

Bottles can Be Toxic



**An Investigative Study
On Bisphenol-A (BPA) in
Baby Feeding Bottles in India**



Toxics Link
for a toxics-free world





ABOUT TOXICS LINK

Toxics Link is an Indian environmental research and advocacy organization set up in 1996, engaged in disseminating information to help strengthen the campaign against toxics pollution, provide cleaner alternatives and bring together groups and people affected by this problem.

Toxics Link's Mission Statement - "Working together for environmental justice and freedom from toxics. We have taken upon ourselves to collect and share both information about the sources and the dangers of poisons in our environment and bodies, and information about clean and sustainable alternatives for India and the rest of the world"

Toxics Link has a unique expertise in areas of hazardous, medical and municipal wastes, international waste trade, and the emerging issues of pesticides, Persistent Organic Pollutants (POPs), hazardous heavy metal contamination etc. from the environment and public health point of view. We have successfully implemented various best practices and have brought in policy changes in the aforementioned areas apart from creating awareness among several stakeholder groups.

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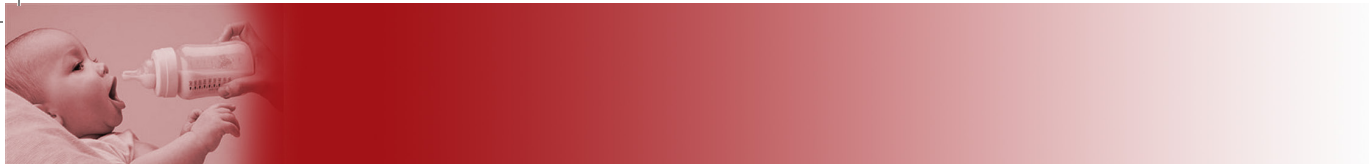




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Abbreviations

AIST: Advanced Industrial Science and Technology

ASRM: American Society for Reproductive Medicines

ASTM: American Society for Testing & Materials

BIS: Bureau of India Standards

BPA: Bisphenol A

ECB: European Chemicals Bureau

EDC: Endocrine Disrupting Chemical

EFSA: European Food Safety Authority

ER: Epoxy Resins

FDA: Food and Drug Administration

GC MS: Gas Chromatography- Mass Spectrometry

HDPE: High Density Polyethylene

IMS Act: Indian Milk Substitute Act

LDPE: Low Density Polyethylene

NOAEL: No Observed Adverse Effect Level

PC: Polycarbonate

PETE: Polyethylene Terephthalate

PP: Polypropylene

ppm: parts per million

SAICM: Strategic Approach to International Chemical Management

TDI: Tolerable Daily Intake

WHO: World Health Organisation





Foreword

The use of chemicals in everyday human life is increasing and almost every aspect of our lives is touched and impacted by chemicals and more chemicals continue to be introduced into the market. These chemicals are added to products to enhance many properties and the market potential of the products while these synthetic chemicals have never been tested for their impacts on human health or on environment. There is growing body of evidence suggesting adverse impacts of these chemicals on environment and human health.

There is an increasing range of such chemicals being used in everyday products that demonstrate properties of endocrine disruption and these chemicals are also used in children's products. This is a matter of serious concern though there is very little information available on such chemicals in India while globally serious debate is ongoing for identifying chemicals which demonstrate properties of endocrine disruption and serious health impacts. One such chemical is Bisphenol-A (BPA) that is widely used in manufacturing of plastics also products exclusively used by children. There are many countries which have started to regulate the use of BPA and other chemicals that exhibit endocrine disrupting properties. In India too there is an attempt to regulate the use of BPA in "feeding bottles" but such a notification is yet to be issued. Chemicals that classically demonstrate properties of endocrine disruption are recent and intense research is ongoing in many countries and is under serious consideration for strict regulation to minimize its usage and exposure.

The current study efforts to create new data on usage of BPA in India also to initiate discussion on such chemicals and the kind of safety and control measures required to use and manage such chemicals. It also attempts to start discussion with industry and government on the issue of product safety and the issue of standards. The study is an attempt to bring the issue of BPA its health impacts and aspect of standards into public domain and create conversation around these critical areas. Though the sample size is small but its findings and results are indicative and provide many opportunities for more in-depth research and new data and conversation on the subject of Endocrine Disrupting Substances. This is a sincere attempt to create opportunity and environment to discuss issues related with such chemicals, perhaps it sets the ball in motion and invites many players into the arena.

