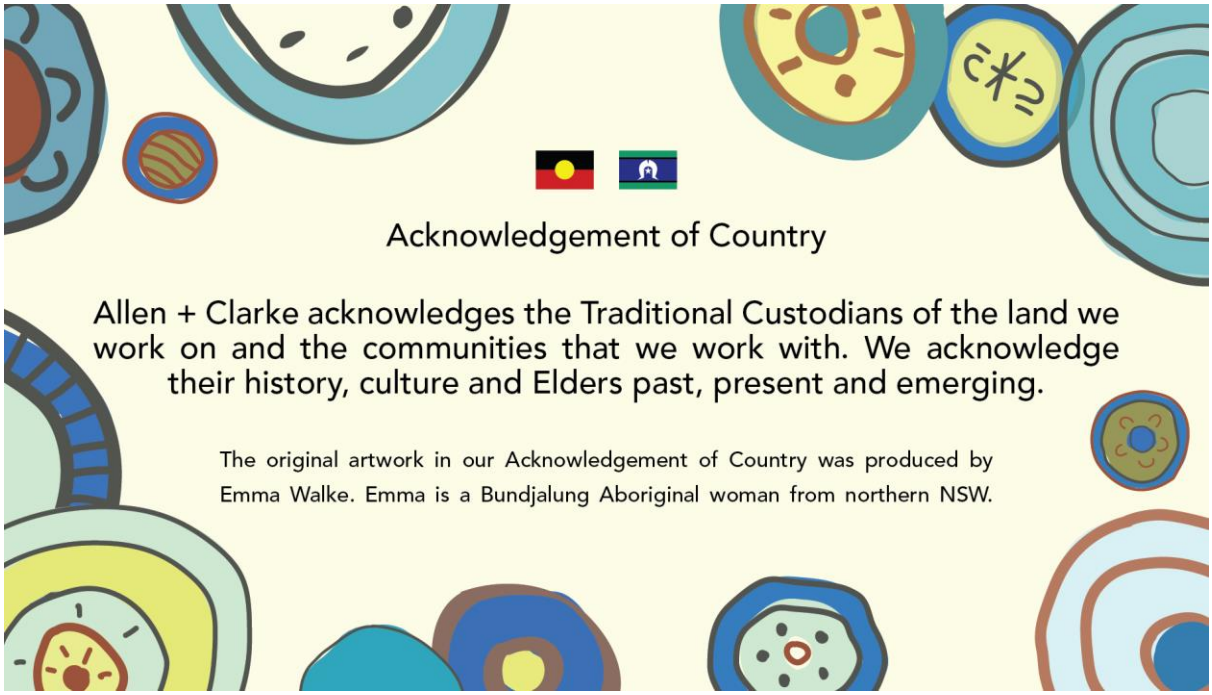
Review of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement

Consultation Paper

20 March 2023

ALLEN + CLARKE CONSULTING



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FOREWORD

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 breast milk substitutes' (COAG, 2019).

As the Strategy states, 'the first 1,000 days (from conception to the end of the child's second year) is the period with the greatest potential to affect health and wellbeing over the life course' (COAG, 2019). Nutrition is one of the greatest influences on child health, and breastfeeding is one of the most effective measures a mother can take to protect the health of her infant and herself.

In Australia, the **Infant Feeding Guidelines** recommend exclusive breastfeeding until around six months and continued breastfeeding to 12 months and beyond (The Australian Department of Health and Aging, 2012). The World Health Organization (WHO) recommends exclusively breastfeeding for the first six months of life, and continued breastfeeding to two years of age and beyond after the introduction of solid food (WHO, 2001).

In 1981, the WHO created the **International Code of Marketing of Breastmilk Substitutes** (WHO Code) which aims to contribute to:

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

The **Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement** (MAIF Agreement) is the primary way that Australia implements the WHO Code. The MAIF Agreement is a voluntary, self-regulatory code of conduct between manufacturers and importers of infant formula products in Australia and has the same aim as 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 breast milk substitutes (Department of Health and Aged Care, Marketing infant formula in Australia, 2022).

Independent Review of the MAIF Agreement

Under Priority Area 1.2 of the Strategy, the Department of Health and Aged Care has committed to commissioning a review of regulatory arrangements for restricting the marketing of breast milk substitutes (COAG, 2019), and in particular 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).

