Study of Levels of Bisphenol A (BPA) in Infant Formula and Water from Infant Feeding Bottles & Sip Cups Supplied in Australia

Australian Competition and Consumer Commission

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1. BACKGROUND

The issue of whether chronic exposure to Bisphenol A (BPA) may have harmful effects is not new. However media attention around BPA and other plasticisers, particularly in relation to infant feeding bottles and food has resulted in the ACCC conducting a study of whether measurable amounts of BPA migrated into infant formula and tap water from typical infant feeding bottles and sip cups that are on the market in Australia, at the time of the study. The study was designed to determine whether measurable migration of BPA occurs under realistic conditions of use.

2. AIM

In Australia, the regulatory responsibility for the issue of possible migration of BPA from reusable polycarbonate infant feeding bottles is of most relevance to the ACCC. The purpose of the study was to look specifically at representative products supplied in Australia and measure levels of BPA in typical infant formula to determine the quantity of BPA likely to have been contributed from the infant feeding bottles ands sip sups. The results of the study were to be used by the ACCC to estimate the exposure of Australian infants to BPA through the use of feeding bottles and assess any potential risk. The data would also be contributed to other regulatory agencies such as FSANZ who also have an interest in the issue of BPA.

3. RATIONALE

While there has been a number of studies into migration of BPA from polycarbonate infant feeding bottles many of these have not focussed specifically on bottles supplied in Australia or been accurate simulations of actual conditions of use. This is due to the use of atypical food simulants, application of extreme temperatures/ timeframes, failure to follow either suppliers instructions or typical use in relation to bottles and/or infant formula. Some migration studies would greatly exacerbate the amount of BPA migrating from PC feeding bottles to the fluid nonetheless, the amount of BPA from formula in PC bottles was a lower contribution to total intake than breast milk and comparable to the environment.

This study investigated the feeding bottles and sip cups typically supplied in Australia when used with leading brands of infant formula made up in accordance with manufacturer's instructions. As the concerns around BPA relate to the potential exposure of infants to BPA from feeding bottles it is appropriate to determine levels of BPA in infant formula (served in the bottles) as formula may be the exclusive food of the infants most exposed from this source. Water is also included in the study as this is also a significant component of the infant diet and the analysis of BPA levels in water is likely to yield a better Limit of Quantification and also give information about the possible levels of BPA in the formula itself.

4. METHODOLOGY

A total of 30 samples of liquid infant formula and water made up in either polycarbonate bottles/sip cups, claimed BPA free bottles/sip cups and glass. The table below summarises the analysis conducted.

Feeding Vessel	Infant formula A Nutricia Karicare *	Infant formula B Wyeth S-26 *	Tap water	Tap water 24 hour steep
PC# Bottle 1	♦	♦	♦	
PC# Bottle 2	♦	♦	♦	
PC# Bottle 3	♦	♦		♦
PC# Bottle 4	♦	♦		♦
PC# Sip Cup	♦	♦	♦	
Non PC# bottle 1	♦	♦	♦	
Non PC# bottle 2	♦	♦		♦
Non PC# bottle 3	♦	♦		♦
Non PC# sip cup	♦	♦	♦	
Glass bottle	♦	♦		♦

* *Leading infant formula brands (A- Nutricia Karicare Gold 1 from Birth & B – Wyeth S-26 Original Progress from 6 months)*

\# *Determination of whether a vessel is PC or not, is based solely on supplier information available at point of purchase.*

A key element of the study was to best represent infant feeding products typically supplied and used in Australia at present. A range of infant feeding bottles and sip cups was purchased from major retail outlets. These products included 5 polycarbonate plastic vessels, 4 self claimed 'BPA free' vessels and 1 glass bottle. In all cases the teats that were supplied with the vessels were correctly attached to the vessel and the fluid for analysis passed through the teat.

Two leading brands of infant formula were purchased from major retailers of infant products. One formula was for infants from birth while the other formula was a progress formula that was intended for infants from 6 months. The study therefore incorporated analysis of infant formula covering the first 12 months of life.

The infant formula and vessels were provided directly to the analytical laboratory. The table below provides the samples information.