Satish Sinha

Associate Director



1 - INTRODUCTION

1.1 About Bisphenol -A (BPA)

Bisphenol A (BPA) or 2,4-isopropylidenediphenol is a carbon-based synthetic compound with the chemical formula $(\text{CH}_3)_2\text{C}(\text{C}_6\text{H}_4\text{OH})_2$ belonging to the group of diphenylmethane derivatives and Bisphenols.¹ BPA was first synthesized in 1881 and is primarily used as a monomer for the manufacture of polycarbonates²

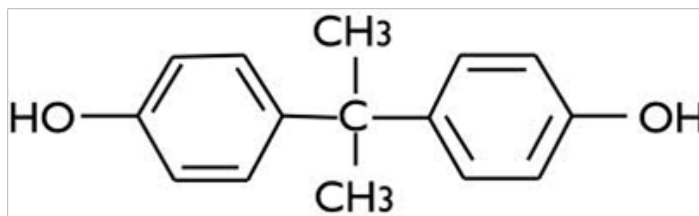


Figure 1 Chemical structure of Bisphenol A

At present two kinds of BPA based plastics are available in the market: one is Polycarbonate (PC), and the other one is Epoxy Resins (ER). Polycarbonates are generally used in baby feeding bottles, dental sealant, tooth coatings, carbonless paper and plastic toys^{3,4}.

ERs are used as protective coatings for food and beverage container, bonding & adhesives, flooring, paving & construction, composites, electrical & electronic laminates, embedding & tooling, vinyl ester resins and other. The surface lining of the food containers accounted for about 50 % of all ER consumption.

1.2 Baby Feeding Bottles

A baby feeding bottle is a bottle with a teat to drink directly from. It is typically used by infants and young children when a mother does not breastfeed, or if someone cannot (as conveniently) drink from a cup, for feeding oneself or being fed. A study conducted by the World Health Organization (WHO) found that Baby feeding bottles are used by 60% of parents either immediately after childbirth or after a breast feeding period of approximately 4 months.

The baby feeding bottles have been emerging as an important market across the globe. The global market trend shows that the overall market size of the baby feeding bottles during 2009 -14 is 2.47 \$ billion and India accounts 5% of the total global market share of the baby feeding bottles. And there is upwards trend of the sales mostly in the urban areas of the country.



