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Dear Mr Hatfield,

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

Thank you for opportunity to provide a final submission following the pre-decision conference on this application. Please see the attached submission, to be read together with our 2 previous submissions on this authorisation, and our 3 submissions to the 2015-1016 authorisation application process.

Yours Sincerely,

Honorary A/Professor Julie Smith
Department of Health Services Research and Policy, College of Health and Medicine

Dr Phil Baker

Mr Alessandro Iellamo

Ms Naomi Hull

Dr Libby Salmon

1. At para 4.80 the ACCC states that it

> *'considers that the assessment of the public benefit and detriment is finely balanced. This is because there is a substantial risk that much of the claimed public benefit will not be realised as a result of the marketing of toddler milk by infant formula companies effectively promoting infant formula.'*

2. At para 5.3 and elsewhere at para XXX, the ACCC states that

> *'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 the Conduct.*

We submit that:

The relevant policy of the Commonwealth Government for this determination is the Australian National Breastfeeding Strategy (ANBS) which was also agreed by all Australian state and territory governments and published by the Council of Australian Governments in June 2019. Two of the six policy objectives of the ANBS are to:

- "Strengthen the regulatory arrangements for marketing of infant formula and breastmilk substitutes so that inappropriate marketing and distribution ceases.
- Increase the proportion of health professionals who receive adequate, evidence-based breastfeeding education and training that is free from commercial influence."

In the absence of further policy statements this, together with the WHO International Code, is the definitive statement of the Commonwealth Government's policy that is relevant to the ACCC's determination.

The ACCC assessment (above, para 4.80) that benefit and detriment are finely balanced and that benefit, if any, is at substantial risk, would in law, preclude and be inconsistent with a finding that there is a net benefit to the public of reauthorising the current MAIF (as at para 5.3).

On net public benefit:

1. MAIF is an ineffective industry self-regulatory arrangement that serves to **detrimentally** substitute for policy measures that fully implement the WHO International Code, with effective monitoring, and enforcement of compliance. Full implementation of the International Code was recommended by the Parliamentary Best Start Inquiry into the Benefits of Breastfeeding in 2007 (House of Representatives Standing Committee on Health and Ageing, 2007). MAIF also substitutes for proper parliamentary accountability for implementing policies that meet Australia's international human rights commitments to children and their mothers through fully implementing the International Code and other relevant international instruments. All products marketed for infants and young children 0-36 months should be brought more firmly and clearly into Australia's food regulatory

system to fully implement the WHO International Code of Marketing, as recommended by the Australian Parliament and as was foreshadowed by the 2010 National Breastfeeding Strategy.

2. There are other important **public detriments from authorisation** because MAIF gives rise to unwarranted benefits for promoting the public image of INC members in the Australian and global milk formula industry, and aids the global formula industry's legal strategies for obstructing countries' legislative implementation of the International Code via international trade fora such as the WTO.

3. MAIF's facilitation of common strategies for promoting milk formula products by INC members to health professionals and health facilities is a further important public detriment, a marketing strategy that is less available to new industry players without the established market position and marketing channels that the dominant multinational companies have. This barrier to entry helps maintain high markups on milk formula products for INC members, because they can better market their toddler milk as well as infant formula products through the vitally important health channels via untransparent and potentially collusive marketing strategies that are denied or difficult to access for new entrants (Coriolis, 2014).

4. **A further, crucial public detriment** highlighted at the pre-decision conference is that, because the MAIF currently excludes toddler formulas, the industry can avoid the current Food Act provision which prohibits health or nutrition claims on infant formula products. It does this through making dubious health or nutrition claims on similarly branded toddler formula. This serves as a proxy to promote infant formula products contrary to the Food Act. The ability to make claims on toddler formula means that Food Act prohibitions on making such claims for infant formula products are rendered ineffective.

