Response to ACCC Queries Following Pre-Decision Conference

Question 1

We note that NHMRC guidelines set a target for 80% of Australian infants to be fully breastfed until around six months of age. Please confirm which rates of breastfeeding are reflected in the data you have provided eg. exclusive breastfeeding, partial breastfeeding, infants who are receiving any breastmilk.

INC Response

The INC uses the breastfeeding definitions provided in the Infant Feeding Guidelines and extracted below for reference.[1]

Table 1 – NHMRC definitions of categories of infant feeding

Category of infant feeding	Requires that the infant receive	Allows the infant to receive	Does not allow the infant to receive
Exclusive breastfeeding	Breast milk (including milk expressed or from wet nurse or breast milk donor)	Prescribed drops or syrups (vitamins, minerals, medicines)	Anything else
Predominant (Full) breastfeeding	Breast milk (including milk expressed or from wet nurse or breast milk donor) as the predominant source of nourishment	Liquids (water, and water-based drinks, fruit juice, oral rehydration solutions), ritual fluids and drops or syrups (vitamins, minerals, medicines)	Anything else (in particular: non-human milk, solid foods, food-based fluids)
Complementary breastfeeding	Breast milk and solid or semi-solid foods	Any food or liquid including non-human milk	
Any breastfeeding	Some breast milk	Any food or liquid including non-human milk	
Ever breastfed	Received breast milk or colostrum on at least one occasion		
Bottle-feeding	Any liquid from a bottle with nipple/ teat	Also allows breast milk by bottle	

The data presented in the INC's First Submission in response to the Draft Determination referred to ‘any breastfeeding'. The INC considers that assessing research regarding whether infants have received 'any breastfeeding' is appropriate for a number of reasons.

- First, 'any breastfeeding' data is the data most commonly collected in surveys (such as the National Health Surveys) and recent empirical studies in the Australian context (including Newby

[1] Infant Feeding Guidelines, p129.

and Davies 2014, Scott et al 2019, and Wen et al 2020). The National Health Surveys have inconsistently collected and reported on other types of breastfeeding rates. They reported on 'exclusive breastfeeding' rates in 1995, 2015, 2017, on 'fully (i.e. predominantly) breastfed' infants in 2001, and reported neither 'exclusive' nor 'full' breastfeeding rates in 2004-05. This is supported by the NHMRC Infant Feeding Guidelines (2012) which focus on assessing whether infants have been 'ever breastfed' or received 'any breastfeeding'.

> *Estimating current breastfeeding rates in Australia is limited by the use of different definitions of breastfeeding and differing study methods (see Glossary and Appendix C). Combining the results of several studies, it is estimated that 90-96% of mothers in Australia initiate breastfeeding (this is the percentage 'ever breastfed'). At 6 months of age, approximately 50-60% of Australian infants are continuing to breastfeed ('any breastfeeding').*[2]

- Second, 'any breastfeeding' data is the most valid data to report on after 6 months of age and arguably after 4 months of age in the Australian context. This is because the definitions for 'exclusive breastfeeding' and 'predominant (full) breastfeeding' do not permit any solid foods to be taken by the infant. However, multiple dietary surveys conducted in Australia demonstrate that a large percentage of parents introduce solid foods to their infant before the age of 6 months.
  - The Australian National Infant Feeding Survey (2010) reported that 91.5% of infants had commenced solids by 6 months of age.[3]
  - Scott et al (2009) reported 93% of infants had started solids in a large study conducted in Perth by 26 weeks of age.[4]
  - Newby et al (2014) reported that 98.4% of infants had started solids by 6 months of age in their cohort study.[5]

Further, in 2017 the Consensus on Australian Infant Feeding Guidelines changed the wording for the age of solids introduction from 'around 6 months' (NHMRC Infant Feeding Guidelines, 2012) to 'at around 6 months, but not before 4 months' (Netting et al, 2017).[6] It should also be noted in an Australian context that infant foods are permitted to be labelled 'From 4 months' by the Food Standards Code.[7]

Due to the narrow definitions of 'exclusive' and 'predominant' (full) breastfeeding, very few infants are being exclusively or predominantly breastfed at 6 months in Australia. As a result these rates of breastfeeding are an unreliable indication of breastfeeding rates.

