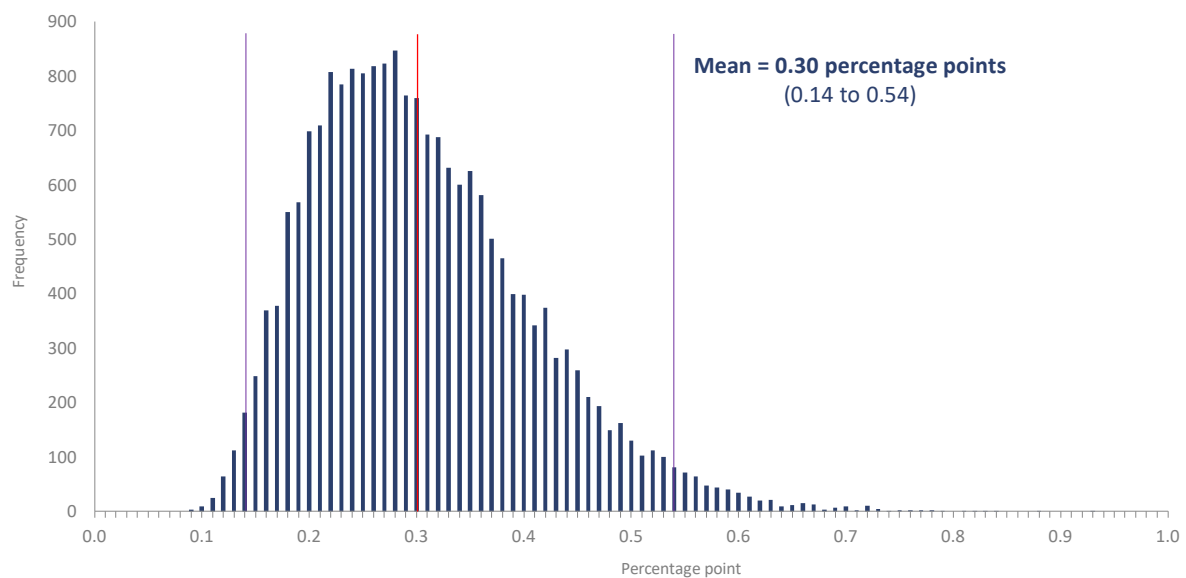
Note these required increases in breastfeeding rates would need to be entirely attributable to the policy initiatives and not from other potential initiatives, such as public education programs. Such assurance in policy effectiveness would require implemented policies to both have the designed impact on infant formula marketing activity and for this change in marketing to induce the required increases in breastfeeding activities.

**Table E8: Minimum percentage point increase in breastfeeding rates required to justify option costs**

Option	Central	Low	High
<b>1 Process enhancements</b>	0.3	0.1	0.5
<b>2 Scope enhancements</b>			
Extend to toddler milk drinks	1.3	0.5	2.8
Extend MAIF membership	2.4	0.8	5.4
Combined	3.7	1.6	7.1
<b>3 Introduce regulations</b>	7.0	3.4	13.1