5. The onus is on the applicant to satisfy the ACCC that the **public benefit test** is satisfied. INC has provided no substantive evidence that the MAIF has provided public benefit through either reducing marketing of infant formula, restraining sales of breastmilk substitutes, or protecting breastfeeding. This is because such evidence of public benefit doesn't exist. Furthermore, INC have provided no robust evidence of public benefit from MAIF reauthorisation to support their contention that the imposition of the Proposed Condition regarding toddler milk formula products would be inappropriate. The onus is also on INC to provide evidence that marketing of toddler milk products and infant formula products by proxy has not reduced breastfeeding, and no such evidence has been provided. **It is our submission that the ACCC does not have the power to reauthorise MAIF without being satisfied there is a net public benefit from doing so, and in all the circumstances, the Proposed Condition is the only basis on which it can reasonably be satisfied that there is likely to be a net public benefit from reauthorising MAIF.**

6. Reauthorising MAIF without the Proposed Condition will, to the contrary, clearly harm public health and child nutrition by permitting the continued ubiquitous promotion of breastmilk substitutes (including infant formula by proxy), expand sales of infant and toddler formula products and reduce breastfeeding.

7. Toddler formula/milk is a breastmilk substitute according to the recognised global authority (World Health Organization (WHO), 2017). It displaces continued breastfeeding and

nutritious foods in the young child's diet, and is unnecessary and potentially deleterious to children's nutrition and health. In 2016, the WHO prepared guidance at the request of the World Health Assembly (based on explicit mandate from the World Health Assembly and in response to Resolutions supported by successive Australian governments (World Health Organization (WHO), 2016)), to clarify that breast-milk substitutes "*should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk), in either liquid or powdered form, 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*)." A WHO *Information Note* published in 2018 entitled 'Clarification on the classification of follow-up formulas for children 6-36 months as breastmilk substitutes' describes the rationale for this interpretation (World Health Organisation (WHO), 2018). Notably, contrary to the INC submission that toddler formulas are not breastmilk substitutes, it states, inter alia, that '*classification of milks as breast-milk substitutes depends on their function, not their composition ... As a result, the different compositional requirements of follow up formulas for children 6-36 months from that of infant formula would not prevent them from being considered breastmilk substitutes*.'

8. Similarly, Australia's nationally authoritative NHRMC Dietary Guidelines incorporating the Infant Feeding Guidelines explicitly state that toddler formula is unnecessary (National Health and Medical Research Council, 2012). "'*From 12 months of age and beyond, toddlers should be consuming family foods consistent with the Australian Dietary Guidelines. Special complementary foods or milks for toddlers are not required for healthy children'*. Furthermore, toddler milk is much more expensive than regular cows' milk with no additional nutritional benefit (McCann, Russell, Campbell, & Woods, 2021). Recent research has demonstrated the high sugar content of toddler formula: despite this, toddler milk products are being heavily promoted as a beneficial, healthy and nutritious product in Australia and elsewhere (Pries et al., 2021).

9. INC's submission wrongly states that recent National Health Surveys show rates of <u>breastfeeding at 12 months</u> rising to 41-46% (INC submission Table 1). However, National Health Survey data, appropriately analysed and interpreted shows that breastfeeding rates at 12 months have remained approximately stable for several decades at around 30% (Scott, Ahwong, Devenish, Ha, & Do, 2019).[1] The large study by Scott was presented as an attachment to the INC submission and states its key findings as follows [**bold added for emphasis**]: "*This research provides insight into the prevalence of continued breastfeeding to 12 and 24 months amongst a contemporary cohort of South Australian mothers. In this study,* ***just under one third of women continued breastfeeding to 12 months or beyond which is similar to that reported for the USA (30.7%) [31] and Norway (36%) [32]. When compared to earlier Australian studies, including a secondary analysis of the 2010 Australian National Infant Feeding Survey (31.2%) [33], the 2014–15 National Health Survey (27.5%) [21] and the 2004 national Longitudinal Study of Australian Children (LSAC) (30%) [34], the proportion of infants breastfed to 12 months has remained relatively unchanged over the last decade or so. Hence, the majority of Australian infants***

[1] The small and ad hoc studies conducted for different purposes in various small Australian populations that are also submitted by INC as evidence of rising breastfeeding rates cannot provide reliable information on national breastfeeding rates or trends in infant feeding practices.

and their mothers are continuing to be deprived of the considerable benefits of continued breastfeeding." [2]

10. Furthermore, there has been little change in breastfeeding initiation from 86% as measured in the National Health Survey in 1993 (L. H. Amir & Donath, 2008) (currently reported in the ABS National Health Survey and AIHW data as 93-96% (AIHW, 2010; Australian Bureau of Statistics, 2019), or in duration at 6 and 12 months. This small improvement in Australia's high rates of breastfeeding initiation since 1993 is unlikely to be attributable to MAIF, but more likely due to updated breastfeeding policies and National Dietary Guidelines including dietary and infant feeding guidelines since 1996 (Australia. Department of Health, 1998; Commonwealth of Australia, 2010; National Health and Medical Research Council, 1996, 2003), and incremental policy support such as the 2011 Paid Parental Leave Scheme (PPL).