Allen + Clarke's Review of the MAIF Agreement has the following objectives:

	Consider contemporary policy issues for 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 agreement scope, alternative regulatory models and MAIF Agreement processes
	Any other related matters deemed appropriate

The Review will examine and respond to the Key Review Questions (KRQs) outlined in Section 3.

This Consultation Paper provides context about the MAIF Agreement and the Review and sets out key questions that the Review is seeking to answer.

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1.0 INTRODUCTION

The Strategy identifies the review of regulatory arrangements for restricting the marketing of breastmilk substitutes as a key action area for the Australian government. The Strategy commits to undertaking a review in order to determine:

- the effectiveness of the MAIF Agreement in restricting inappropriate marketing of breastmilk substitutes and ensuring caregivers are adequately informed
- the feasibility of including all manufacturers of infant and follow-up formula and all retailers (for example supermarkets and pharmacies) in the scope of the agreement
- the transparency of the complaints process and outcomes from MAIF Complaints Committee meetings (COAG, 2019).

The Department of Health and Aged Care (the Department) has commissioned *Allen + Clarke* to undertake a review of the MAIF Agreement in order to progress this key action area. The Review will address the KRQs outlined in Section 3.0 Context.

The sources informing the Review are outlined in Figure 1 below. Consultation is being undertaken to support the Review of the MAIF Agreement and will form part of the evidence used to draw conclusions and provide recommendations.

Figure 1: Sources informing the Review

Review information sources	
	**Desktop Analysis and Literature Review:** • The WHO Code, journal articles, grey literature, published reports from the WHO, UNICEF, the Department of Health and Aged Care, the Australian Competition and Consumer Commission, health research organisations, and other relevant literature.
	**Stakeholder Consultation:** • 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.
	**Online Survey** • Responses received as part of an online survey from interested parties who may include parties subject to the MAIF Agreement, public health and breastfeeding advocates, commercial bodies who sell infant formula like supermarkets and pharmacies, members of the public or other interested parties.

We expect consultation responses will identify opportunities to continue to improve the design, implementation, effectiveness and efficiency of the MAIF Agreement, and its alignment with the objectives outlined in the WHO Code.

2.0 HOW TO PARTICIPATE IN THE REVIEW

An online survey has also been developed in order to facilitate engagement with the Review by interested parties. The survey invites responses aligned with the KRQs and is administered through the **Department's Consultation Hub**. In addition, the Review Team will undertake targeted consultation with key stakeholders.

Participation in the Review is voluntary.

How will consultation data be stored and managed?

Department of Health and Aged Care

Survey responses for this review, where consent has been received, will be published on the Department's website **www.health.gov.au** after the consultation closes. The views expressed in the survey responses are those of the individuals or organisations who submit them, and their publication does not imply any acceptance of, or agreement with, these views by the Department. A summary of the key themes from the targeted consultation will also be made available on the Department's website.

The Department publishes survey responses on the website to encourage discussion and inform the community and stakeholders. However, the Department retains the right not to publish survey responses, and will not place on the website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the consultation.

Before publication, the Department will remove any personally identifying information from survey responses, such as personal email addresses, telephone numbers and home addresses. Whole or parts of survey responses which contain information which is requested to be treated as confidential will not be released, unless consent is subsequently received.

Any request for access to a confidential survey response will be determined in accordance with the *Freedom of Information Act 1982 (Cth)*, which has provisions designed to protect personal information and information given in confidence.

Please note the Department will be unable to accept:

- comments which, in the opinion of the Department, are inappropriate, including those not in scope of the Review's Terms of Reference; and
- comments received after the consultation deadline, 30 April 2023.

Allen + Clarke

Survey responses received by the Department will be shared with *Allen + Clarke* to inform the Review's final report.

Allen + Clarke's Information Handling policy adheres to the *Privacy Act 1988 (Cth)* and the associated Privacy Principles and sets out how information should be collected, managed, stored and disposed. This includes handling of information off-site (including when working from home). *Allen + Clarke* maintains appropriate computer security, including virus software and firewalls, and all devices have two-factor authentication. Review material and data will be stored on *Allen + Clarke's* secure server.

Further information or questions

Questions about the Review can be directed to: **MAIFreview@allenandclarke.com.au**

3.0 CONTEXT

To focus stakeholder engagement, consultation questions have been grouped under each of the KRQs, presented in Figure 2 below.