To avoid concerns of reliability and availability of consistent data, the INC has preferred to rely on 'any breastfeeding rates' in its submission to the ACCC.

Question 2(a)

If the data reflects rates other than exclusive breastfeeding, please provide any data or information available which indicates how much formula partially breastfed infants may be receiving, and changes in this over the period

INC response

The INC is not aware of any data or information available which indicates how much Infant Formula partially breastfed infants may be receiving.

[2] Infant Feeding Guidelines, p11.
[3] Australian Institute of Health and Welfare, 2010 Australian National Infant Feeding Survey – Indicator Results, p11.
[4] Scott, J, et al 'Predictors of the early introduction of solid foods in infants: results of a cohort study' *BMC Pediatrics* (2009) 9:60, p3.
[5] Newby, RM, & Davies, PS, 'A prospective study of the introduction of complementary foods in contemporary Australian infants: What, when and why?' *Journal of Paediatrics and Child Health* (2014), p4.
[6] Netting et al, 'An Australian Consensus on Infant Feeding Guidelines to Prevent Food Allergy: Outcomes From the Australian Infant Feeding Summit' *Journal of Allergy Clin Immunol Pract* November/December 2017, p1622.
[7] Australia New Zealand Food Standards Code – Standard 2.9.2-7.

Question 2(b)

If the data reflects rates other than exclusive breastfeeding, please provide data on exclusive breastfeeding rates over the period (from the same or different sources).

INC Response

The table below includes data on 'exclusive breastfeeding' or 'predominant (full) breastfeeding'. The various studies rely on different definitions for each of these rates. These are set out in the table below.

Table 2 - Trends in 'exclusive' or 'fully' breastfeeding in Australia

Data source	Type of breastfeeding rate	At 2 months	At 4 months	At 6 months
1995 NHS	Exclusive breastfeeding	Not reported (63.8% at 3 months)	Not reported	7.2%
2001 NHS	Fully breastfeeding	64.3%	48.9%	16.7%
2004-05 NHS	N/A	Not reported	Not reported	Not reported
2014-15 NHS	Exclusive breastfeeding	72.6%	61.6%	24.7%
2017-18 NHS	Exclusive breastfeeding	73.8%	61%	29.1%
Wen et al 2020 (NSW)	Exclusive breastfeeding	Not reported	Not reported	4%

The Newby & Davies (2016) and Scott et al (2019) studies have not been included in the table above as these did not rely on exclusive breastfeeding rates.

Question 2(c)

If the data reflects rates other than exclusive breastfeeding, please provide information on the extent to which supplementary formula for infants affects the health benefits when compared to exclusive breastfeeding, particularly in the first six months.

INC response

Infant Formula may be considered necessary to supplement breastmilk in individual cases. Infant Formula may also be recommended by a health professional based on the individual's circumstances, or may be recommended to enable the infant's mother to return to the workforce.

The quality of data measuring the health benefits of supplementary formula feeding is limited. This is because it is difficult to isolate the causal effect of supplementary formula feeding, as there are many variables which impact on health benefit for the infant. Those factors include:

- the amount of supplemental formula,
- the country in which the formula use is occurring;
- the age at which supplementary feeding occurs – as the younger the infant, the more immature the digestive and immune systems are; and
- the type of infant formula that is supplemented.

The INC submits that:

- Based on the available data there is no evidence that 'exclusive breastfeeding' is any more protective to infants than 'any breastfeeding' with regards to obesity risk reduction.[8] The Infant Feeding Guidelines state that *'Exclusive breastfeeding to around 6 months is associated with the lowest short, medium and long-term risk of morbidity and mortality among infants'*, and *'Any breastfeeding and prolonged breastfeeding are associated with the lowest of later obesity'*.[9]
- Looking at other health outcomes, a recent study (Chin et al, 2021) conducted in the USA reported on the immune and gastrointestinal effects of supplementary infant formula use (with supplementary formula needed to have begun by one month of age). Detailed microbiome and immune development analysis was conducted.[10] The study found that '*Supplementation with formula during breastfeeding transiently changed the composition of the gut microbiome, but the impact dissipated by six months of age…These data suggest that early formula supplementation, given in addition to breast milk, has minimal lasting impact on the gut microbiome or immunity*'. However, an earlier study (Forbes et al, 2018) from Canada suggested that early formula use was associated with microbiota differences (less bifidobacteria) at 12 months of age, so further studies are needed in this area.[11]

Question 3

The data provided indicates the percentage of infants who are breastfed until 12 months increased from 21.3% (1995) to 46.8% (2014-15) then decreased to 40.8% (2017-18). Please provide information on what is known about the reasons for this decrease.