11. In fact, the Commonwealth Government commissioned a 2014 evaluation of the breastfeeding outcomes of the PPL, which substantiated using a strong and well controlled before-after experimental design that PPL slightly increased breastfeeding duration at 12 months (Martin et al., 2014). This increase due to PPL was statistically significant: "*At 52 weeks after the birth (one year), 30 per cent of post-PPL mothers continued to breastfeed, compared to 26 per cent of pre-PPL mothers*". Importantly, as noted in early submissions, notwithstanding any increase in breastfeeding initiation, NSW and Victorian government statistics both show substantial increases in the past decade in the proportion of newborns leaving hospital having received infant formula. Around 30% of Australian newborns are now fed infant formula before leaving hospital, up from around 20% less than a decade ago (L. Amir, 2020).[3]

12. Even if breastfeeding rates are as high as INC asserts in its submission, this reinforces that milk formula products for older babies and toddlers are a substitute for breastfeeding among a substantial proportion of children (at least 30%) in their second year. The study by Scott (Scott et al., 2019) found that even among mothers who continued breastfeeding older infants, those who introduced milk formula before 12 months were more likely than those who had not done so to have cease breastfeeding in the second year.

13. There is a significant risk that there is no public benefit from authorisation of MAIF. It is unlikely any claimed public benefit will be realised from authorising MAIF as it stands, because the marketing of toddler milk by INC members in effect markets and promotes infant formula by proxy. It is essential for the ACCC to make any authorisation of MAIF conditional on any such agreement being expanded in scope to including toddler formula products so as to increase a likelihood of public benefit from authorising MAIF. The ACCC has the power to place such conditions on authorisation and has in the past exercised its powers with a broad view of public interest and public detriment. It should do so here.

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[2] This study also showed that almost all women (94.9%) in the cohort initiated breastfeeding, 31.8% breastfed to 12 months and 7.5% to 24 months, with breastfeeding at 12 months and 24 months independently negatively associated with the use of formula at any age before 12 months and with the introduction of complementary foods before 17 weeks.

[3] Scott's study showed that the chance (adjusted odds ratio, AOR) of still breastfeeding at 12 months for an infant who had received formula in the first 4 weeks was about 5% of the probability for those who had never received formula during the first 12 months. The use of formula at any age up to 12 months was strongly negatively associated with the odds of breastfeeding to 24 months.

On the reauthorisation period:

14. We submit that the proposed reauthorisation period and its relation to the MAIF review proposed in the Australian National Breastfeeding Strategy (ANBS) is excessive, and that industry has not demonstrated any effective response to warnings by the ACCC in 2016 about industry marketing practices on toddler formula. During the pre-decision conference on 13 April, the Department of Health has also stated that it 'could work with any time frame', and 'a lesser authorisation would not cause major issues' for them (Australian Competition and Consumer Commission, 2021). We submit that a higher regulatory burden on industry of a 2-year authorisation is not a relevant consideration in terms of any public benefit, any burden applies equally to other stakeholders (including those seeking a 2 year authorisation) and involves no inequity.

15. We urge that the ACCC limit any authorisation period to 2 years to ensure that industry marketing activity can be monitored, and prompt action taken to improve enforcement and compliance. We also urge that the ACCC place this industry under close surveillance through a market review to ensure adequate data is collected to assess future applications for MAIF reauthorisation to be make on evidence rather than INC assertations.[4]

16. During this period, we urge that INC be required to report all its members' marketing and 'education' activities at or near health facilities or to health professionals, and an independent audit be conducted and published of the conditions and quantities of supply arrangements by INC members and non-members to health facilities. This would provide information relevant to future ACCC authorisation decisions on MAIF, including on inappropriate e.g., exclusive agreements between facilities and INC members. Furthermore, a right of review and appeal should be established for consumers whose complaints are rejected as out of scope or determined by the MAIF Complaints Committee to not be breaches of MAIF.