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

The following section provides background information in relation to the Key Review Questions.

Effectiveness in achieving the aims of the Agreement

This Review seeks to understand whether the MAIF Agreement is effective in achieving its aims.

The MAIF Agreement and WHO Code share the same aim, which is to:

> *contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information and through appropriate marketing and distribution* (WHO, 1981) (MAIF Agreement, 1992).

The MAIF Agreement 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. Key requirements of the MAIF Agreement are that:

1. the advertisement or promotion of infant formulas (up to 12 months of age) to the public are prohibited
2. 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
3. marketers must not seek contact with pregnant people or parents of infants and young children

4. infant formulas must conform to the Food Standards Australia New Zealand 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 penalty for breaching the MAIF Agreement, other than the breaches being recorded on the Department of Health and Aged Care website. 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 Agreement Complaints Committee.

Other considerations in relation to effectiveness of the MAIF Agreement include whether the MAIF Agreement is effective in restricting inappropriate marketing of breastmilk substitutes, whether it protects and promotes breastfeeding and the provision of adequate information to caregivers to ensure safe use. The Review Team also welcomes evidence on whether breastfeeding rates are influenced by marketing (both appropriate and inappropriate) of infant formula impacts in Australia.

Appropriateness of the MAIF Agreement in the current policy environment

The Review seeks to understand whether the scope of the MAIF Agreement is appropriate in the current policy environment. Considerations include whether the parties and products in scope remain appropriate, and whether the Agreement is appropriate in the context of changes to the marketing environment since 1992.

The MAIF Agreement outlines obligations for companies making and selling infant formula to ensure that formula is used properly, and parents can make informed decisions. The MAIF Agreement was first implemented in 1992, and it is important to consider how reflective it is of the current policy, regulatory and marketing environment. The WHO has provided guidance and recommended that the restrictions to marketing of breast milk substitutes should be expanded to:

> *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).

Australia has several other mechanisms to implement the WHO Code. These include the Food Standards Australia and New Zealand (FSANZ) Code which contains mandatory labelling and composition provisions for infant formula products; and the National Health and Medical Research Council's Infant Feeding Guidelines which review evidence and provide recommendations on infant feeding to assist health workers to provide consistent advice.

Products

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:

1. Infant formula (suitable for infants aged 0 - <12 months)

2. Follow-on formula (suitable for infants aged from 6 - <12 months)

3. Infant formula products for special dietary use. The Food Standards Code imposes some restrictions on the types of claims and statements that can be included on labels for these products.

Standard 2.9.1 specifies the mandatory nutrient content for infant formula and follow-on formula to ensure that the nutrition requirements of infants aged up to 12 months are met. This is particularly important for the period up to the introduction of complementary feeding.

Products covered under the MAIF Agreement are narrower in scope than those included in the WHO guidance on the International Code. The MAIF Agreement prohibits manufacturers and importers from advertising 'infant formula', which it defines as human milk alternatives 'for the feeding of infants up to the age of 12 months' (The MAIF Agreement, 1992, p. cl. 3(e)). It also restricts the promotion of 'breast milk substitutes' which includes 'any food marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose' (The MAIF Agreement, 1992, p. cl. 3(e)).

Under the MAIF Agreement, manufacturers and importers are able to advertise toddler formula, baby food and products such as bottles and teats. Availability of these products is in line with Infant Feeding Guidelines which recommend that infants start to receive complementary foods from around 6 months (The Australian Department of Health and Aging, 2012). Products must meet FSANZ labelling requirements – for example, they must indicate the age range and suitability of products. As consumer goods they must also meet consumer law provisions relating to issues such as unsolicited supply and misleading consumers.

Entities which are not signatories to the MAIF Agreement, such as retailers, are also not subject to marketing restrictions. Many signatories to the MAIF Agreement also produce other baby products such as toddler milks, infant foods and feeding bottles and teats.

Marketing practices

With the rise of the internet and social media, marketing practices have evolved considerably since the MAIF Agreement was established. Marketing is becoming increasingly targeted beyond traditional settings such as retail outlets. The rise in, and popularity of, social media channels, as well as internet sites for pregnant women and mothers, has provided manufacturers and distributors with new and often unregulated channels to market their products (WHO, 2017), (UNICEF, 2020).