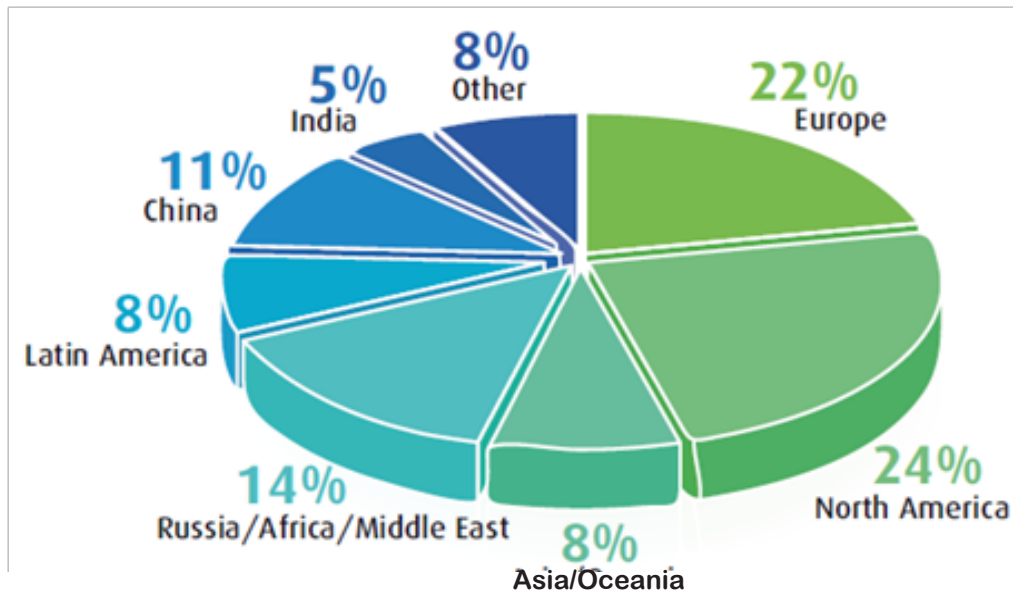


Figure 2 Geographical split of the baby bottles market worldwide

Sources: Icon Group "The 2009-2014 World Outlook for Baby Bottles" - Philip M. Parker, Ph.D/SGD

The feeding bottles in India are regulated by the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 as Amended in 2003 (IMS Act). The act mandates that all the baby feeding bottles to be sold in India will be subjected to the standard IS-14625 specified by the Bureau of Indian Standards (BIS). The IS-14625 was adopted in 1999 and has been revised in 2002 and 2004 considering certain environmental parameters. According to the 2002 amendment of IS-14625, only virgin Polycarbonate is allowed for the baby feeding bottles. The Bureau of Indian Standards (BIS) has revised the standard for baby feeding bottle in 2013. The draft notification has stated that BPA will not be used in the baby feeding bottles. However the draft has not been published yet.





2. STUDY RATIONALE

Bisphenol-A (BPA) as a chemical has been widely used in various products.

However research studies have indicated that BPA has the potential to impact the endocrine system of human beings and has been designated as an Endocrine Disrupting Chemical (EDC).

2.1 BPA and Human Health

- The epidemiological studies found correlations between BPA exposure and heart diseases, liver toxicity and metabolic syndrome (diabetes obesity);⁵
- A study conducted in USA in 2009 reported an average of 2.8 ng/mL BPA in the blood of 9 out of the 10 umbilical cords tested;⁶
- Another study conducted on 244 mothers found that exposure to BPA before birth could affect the behavior of girls' at age 3. Those girls, whose mother's urine contained high levels of BPA during pregnancy scored worse on tests of anxiety and hyperactivity.⁷
- American Society for Reproductive Medicine's (ASRM) found that women with the highest levels of BPA in the blood are more likely to miscarry than women with the lowest levels of the BPA.;⁸
- Researchers have reported that exposure to low doses of BPA lead to disruptive effects in androgen or estrogen responsive tissues, within the immune system, the thyroid, and the developing nervous system.;⁹⁻¹⁰
- Some studies in animal have confirmed that BPA can cause change in prostate growth and development, mammary gland organization, sexually dimorphic behavior, onset of oestrus cyclicity, early puberty, body weight, genital malformations.;¹¹⁻¹²

Endocrine disrupting chemical (EDC) is defined as “an exogenous agent that interferes with the production, release, transport, metabolism, binding, action, or elimination of natural hormones in the body responsible for the maintenance of homeostasis and the regulation of developmental processes”. The issue of EDCs has been considered as a serious health issue globally and has been accepted as an emerging issue in the Strategic Approach to International Chemical Management (SAICM).

2.2 Children Exposure to BPA

It has been found that generally in humans orally administered BPA is rapidly and efficiently (>95% of dose) absorbed from the gastrointestinal tract and undergoes extensive first-pass metabolism in the gut wall & in the liver. However, newborns are expected to be exposed to higher internal BPA values due to immature glucuronidation activity and impaired sulphation pathway. This makes newborns susceptible to harmful effects of BPA. Further younger





individuals usually have a higher daily intake of food/drink per volume of body than adults. This in combination with less developed systems (at least in infants) to metabolize BPA is a likely cause of higher urinary concentrations.

Numerous studies found that the BPA exposure to the children can lead to health implications.