On marketing to health professionals:

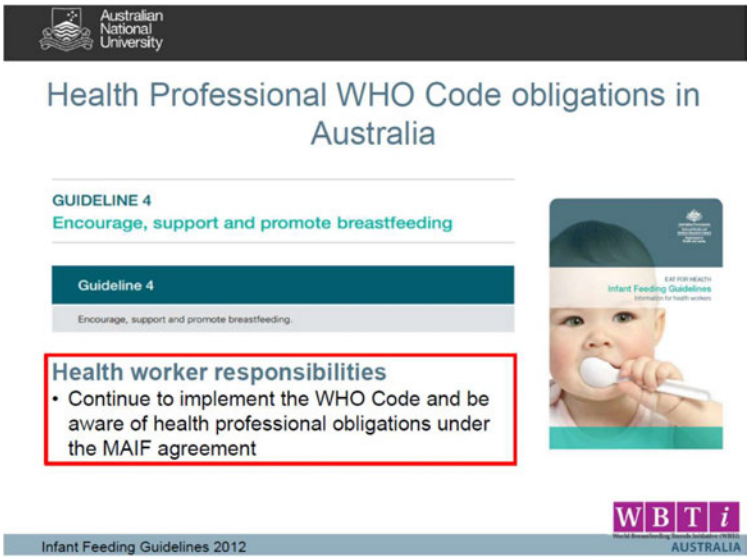
17. MAIF legitimises marketing to health professionals and gives formula industry sales representatives unwarranted status in providing industry 'education' on infant feeding and breastfeeding, while purporting to regulate marketing. MAIF guidelines are far from reflecting the WHO Code requirements on health facilities and health workers. We have shown that the balance of evidence in similar industries to milk formula, such as pharmaceutical marketing, is that such marketing works to influence health professional practice and reduces the quality and integrity of health care. We have also provided evidence that Australian health facilities and health professionals push formula on mothers, including specific brands. Although the ACCC considers that health professional codes of practice effectively regulate health professional practice in implementing the WHO guidance for health workers, we have shown through a review of health professional codes of practice that this is not the case; only one in 29 Australian health professional

[4] In particular, protocols for baby food market monitoring have been prepared and validated by WHO for such purposes and could be used by ACCC to conduct such monitoring of inappropriate promotion of breastmilk substitutes in Australia.

organisations examined had comprehensive implementation of WHO guidance on the WHO Code in their codes of professional practice.

18. The failure of health professional codes of practice to regulate their members in relation to the International Code and infant feeding in Australia is evidence that the ACCC must take into account in assessing the potential public detriment of the MAIF's failure to regulate marketing through health channels.

19. MAIF must be required to meet the global standards and detailed guidance stated by the WHO and the International Code, which are brought into Australian policy and practice through the NHMRC Dietary Guidelines and Infant Feeding Guidelines for Health Workers. These include that health workers should 'encourage, promote and support breastfeeding', and have a responsibility 'to implement the WHO Code in Australia'. This needs to be monitored and enforced by regulatory agencies such as ACCC and AHPRA, including through accreditation of training and education programs, and by requiring the collection and publication of relevant information as a condition of authorisation of health professional or health professional organisation activities..



On what would happen without the MAIF:

20. We have argued supported by a number of other participants that the counterfactual by which the ACCC should assess any public benefit from authorising MAIF is not a 'wild west' scenario and is unlikely to be significantly difficult from what occurs now. Even if industry self-regulation is lower cost to government, this has adverse redistributive effects as it shifts the costs of monitoring and enforcement to the public. As such arrangements are not effective, it cannot be concluded that MAIF is cost effective and therefore enhancing economic efficiency. To the contrary, it is more efficient for government to regulate marketing of milk formula and baby food directly, because, even if it costs the government more (which is doubtful as the taxpayer through the Commonwealth Department of Health is already opaquely bearing the costs of running the complaints department for INC members), the arrangement would be more cost effective.