Photograph 1 – Infant feeding bottles and sip cups used in the analytical survey

Feeding Vessel	Product description	Purchase details
PC# Bottle 1	The Wiggles 2 x 250ml Feeding Bottles Distributed by Funtastic Ltd Glen Waverley VIC 3150 Made in Thailand	15 February 2010 Toys R Us Belconnen ACT
PC# Bottle 2	Tommee Tippee 260ml twin pack designer bottles with silicone teats Made in Thailand	15 February 2010 Woolworths supermarket Belconnen ACT
PC# Bottle 3	AVENT Airflex feeding bottle 125ml Au 1300 364 474 Made in England	15 February 2010 Kmart Belconnen ACT
PC# Bottle 4	Pigeon Standard-neck Bottle 150ml Peristaltic Nipple Made in Indonesia	15 February 2010 Toys R Us Belconnen ACT
PC# Sip Cup	Heinz Baby Basics First Trainer Cup With Handles Distr by Nice Pak Products Moorabin VIC 3189 Made in China	15 February 2010 Kmart Belconnen ACT
Non PC# bottle 1	Nuby Natural Touch Softflex Natural Nurser - 0% Bisphenol A Dist by Nuby Aust Heatherton VIC 3202 Made in China	15 February 2010 Toys R Us Belconnen ACT
Non PC# bottle 2	Tommee Tippee easier to combine	15 February 2010

	breast and bottle feeding 260ml bottle	Terry White Chemist Belconnen ACT
Non PC# bottle 3	Bebelle Baby Bottle 250 ml BPA free McPherson's Consumer Products Kingsgrove NSW 2208 Made in Thailand	15 February 2010 Kmart Belconnen ACT
Non PC# sip cup	Nuby Non drip standard neck bottle with handles BPA free Dist by Nuby Aust Heatherton VIC 3202 Made in China	15 February 2010 Toys R Us Belconnen ACT
Glass bottle	NUK Air system glass bottle 120 ml Distributed by Simes Australia Pty Ltd SA 50	15 February 2010 Terry White Chemist Belconnen ACT
Infant Formula A	Nutricia Karicare Gold 1 from Birth Batch 9034 Production Feb 2009 Use by April 2010	15 February 2010 Toys R Us Belconnen ACT
Infant Formula B	Wyeth S-26 Original Progress from 6 months MFGD 17 06 2009 Use by 15 06 2012 Batch 9168 0018	15 February 2010 Kmart Belconnen ACT

Photograph 2 – Infant formula used in the analytical survey

4.1 Preparation of bottles and sip cups

Typical preparation instructions for infant feeding bottles are for the bottle to be washed and scrubbed with a bottle brush and then boiled in water. It is also common practice in Australian households to use a dishwasher to clean bottles and cups. There has been speculation that newer bottles may contribute more to BPA migration in their initial use but there has also been the suggestion that older scratched vessels may release more BPA. This study will purchase leading brands of new bottles and clean them once and then place them in boiling water to 'sterilise' them.

- The new bottles should be unpacked and all parts placed in a domestic dishwasher and run for one full cycle with standard dishwasher detergent. All bottles may be washed in the same load.
- Prior to analysis place each bottle and the parts such as the teats in a stainless steel pot and cover with tap water.
- Make sure there are no air bubbles trapped inside the bottles.
- Put the saucepan lid on and bring to the boil.
- Allow five minutes of rapid boiling.
- Turn off heat remove bottles and parts and allow to cool to room temperature before filling with infant formula or water.
- Note each bottle should be boiled in separate and new water to avoid the possibility of cross contamination.

4.2 Preparation of infant formula

Two top selling brands of infant formula were used to best represent the typical formula used in Australia. Formula will be made up in accordance with the suppliers instructions as set out on the product information to best represent the correct and typical preparation and consumption. The following text is the instructions for one brand of infant formula and these are indicative of instructions provided in Australia.