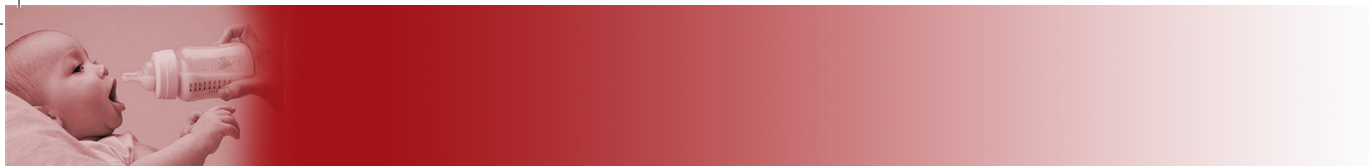
- A study on the impact of Bisphenol-A on children found that gestational BPA exposure affected behavioral and emotional regulation domains at 3 years of age, especially among girls.;¹³
- Another study found that Bisphenol-A exposure is associated with low-grade urinary albumin excretion in children of the United States.;¹⁴
- There is a research study which has linked BPA to depression and anxiety among the boys.;¹⁵
- Research shows association of urine BPA concentration and daily BPA intake estimate with BMI in Chinese school children.;¹⁶
- A recent report in April 2014 published by Institute of Functional Genomics of Lyon, France & Deakin University Metabolic Research Unit, Australia, on harmful effect of BPA on unborn babies & infants, discovered a new pathway for BPA to spread through the body via a protein known as ERR γ (Oestrogen-Related Receptor). Researchers found that ERR γ was 1000 times more sensitive to BPA than oestrogen receptors and played an important role in metabolism and added weight to the possibility that BPA could be a cause of obesity and diabetes.
- An expert panel of the U.S. National Toxicology Program concluded that BPA exposure to fetuses and to children could impact their behavioral and neural systems.;¹⁷

2.3 Leaching of BPA from Baby Feeding Bottles

Several research studies confirmed leaching of BPA from the baby feeding bottles. Brede et. al. (2003) reported migration of Bisphenol-A from PC baby bottles after dishwashing, boiling and brushing¹⁸. Similar findings have been reported from India too. Sapna et al. (2013) detected BPA up to 46.05 ppb in the water used for sterilization of baby bottles¹⁹. Recently In India, Shrinithiviahshini et al. (2014) revealed that BPA migrates from PC baby feeding bottles at on average 19ng/ml to hot water at 70°C²⁰.

Many prominent national regulatory bodies, such as the European Chemicals Bureau (ECB; 2003, 2008), European Food Safety Authority (EFSA; 2006), US Food and Drug Administration (FDA, 2008), Environment Canada and Health Canada (2008), and the Japanese National





Institute of Advanced Industrial Science and Technology (AIST; 2007) have undertaken studies to measure the hazard and risks associated with of BPA.

There are studies which suggested that even low dose BPA can also be harmful. The presence of BPA in baby bottles and its potential for children exposure, with accumulating scientific evidences on BPA toxicity, has led Toxics Link to raise the issue of BPA in baby bottles in India.





3. OBJECTIVES

BPA has been used widely in various consumer products, however its use in feeding bottles make the children particularly vulnerable, as research studies confirmed the leaching of BPA in the feeding bottles to the beverages contained in the bottles. Many countries across the globe banned the use of BPA in baby feeding bottles and have shifted to the better alternatives. Though India has formulated a standard for BPA free bottles, but it has not been published yet.

Thus the present study aims to give a perspective on the overall scenario of baby feeding bottles available in the market with the following objectives:

OBJECTIVES OF THE STUDY

- To detect the presence of Bisphenol -A (BPA) in baby feeding bottles sold in Indian market.
- To find the truth to the claim of BPA free baby feeding bottles being sold in the market.
- To highlight the urgent need of regulation in place for BPA free baby feeding bottles.
- To understand the overall consumer perspectives towards BPA and BPA free bottles in India.





4. SAMPLING & METHODOLOGY

4.1 SAMPLING

Fourteen samples of baby feeding bottles were randomly collected from three different cities in India: Delhi-NCR, Baripada (Odisha) and Bhopal (MP). From the socio-economic point of view, Delhi-NCR is a metropolitan area having high purchasing power. During the collection of the samples, we came to know that there is a consumer demand for BPA free products in the high end market in Delhi. On the other hand in Bhopal the capital city of Madhya Pradesh, there is a limited demand of BPA free products. And in Baripada, relatively a small city of Odisha, as such there is no demand for BPA free products from the consumers. The samples collected include both branded and local feeding bottle sample of different companies. Most of the samples collected have labeled polycarbonate and four of the collected samples have been labeled as BPA free and polypropylene. One of these four samples collected was labeled with “0% BPA”.