21. NOUS has provided options for moving regulation of marketing to more independent bodies demonstrating a number of options that would be considered as an alternative to MAIF it if were not to be reauthorised. Furthermore, we have argued with support from others that the MAIF displaces effective regulation. In our 2013 study, data on advertising activity prior to the WHO code shows that marketing of infant formula in Australia ceased in the late 1970s due to public opprobrium leading up to the WHO Code in 1981, and resumed once self-regulatory arrangements were in place from 1992, in the form of toddler formula marketing. This shows that the counterfactual is public regulation and/or a significant degree of self-regulation of marketing by major industry players.

22. Nagarajan (Nagarajan, 2013) points out the problems with a regulatory system that relies on weak (poorly resourced) actors (that include poorly informed health professionals). States themselves become weak actors without transparent governance processes in their dealings with transnational corporations. We re-emphasise here that this is about global interests operating in Australia, not just a local issue

23. Hence any assessment of the net public benefit must take account of the risk that policy displacement is the reality, and industry will regulate its behaviour just to the extent necessary to avoid effective public regulation. Crucially, we have argued, the industry uses the MAIF to argue in international trade fora that public regulation is unnecessary because MAIF is a more proportionate response to the public health problem, thus industry has a strong interest in maintaining MAIF as an 'exemplary' self-regulatory arrangement. Authorisation of MAIF makes Australia complicit in industry strategies of opposing WHO Code implementation through legislation in other countries such as Hong Kong, Philippines and elsewhere in the world.

The conduct of Australian companies in marketing milk formula products in export markets

24. We have argued that the ACCC does have the power to require the MAIF to cover exports by INC members because it can regulate companies operating in Australia and because it has a wide public benefit test which can and should include the public benefit of preventing the marketing of breastmilk substitutes in Australian export markets. Many of these are developing, low- or middle-income countries in Asia where there is very much to gain from protecting breastfeeding, but where governments have difficulty enforcing regulations in the face of the power of large multinational corporations and limited resources of governments. To the extent that Australia is obligated to respect and protect the rights of children and mothers under international human rights instruments such as the Convention on the Rights of the Child, this obligation extends to the obligation on Australian regulatory agencies where they have influence regarding the conduct of Australian companies in marketing milk formula products in export markets. INC has stated that its member countries comply with a code of practice in export markets. If this is the case, and INC is genuinely committed to MAIF being effective in restraining marketing, then INC should happily extend the application of the MAIF to export markets in which its member companies operate.

25. There is more than a moral argument for inclusion of overseas markets in Australian regulatory decisions. Unanimous WHA resolutions have mandated a 'joint standard'. WHO Code legislation across destination countries may make national governments less

vulnerable to the power of transnational corporations - i.e. help governments 'bite back' and avoid ‘regulatory chill’.

26. While ACCC powers to regulate companies under the Trade Practices Act may be limited to conduct within Australia, it has previously been accepted that the ACCC assessment of public benefit can encompass an arrangement that contributes to limiting the risk to human health and the improvement of the environment would benefit the Australian public and may also benefit the total world population and environment. Recent research has demonstrated the important role of toddler milk and its marketing in reducing breastfeeding and increasing greenhouse gas emissions and environmental harms in both producer and consumer countries (Baker et al., 2021; Baker et al., 2016; Dadhich, Smith, Iellamo A, & Suleiman A, 2021 ; Karlsson, Garnett, Rollins, & Röös, 2019; Smith, 2019)..
27. Furthermore, in law it has been accepted that where Australia has signed a treaty but not made this treaty into domestic law by passing new legislation, that existing legislation should nevertheless be implemented consistent with the treaty where possible. We suggest therefore that the ACCC must, where possible, take Australia’s international human rights obligations into account for mothers, infants and young children everywhere in line with the Maastricht principles of the extraterritorial obligations of states (De Schutter et al., 2012).