Social networking sites and online communities have also changed the landscape for the promotion, protection, and support of breastfeeding (Abrahams SW, 2012), (UNICEF, 2020). New products such as home-made baby formula and brew recipes are increasingly advertised online and on social media (Thatcher, 2022) (Food Standards Australia and New Zealand, 2015).

Appropriateness of MAIF Agreement processes

The Review seeks to understand whether the MAIF Agreement's processes, including the complaints handling processes, are appropriate. Considerations include whether the complaints handling process is appropriately independent and transparent, whether complaints are administered in a timely manner, and whether appropriate enforcement mechanisms are in place.

The MAIF Agreement Complaints Committee (the Committee) was established in 2018 following an independent review of the MAIF complaints handling process. It is responsible for receiving and investigating complaints made against organisations who have signed the MAIF Agreement (Department of Health and Aged Care). Previously, complaints were processed by the Department of Health and Aged Care's Advisory Panel on the Marketing in Australia of Infant Formula, and then overseen by an independent body, the Ethics Centre, between 2014 – 2017.

The Committee consists of three members, appointed by the Department: an independent representative; a public health representative; and a representative of the infant formula industry. Complaints can be made by members of the public through the online complaint form and submitted by email or post to the Secretariat. All complaints are then sent to the Committee for review. If a complaint is in scope, the relevant company is advised of the complaint and invited to submit a response within four weeks. The Committee then reach a decision about 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's **website**. In 2020 – 2021, 66 complaints were considered. Of these, 55 complaints were resolved (18 in scope, 37 out of scope). Of the 18 in scope, the Committee found 10 breaches by signatories to the MAIF agreement including on social media platforms, Google search advertising and email marketing campaigns. The majority of complaints were dismissed because they related to companies which had not signed the Code, or the promotion of toddler milks or retailers' marketing activities, which are not in scope of the Agreement (Department of Health and Aged Care, 2022), (Daniel, D, 2022).

The Department of Health and Aged Care also provides **guidance** on the application and interpretation of the MAIF Agreement. These guidance documents assist with interpreting specific clauses of the MAIF Agreement.

Regulatory models, and whether the voluntary self-regulatory approach is fit-for-purpose

The Review seeks to understand whether the voluntary, self-regulatory approach of the MAIF Agreement is fit for purpose, and whether alternative approaches should be considered.

The WHO has stated that full application of the Code 'is essential to ensuring that parents and other caregivers are protected from inappropriate and misleading information' (WHO, 2022). As of March 2022, 144 of the 194 (74%) WHO Members 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 substantially align with the WHO Code (WHO, 2022, p. 12).

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'. The Department'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.'

Regulation can take many forms including self-regulation, compliance with industry codes or practice, through to an enforcement-based approach. There is a broad diversity of views in the literature regarding whether the current regulatory model that the MAIF Agreement sits within is fit for purpose, and about the applicability of other regulatory models (including potential establishment of a legislated statutory framework) in the Australian context.

Benefits, costs and limitations of changes and expansion of scope, models and processes

The Review seeks to understand the benefits, costs and any limitations of changes and expansion of the agreement scope, alternative regulatory models and MAIF Agreement processes. Potential costs, benefits and limitations of changes to, and expansion of, the Agreement can be considered in two ways: those generic impacts that would arise as a consequence of the changes (for instance, those associated with moving to a legislative or more highly regulated model), and those that would be a product of particular policy decisions made through changes to the MAIF Agreement (for instance, in parties or products covered).

Changes to the expansion of the MAIF Agreement scope, model or processes would be intended to enhance the MAIF Agreement's ability to satisfy its primary aims. Any changes to the MAIF Agreement or model would be undertaken with the intention of restricting marketing of breastmilk substitutes to promote and protect breastfeeding rates in Australia. Such changes could consist of changes to the parties to the MAIF Agreement, changes to the products that are in scope, changes to or a greater level of specification about the marketing practices that are in scope, and changes to administrative arrangements like the complaints process. The Review will also consider changes to the level of regulatory burden (potential regulatory costs imposed on businesses, community organisations and individuals) that would arise through changes to the MAIF Agreement or regulatory model.

Other costs and limitations associated with the MAIF Agreement and potential changes to the Agreement or regulatory model could include increased anti-competitiveness including market entry barriers arising from companies not being able to market their products, increased costs of products, and impacts on product innovation/improvement (ACCC, 2021, p. 28). 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.

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