Total fourteen samples were collected and each sample was collected in triplicate. The samples were marked as TLS-1A, 1B, 1C to TLS-14A, 14 B, 14C. Then the samples were sent to the Shriram Institute for Industrial Research (SIIR), 19, University Road, Delhi-110007 for quantitative analysis of Bisphenol-A.

4.2 METHODOLOGY

Quantitative analysis of Bisphenol-A was performed as per the guidelines of **American Society for Testing & Materials (ASTM)-D7065-11** using GC-MS.

❖ SCOPE

This test method covers determination of Bisphenol-A (BPA) using gas chromatography and detected with mass selective detection.

❖ STANDARD PREPARATION

- Prepare stock solution by adding 8 μ l BPA (40,000 μ g/ml) to 10ml of methylene chloride.



Figure 3. Sample collection Site





- Aliquots of stock are diluted with methylene chloride to prepare the calibration level of 2,4,8,16,32 ng/L. A 0.50-mL aliquot of each diluted standard is transferred to a 2-mL crimp-top GC autosampler vial and 6.25 μL of a 2000 ng/ μL Internal Standard solution is added.
- The internal standards (IS) to be used are acenaphthene-d10 and phenanthrene-d10. To obtain a working internal standard at a concentration of 2000 $\mu\text{g}/\text{mL}$, 1.0 mL of internal standard stock solution at 4000 $\mu\text{g}/\text{mL}$ is diluted to 2 mL in methylene chloride.

❖ **SAMPLE PREPARATION**

- To the 2-L separatory funnel is added 1 L of sample followed by the BPA standard.
- The pH is then adjusted to 2 using sulfuric acid and shaken.
- The sample is extracted three times with 60 mL portions of methylene chloride.
- The three 60 mL methylene chloride extracts are combined in an Erlenmeyer flask.
- The water sample is then drained from the extractor and another 60 mL portion of methylene chloride is added to the separatory funnel to rinse any target analytes adhered to the surface of the glassware. This rinse is added to the extract in the Erlenmeyer flask and dried with anhydrous sodium sulfate.
- The extracts are then reduced to 0.5 mL and placed in 2 mL crimp top GC vials. 6.25 μL of a 2000 ng/ μL Internal Standard solution is added to vial and the vial is sealed.

❖ **CALCULATIONS: Detection limit is 0.1 ppm**

$$\text{Conc. } \mu\text{g}/\text{L} = \frac{(A^x) (I^s) (V^t) (D^f)}{(A^{is}) (ARF) (V^o) (V^i)}$$

where:

A^x = area of the characteristic ion for the compound to be measured,

A^{is} = area of the characteristic ion for the internal standard,

I^s = amount of internal standard injected in nanograms (ng),

V^o = volume of water extracted in milliliters (mL),

V^i = volume of extract injected in microliters (μL),

V^t = volume of the concentrated extract in microliters (μL),

D^f = dilution factor





5 RESULTS

The study results clearly indicate that most of the feeding bottles available in Indian market contain Bisphenol-A irrespective of the brands. Trace of BPA has been detected in all the samples collected from Bhopal and Baripada. BPA was also found in the branded sample.