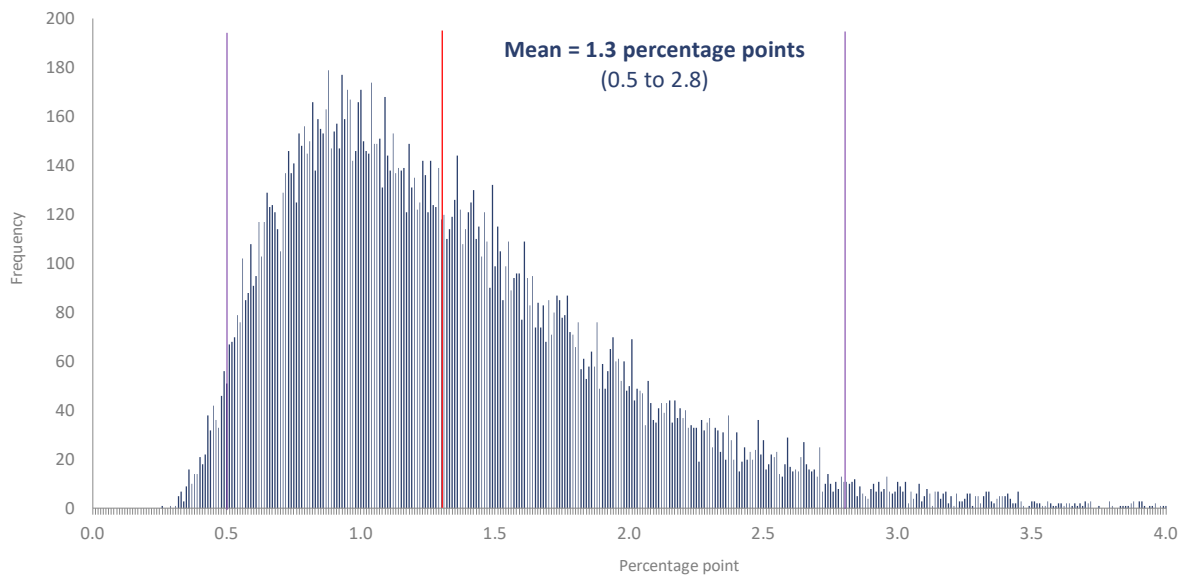
**Figure E7**

**Distribution of percentage point increase in breast feeding required to justify Option 1 expected costs**



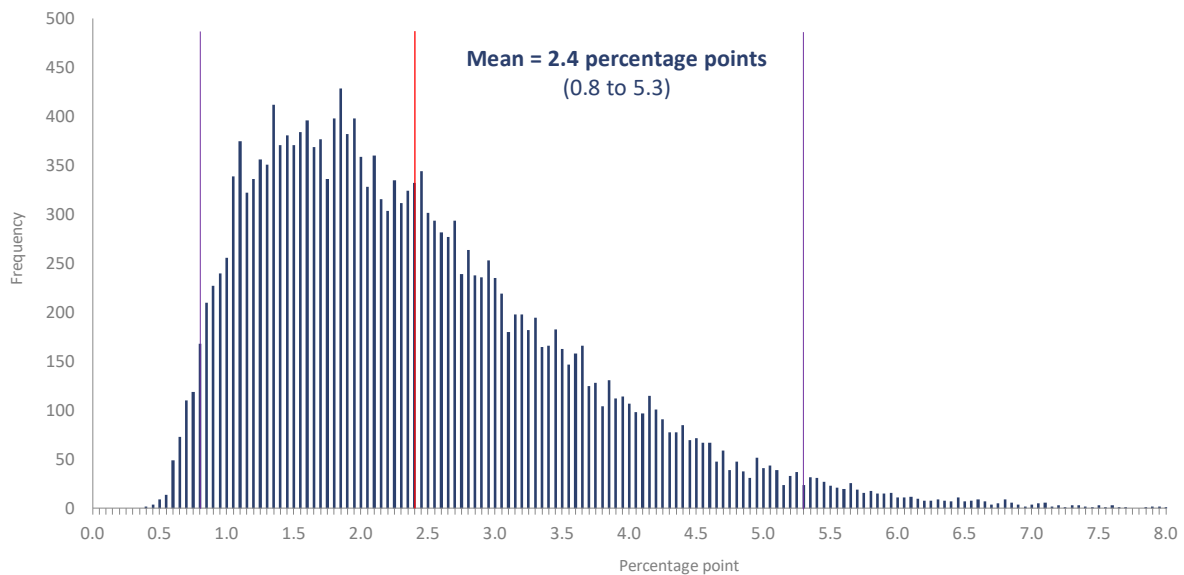
**Figure E8**

**Distribution of percentage point increase in breast feeding required to justify MAIF extension to toddler milk**



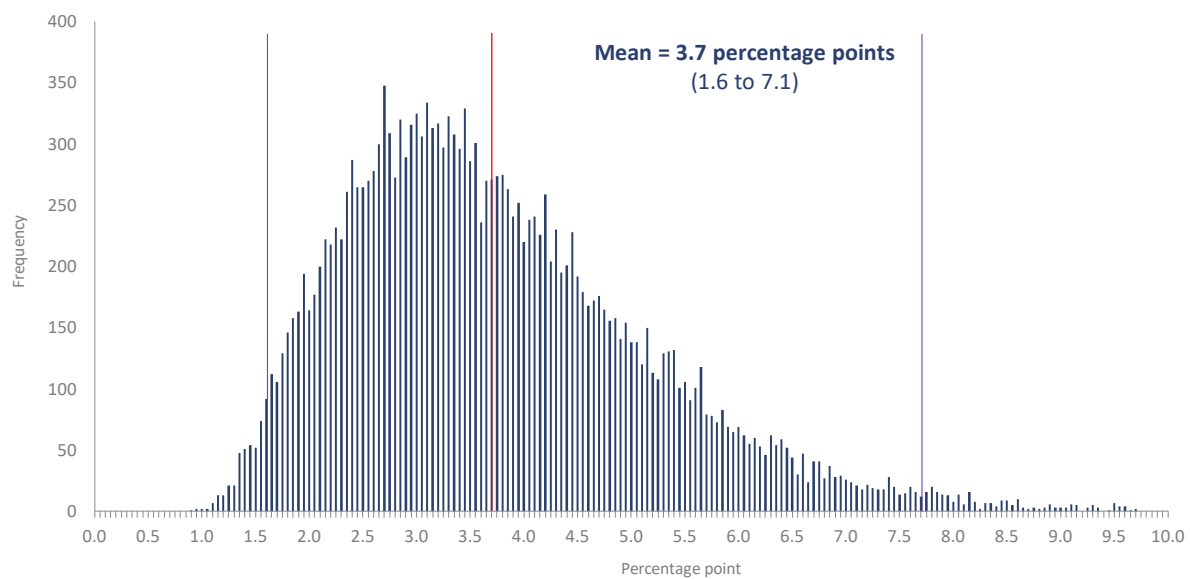