SUMMARY

28. It is our submission that the ACCC must not grant this authorisation unless it ensures that the net public benefit is both certain and substantial. It is beyond power to grant the authorisation when the ACCC assessment is that the net benefit is both uncertain and finely balanced.
29. No evidence has been presented by INC or identified by ACCC that shows the MAIF actually provides significant and certain public benefit in terms of protecting and promoting breastfeeding. The evidence including since 2016 is to the contrary. Reauthorising MAIF delays effective regulation and public benefit, and detrimentally gives a highly concentrated and powerful industry the gift of an unwarranted ‘social licence’, reputational benefit, and strategic tools for resisting public health regulation globally. Furthermore, there is plausible evidence of detriment, and demonstrably high costs to civil society organisations and individual women of futile attempts to regulate industry behaviour when the Australia government itself fails in its responsibility to act to protect public health.
30. If the ACCC does grant this authorisation, it must take steps to increase the certainty and the level of public benefit by imposing strong conditions, and ensuring outcomes are closely monitored over a short period of time, with ample room to move if an Australian government decides to implement the decisions of parliament over many decades.
31. Existing ACCC principles of enhancing information provided to stakeholders, improving in-house complaints and dispute resolution processes, and mandating external reviews of corporate compliance should provide the basis for conditions attached to any reauthorisation of MAIF, to strengthen self-regulation and bring it into line with community expectations and standards.

To this end we recommend at least the following:

DETAILED RECOMMENDATIONS

1. That the ACCC not reauthorise the MAIF due to the lack of evidence of public benefit. If it does, it should increase the likelihood of public benefit by imposing a condition on any authorisation which extends the limitations on advertising set out in Clause 5(a) of the MAIF Agreement to apply to all breastmilk substitutes, including toddler milks. Clause 5(a) Manufacturers and importers of infant formulas should not advertise or in any other way promote formulas to the general public. (WHO Code Article 5.1) We further recommend that for any future authorisation of MAIF, the ACCC require INC to provide robust evidence on the extent to which MAIF has prevented or reduced promotion or sales of breast milk substitutes, or had positive effects on breastfeeding practices, as well as public detriment.
2. That any reauthorisation period should be for 2 years. The ACCC should publicly indicate its intention to place this market under formal market review during 2021-22. During this period, INC be required to report all its members' marketing and 'education' activities to health facilities and health professionals, and an independent audit be conducted and published of the conditions and quantities of supply arrangements of formula to health facilities. Furthermore, a right of review and appeal should be established for consumers whose complaints are rejected as out of scope or not breaches of MAIF.
3. That the ACCC require as a condition of authorisation that INC revise its guidance documents covering interactions in health channels and with health professionals to achieve full compliance with the WHO International Code guidance for health workers within 2 years. These guidelines should be a formal element of MAIF. We further urge that the ACCC encourage all health professional organisations seeking ACCC authorisations to similarly add all aspects and full Code compliance into their ethical and professional codes of practice, and itself require public information on this and on systems for monitoring compliance as a condition of any authorisation of health professional association bodies' activities. AHPRA should monitor and encourage International Code compliance similarly.
4. That the ACCC account for and gather evidence of the regulatory cost to civil society organisations and individuals and compare these with the regulatory costs and net fiscal benefit of effective legislation to implement the Code and thereby increase breastfeeding in Australia.
5. That the ACCC's assessment of public benefit include marketing conduct of INC members in export markets, as required by Australia's trade practices law and human rights commitments, and that INC be required to extend the coverage of MAIF to the marketing activities of its members in export markets. This should be independently audited.

CONCLUSION

We conclude that all products marketed for infants and young children 0-36 months should be brought more firmly and clearly into Australia's food regulatory system to fully implement the WHO International Code of Marketing in line with Australia's international obligations to women and children everywhere. ACCC as Australia's consumer protection and trade practices regulatory body has an important role in this process.

It is noteworthy that a model law for implementing the International Code has long existed (Sokol & Organization, 1997), and according to the latest WHO/UNICEF monitoring report (2020), 136 (70%) of 194 reporting countries have adopted provisions of the International Code into national law. Australia is reported as being among the 58 (30%) countries that have failed to adopt any provisions into law (World Health Organization (WHO), UNICEF, & IBFAN, 2020).

Consumer protection, advertising and food laws must operate effectively together to protect breastfeeding and optimal infant and young child feeding as is longstanding Australian policy, rather than operating in silos which leave loopholes for harmful marketing of food products targeting vulnerable consumers.

The expected standards of health professional policy and practice as stated in the National Dietary Guidelines and Infant Feeding Guidelines for Health Workers should fully reflect relevant International Code guidance for health workers, and compliance with these standards should be monitored and enforced by regulatory bodies such as ACCC and through the Australian Health Practitioners Regulatory Authority.

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