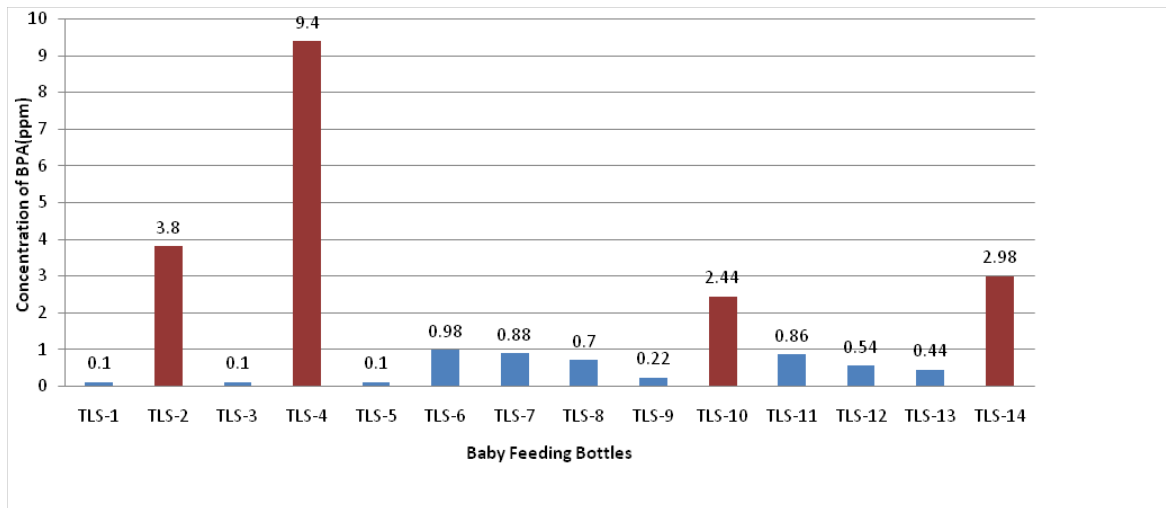
- Out of the fourteen baby feeding bottle samples analyzed 78.5% samples contain BPA.
- The maximum concentration of BPA was found to be 9.8 ppm.
- Average concentration of BPA was found to be 1.68 ppm.
- In 50% of BPA-free samples BPA had been detected above EU threshold limit of 0.6 ppm.
- BPA has been detected in a bottle that has been marked as 0 % BPA.

Table 1: Concentration of BPA (ppm) in baby feeding bottles*

Samples	Concentration of BPA (ppm)
TLS-1	0.1
TLS-2	3.8
TLS-3	0.1
TLS-4	9.4
TLS-5	0.1
TLS-6	0.98
TLS-7	0.88
TLS-8	0.7
TLS-9	0.22
TLS-10	2.44
TLS-11	0.86
TLS-12	0.54
TLS-13	0.44
TLS-14	2.98

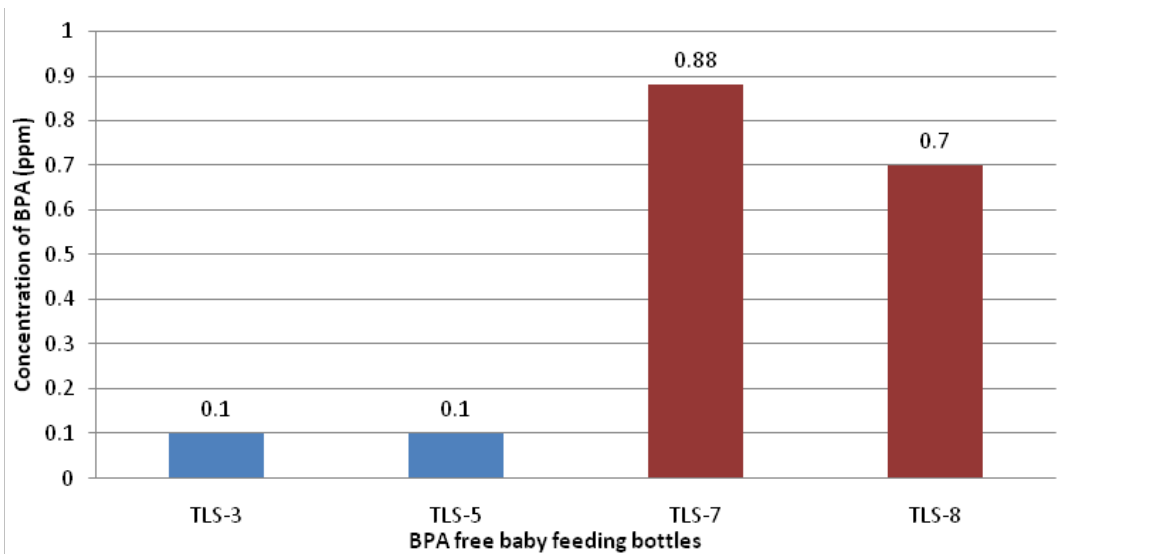
**Detection limit is 0.1 ppm*





Graph 1 Graphical representation of BPA concentration in baby feeding bottles

The above figure indicates that the concentration of BPA in TLS-1, TLS-3 & TLS-5 is below detection limit i.e. 0.1 ppm.