INC response

The breastfeeding rate data relied upon by the INC is intended to illustrate trends in breastfeeding rates in Australia over recent decades. The INC was particularly interested in considering this data to assess any observable trends since the MAIF Agreement came into effect (1992) and since Toddler Milks were introduced into the Australian market (in the late 1990s). The National Health Survey (***NHS***) data provided in the INC Submission includes 18 data points, 17 of which evidence an increase in the breastfeeding rate since 1995. The only anomaly is the 12 month data point from the 2017-18 NHS, which showed a breastfeeding rate of 40.8% compared to the 2014-15 NHS breastfeeding rate of 46.8% in 2014-15. No reason is provided for this change within the 2017-18 NHS Report. Indeed, the 2017-18 report states *'The rates of children receiving breast milk as well as those exclusively breastfed have remained consistent since 2014-15'*.[12]

To the extent that there was any decrease in the breastfeeding rate at 12 months of age between the 2014-15 and 2017-18 studies, the INC is not aware of the reason for this difference.

[8] NHMRC Infant Feeding Guidelines, p 11.
[9] Infant Feeding Guidelines, p11.
[10] Chin et al, 'Transient Effect of Infant Formula Supplementation on the Intestinal Microbiota' *Nutrients* March 2021.
[11] Forbes et al, 'Association of Exposure to Formula in the Hospital and Subsequent Infant Feeding Practices with Gut Microbiota and Risk of Overweight in the First Year of Life' 172(7) *JAMA Pediatrics*
[12] 'Australian Bureau of Statistics Breastfeeding – 2017-18 financial year' Available at: https://www.abs.gov.au/statistics/health/health-conditions-and-risks/breastfeeding/latest-release.

Question 4

Interested parties – including Dr Julie Smith et al, Australian Breastfeeding Association, VicHealth, Breastfeeding Advocacy Australia, and IBFAN - have cited data on breastfeeding rates from alternative sources, many of which appear to measure different feeding practices and reflect different trends to those reflected in the data provided by the INC. Please consider whether you wish to provide any comment on this other data provided and the apparent discrepancies.

The Australian Infant Feeding Guidelines (2012), published by the Australian Government and developed by the NHMRC clearly state:

- *'There have been significant increases in both the rate and duration of breastfeeding over the last few decades'*; and
- *'Australia has been successful in increasing breastfeeding rates over the last few decades…'*.

Dr Julie Smith

Dr Julie Smith submits that *'Breastfeeding duration and exclusivity has barely improved or reduced in the thirty years since APMAIF was introduced in 1992'* and that *'Breastfeeding has declined and formula markets expanded in Australia since 1992'*.[13] These comments are clearly at odds with the NHMRC's conclusions in the Infant Feeding Guidelines and the empirical evidence and findings of the nationally-representative National Health Surveys of 1995, 2001, 2004-05, 2014-15, and 2017-18 (discussed in detail in the INC's repose to Question 2(b)).

As already outlined in the INC's response to Question 1 above, caution should be exercised when considering breastfeeding exclusivity in Australia due to the strict definition of 'exclusive breastfeeding' and the common practice of introducing solids before the age of 6 months.

In addition, it appears that Dr Smith's submissions rely on state-based data rather than national data. Dr Smith does not provide any clear rationale for why state-based data is relied on. The INC submits that utilising nationally-representative data (such as the data relied on by the NHMRC) provides a more robust view of the national situation than data from individual state-based studies.

The ABA and the BAA

The Australian Breastfeeding Association (***ABA***) and Breastfeeding Advocacy Australia (***BAA***) similarly rely on state-based data, rather than the independent and nationally representative data to support the contention that breastfeeding rates are declining.