**Figure E9**

**Distribution of percentage point increase in breast feeding required to justify extending MAIF membership**



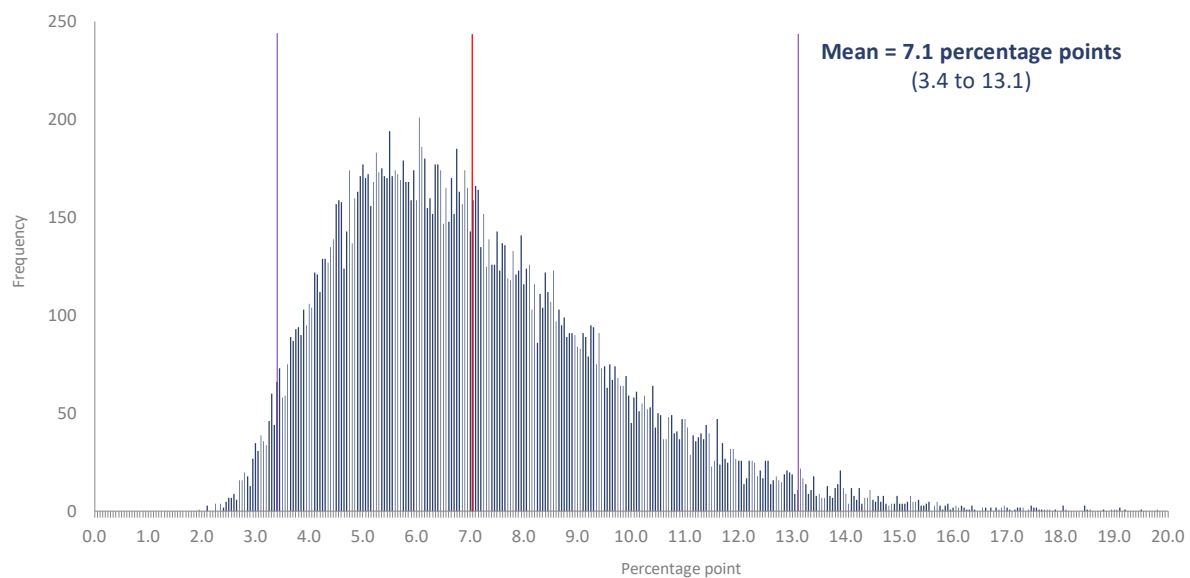
**Figure E10**

**Distribution of percentage point increase in breast feeding required to justify Option 2**



**Figure E11**

**Distribution of percentage point increase in breast feeding required to justify Option 3**



## Appendix F: Reference list

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