> Check the expiry date on the packaging to make sure contents are within the use by date.
> Always wash your hands thoroughly and sterilise bottles and utensils before starting to prepare your formula.
> Follow instructions on the can regarding the correct ratio of water to powder scoops, as this may vary between formulas.
> Always use cooled, boiled water for baby's formula. Boil fresh drinking water for a minimum of five minutes, then cover and allow to cool.
> Prepare each bottle individually, adding first water then powder in that order.
> To correctly measure the powder, use the scoop provided in the can (it is important to note that scoops can vary in size between different formulas). Don't tap a filled scoop on the side of the tin as this will pack down the powder. Use a sterilised knife or something similar to level off the contents at the top – and add to the bottle.
> Do remember to close the can immediately and store it in a cool dry place such as in a pantry to avoid moisture affecting the quality of the powder.
> Seal the bottle tightly then shake until the contents are mixed. Ideally, formula should be prepared just prior to feeding, otherwise refrigerate prepared formula and ensure it is used within 24 hours. (Note: For S-26 AR, avoid making up in advance for best results.)
> To warm up the bottle, stand it in a jug of warm water for a time. DO NOT use the microwave to heat up baby's feed. Microwave ovens heat liquids unevenly and may create 'hot spots' in the milk.
> Test the temperature of the milk on your wrist before feeding to make sure it is not too hot for your baby.
> Any unfinished formula milk should be discarded immediately. Never save unfinished milk for the next feed as it may then harbour bacteria.

The bottles were filled with infant formula and stood in a saucepan of warm water heated to 35°C - 40°C to reflect the practice of warming bottles to a maximum body temperature range. The bottles to be filled with tap water were not heated as this is not usual practice.

All the formula samples and 5 of the tap water samples were allowed to stand in the bottle for a period of two hours prior to the sample being drawn down for analysis. A uniform 2 hour steep period represents the maximum period that a made up bottle of formula may take to consume. Instructions on infant formula strongly advise for bottles to be made up immediately before feeds and state that unconsumed formula should be discarded.

The remaining 5 tap water samples were allowed to steep for 24 hours to represent the possibility that tap water in bottles or sip cups may be left in the vessel for longer periods and later consumed, particularly by older infants/toddlers.

In all cases the sample for analysis was drained out from the bottle/cup through the teat or orifice as it would be taken into the mouth by an infant.

5. ANALYTICAL METHOD

Analysis was undertaken by the National Measurement Institute using a validated a method of High Pressure Liquid Chromatography with fluorescence detection for the formula matrix. The Limit of Reporting/Quantification was 10 micrograms/kilogram equivalent to 10 parts per billion (ppb) which is sufficiently sensitive to provide useful safety data.

6. RESULTS

As indicated in the table below, no BPA was detected in any of the samples tested.

Feeding Vessel	Infant formula A Nutricia Karicare *	Infant formula B Wyeth S-26 *	Tap water	Tap water 24 hour steep
PC# Bottle 1	ND	ND	ND	
PC# Bottle 2	ND	ND	ND	
PC# Bottle 3	ND	ND		ND
PC# Bottle 4	ND	ND		ND
PC# Sip Cup	ND	ND	ND	
Non PC# bottle 1	ND	ND	ND	
Non PC# bottle 2	ND	ND		ND
Non PC# bottle 3	ND	ND		ND
Non PC# sip cup	ND	ND	ND	
Glass bottle	ND	ND		ND

* *Leading infant formula brands (A- Nutricia Karicare Gold 1 from Birth & B – Wyeth S-26 Original Progress from 6 months)*

\# *Determination of whether a vessel is PC or not, is based solely on supplier information available at point of purchase.*

ND = *Non detection at a Limit of Quantification of 10 micrograms/kilogram which is equivalent to 10 parts per billion (ppb)*

The Limit of Reporting/Quantification was 10 micrograms/kilogram or 10 parts per billion (ppb). The analyst's additional qualitative commentary was that every one of the chromatographs was very flat and clean with no suggestion of any detections of BPA.

7. CONCLUSIONS

The Product Safety Hazard Response Branch of the ACCC has assessed the results of this study in the context of other published studies of BPA migration from vessels. These results are consistent with other studies (see Attachment A) that reflect actual use conditions and reaffirm the ACCC's position that there is no quantifiable exposure to BPA in Australian infants from polycarbonate feeding vessels. Infant exposure to BPA from feeding bottles and sip cups supplied in Australia is not of concern.