Graph 2. Graphical representation of BPA concentration in BPA-free baby feeding bottles

The above figure indicates that the concentration of BPA in TLS-3 & TLS-5 is below detection limit i.e. 0.1ppm while the BPA concentration in TLS-7 and TLS-8 is just above the EU threshold limit of 0.6 ppm set for BPA free bottles.¹⁷



6 CONCLUSIONS & RECOMMENDATIONS

6.1 CONCLUSIONS

The science of health impacts of BPA is now an accepted fact and serious efforts have been made by the countries to restrict the use of BPA in various products. The studies claimed that Children are most prone to the exposure of BPA due to lack of development of metabolic pathways. The exposure of children is perhaps also due to higher daily intake of food/ beverages per body volume unit than adults. So many countries across the globe have phased out and banned the use of BPA in baby feeding bottles.

Table 2 Global Regulation of BPA in Baby Feeding Bottles

Country	Regulation of BPA in baby feeding bottles
Canada	First country to ban the import, sale, and advertisement of baby bottles containing Bisphenol A.
USA	Banned
European Union	Banned the use of Bisphenol-A (BPA).
Australia	The Australian Govt. has introduced a voluntary phase out of BPA use in baby feeding bottles. The Australia and New Zealand Food Safety Authority (Food Standards Australia New Zealand) suggests the use of glass baby bottles.
Japan	Voluntary phase out by the industries
France	Banned
Germany	Banned
Denmark	Banned
Belgium	Banned
China	Banned
Malaysia	Banned
South Africa	Banned
Turkey	Banned
India	Not Banned





Further recent research in India by Shrinithiviahshini et al. (2014) and Sapna et al. (2013) revealed that BPA migrates from PC baby feeding bottles. This study further reaffirmed presence of BPA in the baby feeding bottles sold in the Indian market and the danger it poses to the children health.

We also found that there is a growing demand for BPA free feeding bottles mostly in Delhi though in other two cities there is hardly any understanding to differentiate between BPA and BPA free products. But the most disturbing fact is that the BPA has been detected in some of the bottles which have been labeled as BPA free.

6.2 RECOMMENDATIONS

Though BPA is an important chemical and has been used in wide range of the products, efforts have been made across the globe to regulate its use in various products. Apart from the baby feeding bottles, some countries have initiated actions to phase it out in other products as well, especially children products. Many countries like the USA, Canada, and the EU etc. have prioritized to study the impact of BPA in their research agenda, where the chances of contamination of the food are high. The countries have also defined the tolerable daily intake (TDI) of BPA for the human being.

However in India there are very little developments going on BPA. So considering the global developments, following points can be considered for the suitable policy actions.



STANDARD:

The revised standard to phase out BPA in baby feeding bottles has not been published yet by the Bureau of Indian Standards (BIS). So considering the positions taken by the countries across the globe BIS should notify the revised standard immediately and issue ban of BPA containing baby feeding bottles in India. As BPA has been detected in BPA free bottles, the revised standard also need to look into the threshold limit based on the scientific evidence.



POLICY DIRECTIVE:

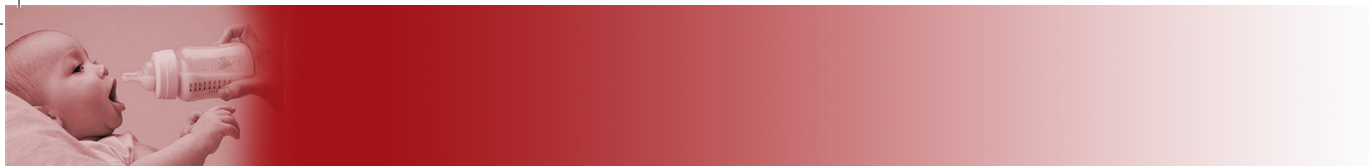
BPA has been accepted as a toxic chemical and is a reason for growing concern at a global level and so also in India. Therefore India should take some affirmative action to regulate the use of BPA in the various products especially where the possibility of the contamination in food is very high. There is also need to develop a policy for BPA free products in the market with prioritizing the products that are being used by the children.