- The ABA relies on the Health and Wellbeing Survey undertaken yearly in WA over the period 2003 to 2018 (***WA Breastfeeding Data***) to conclude rates of exclusive breastfeeding to 6 months in WA have not changed since 2003 and are very similar to the 2010 Australian National Infant Feeding Survey figure of 15.4%.[14]
- The ABA also relies on the Victorian Maternal and Child Health Service data collected in clinics in Victoria from 1944 to 2017/18 (***Victorian Breastfeeding Data***) to conclude that (i) breastfeeding rates have been stable since that late 1980s; (ii) no increase in breastfeeding was seen after the signing of the MAIF Agreement in 1992; and (iii) the rates of babies fully breastfed to 6 months appear to have been falling since 2007/08.[15]
- The BAA relies on data collected as part of the NSW Mothers and Babies Report (***NSW Breastfeeding Data***) over the period 2014-2018 to conclude there has been an increase in the

[13] Dr Julie Smith et al Submission dated 11 December 2020, pp6-7.
[14] ABA Submission after pre-decision conference, p 3.
[15] ABA Submission after pre-decision conference, p 4.

use of formula in hospitals over a period of 5 years (said to be evidenced by a decrease in breastfeeding on discharge from hospital).[16]

The ACCC should exercise caution when considering this state-based data.

- The WA Breastfeeding Data presented in Figure 1 by the ABA includes considerable year to year swings in the exclusive breastfeeding rate. Notwithstanding this, the trend over time appears to be an increase in the exclusive breastfeeding rate from 13.8% in 2003 to 16.4% in 2019 (or the much higher 24.8% in 2018). The INC submits that the ACCC should exercise caution drawing conclusions from this data given the large variations in the data, its state-based nature and the use of 'exclusive breastfeeding' as a metric.
- In the Victorian Breastfeeding Data *'a fully breastfed infant is defined as an infant who does not regularly (at least once a day) receive milk other than breastmilk but may receive some solids'*. This differs from the NHMRC definition and indeed the WHO definition of 'full breastfeeding' which do not permit any infant formula use or solid foods intake, whilst the Victorian definition allows both. This highlights the difficulty in comparing rates across different studies, which may adopt different definitions and methodologies. Again, the INC submits that the ACCC should exercise caution drawing conclusions from this data given its state-based nature and the use of 'fully breastfed' as a metric.
- The BAA itself notes that the NSW data is 'minimal' and only relates to a limited sample of mothers and that they have excluded the Far West Region of NSW which recorded an increase in 'full' Breastfeeding from their analysis.[17] The INC submits that the ACCC should exercise caution drawing conclusions from this data given its state-based nature and the limitations inherent in the methodology.

VicHealth and IBFAN

VicHealth cites data based on the low exclusive breastfeeding rate at 6 months: '*Despite evidence of the benefits of exclusive and continued breastfeeding for children, women and society, rates in Australia remain sub-optimal. In 2014–15, only 24.7% of children aged 6–24 months had been exclusively breastfed to at least six months of age*.'[18]

IBFAN also cites data reported by the Australian Bureau of Statistics in support of the contention that Australia's exclusive breastfeeding rates have not increased since 2014-2015.

As previously outlined, exclusive breastfeeding rates should be carefully scrutinised in the Australian context given our feeding practices – including consensus recommendations and labelling laws – effectively allow the introduction of solid foods from 4 months of age. In this context, the 'exclusive' breastfeeding rate at 6 months will always appear to be low.

[16] BAA submission in response to application for Authorisation, dated 4 December 2020, p 3.
[17] BAA submission in response to application for Authorisation, dated 4 December 2020, p 3.
[18] IBFAN, submission before pre-decision conference, p 3.

Question 5

Further, interested party submissions have raised concerns that the INC has not demonstrated or provided evidence for the benefits it claims has resulted, and are likely to continue to result, from re-authorisation of the MAIF Agreement. Please consider whether you wish to provide any evidence or information to support the benefit claims made in the application, particularly in relation to the MAIF Agreement resulting in increased breastfeeding compared to the counterfactual.

INC response

The INC's response to this question is included in its Supplementary Submission of today's date.

Question 6

Finally, the submissions of Dr Julie Smith et al have provided data based on Euromonitor reports which indicate increasing sales in Australia across the range of breastmilk substitutes since 2006. Please consider whether you wish to provide any comment or further information on this data.

INC response

The INC's response to this question is included in its Supplementary Submission of today's date.

11 May 2021