Typical infant feeding bottles and infant sip cups that are currently available on the Australian market do not expose infants to detectable amounts of Bisphenol A and are safe for their intended purpose.

In terms of potential infant exposure to Bisphenol A, there is no discernable difference in safety between the use of glass, non-polycarbonate plastic and polycarbonate plastic infant feeding vessels.

There is no sound factual basis for suppliers of non-polycarbonate infant bottles and sip cups to assert that their products are safer than polycarbonate infant bottles and sip cups due to the composition of the plastic.

Bisphenol A is also not present in detectable quantities in two leading brands of infant formula supplied in Australia namely, Nutricia Karicare Gold 1 from Birth and Wyeth S-26 Original Progress from 6 months.

Bisphenol A is also not present in detectable quantities in Melbourne tap water.

The study was well conducted and provided timely and useful information to inform the risk assessment undertaken by the ACCC Product Safety Hazard Response Branch.

Attachment A

Summary of other BPA from polycarbonate bottle studies

Each of the studies conducted by the government agencies included or focused entirely on baby bottles. In most cases, new baby bottles were studied under well-characterized laboratory conditions. In each case, migration of BPA from new baby bottles, when detected, was less than 5 parts per billion.

The Japanese National Institute of Health Sciences (Kawamura et al, 1998) conducted the most sensitive study on 4 commercially available baby bottles. Because of the use of food simulants (i.e., water, 20% ethanol, 4% acetic acid, heptane), which facilitate the analytical measurement of BPA, the limit of detection was 0.5 parts per billion. Temperature and time conditions as severe as 30 minutes at 95oC followed by 24 hours at room temperature were examined. With the exception of one data point, migration of BPA was less than 1 part per billion for all test conditions and, for the majority of samples, no BPA was detected at the 0.5 part per billion limit of detection. The one exception involved a new unwashed bottle, which resulted in migration of 3.9 parts per billion. After washing, migration from this bottle decreased to the limit of detection.

A similar study was sponsored by the United Kingdom's Department of Trade and Industry (DTI), Consumer Affairs Directorate, Consumer Safety Research program and conducted by LGC Ltd (Earls et al, 2000). The study examined 21 new baby bottles purchased from various retail outlets in the London area and tested under "realistic worst-case conditions of use." The bottles were washed and sterilized, filled with either boiling water or 3% acetic acid solution, capped, and placed in a refrigerator for 24 hours at 1-5oC. After warming briefly, the contents were analyzed using a method with a 10 part per billion limit of detection. In every case, no BPA was detected.

The U.S. Food and Drug Administration and the U.K. Ministry of Agriculture, Fisheries and Food (MAFF) both measured migration of BPA from polycarbonate baby bottles into infant formula or fruit juice. In the FDA study (Biles et al, 1997), bottles were washed, sterilized, filled with apple juice or infant formula and refrigerated for 72 hours. These conditions were characterized as typical or normal. No BPA was found in any sample with a 100 part per billion limit of detection. Likewise, in the extensive UK MAFF study (Mountfort et al, 1997; MAFF, 1997), baby bottles were repeatedly processed through a sequence in which the bottles were washed, sterilized (three methods tested), filled with fruit juice or infant formula, warmed in a microwave oven, cooled, and analyzed. After as many as 30 cycles, BPA was not detected in any sample with a 30 part per billion limit of detection. In addition, no detectable levels of BPA were found when the bottles were periodically filled with water and held at 40oC for 10 days.

In the UK DTI study, a small number of used baby bottles of uncertain age and history were also tested under the same conditions as the new bottles. For both water and 3% acetic acid solution, no migration was detected in 8 of the 12 bottles tested. In 4 bottles, migration of BPA was detected at levels of 20 to 50 parts per billion. However, the results were inconsistent and there was no correlation between migration levels and the food simulant, estimated age of the bottles or sterilization method reported to have been used. After reviewing all available migration data on new and used bottles as well as other polycarbonate articles, the European Commission's Scientific Committee on Food concluded, "There is no significant effect from repeated-use, abrasion, heating, or chemical sterilization of these plastic articles." (SCF, 2002)