MARKET FOR BPA- FREE PRODUCTS:

Many countries across the globe are taking steps to phase out of BPA from products. Indian industries also need to step in and promote BPA free safer products in the domestic and global market.





RESEARCH AGENDA:

The Govt. of India needs to come out with a research agenda to identify the source contamination of BPA from various products and its impact on human health.

ISSUE OF LABELING:

Alarmingly, the study also found BPA in the products that have been labeled as BPA free. Though the BPA concentration is found to be very low in BPA free products, however with growing demand for BPA free products in the market, there is fair chance of misuse of the BPA free label to push the sales of the products. Therefore there is a need for a strong monitoring system in place, to stop the passing of products in name of BPA free.

CONSUMER AWARENESS:

Consumers need to be aware on the negative aspects of BPA containing products and should use BPA free products and products from steel and glass, especially in products for children and in food containing articles. At the same time cross sections of the society need to be made aware of the issue.



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ANNEXURE-I : Details of Sample Collection

SN	Sample No.	Date of Collection	Collected from
1	TLS-1	14/03/14	Bhogal, Delhi
2	TLS-2	14/03/14	Bhogal, Delhi
3	TLS-3	18/03/14	RML Medical Store Area, Delhi
4	TLS-4	18/03/14	RML Medical Store Area, Delhi
5	TLS-5	18/06/14	Lajpat Nagar, Delhi
6	TLS-6	18/06/14	Lajpat Nagar, Delhi
7	TLS-7	18/06/14	Lajpat Nagar, Delhi
8	TLS-8	18/06/14	Lajpat Nagar, Delhi
9	TLS-9	19/06/14	Baripada, Orissa
10	TLS-10	23/06/14	Baripada, Orissa
11	TLS-11	30/06/14	Bhopal, Madhya Pradesh
12	TLS-12	1/7/2014	Viashali, Ghaziabad, U.P.
13	TLS-13	4/7/2014	Neb Sarai, Delhi
14	TLS-14	7/7/2014	Bhogal, Delhi



ANNEXURE –II: Tolerable Daily Intake (TDI) for BPA

Country/ Organization	TDI ($\mu\text{g/kg bw/day}$)
European Food Safety Authority (EFSA)	50 (soon to be 5.0 μg)
FDA EPA	50
Australia	50
Chinese	50
Korean Food Safety Authority	50
India	No standards

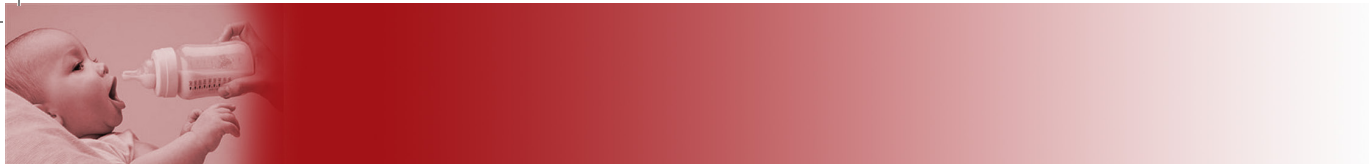


ANNEXURE –III: Usages of BPA

USES OF BPA

- | | |
|--|---|
| <ul style="list-style-type: none">• Food and drink packaging: Reusable water and infant bottles,• Impact-resistant safety equipment• Metal products
Food & beverages cans,
Bottle tops, and
Water supply pipes• Dental sealants and composites• Receipt Papers at grocery store & restaurants. | <ul style="list-style-type: none">• Precursor of flame retardant tetrabromobisphenol A• Bicycle helmets• Carsafety seats• Water coolers• Medical devices• CDs, credit cards, cell phones, computers,• Sports equipment• Household electronics• Electrical laminates |
|--|---|





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