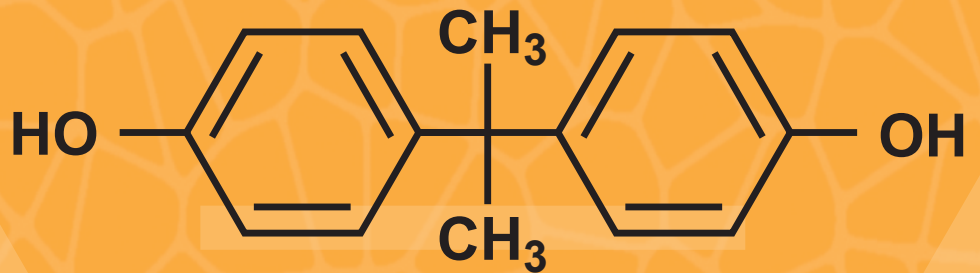


NO MORE BPA REPORT

Breast Cancer UK



NO MORE



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Breast Cancer UK

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The information, opinions and analysis are those of Breast Cancer UK alone and should not be attributed to any other organisation.

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Contents

Introduction	4
BPA and the hormonal system	4
Oestrogen levels and breast cancer	5
BPA: The body of evidence	5
BPA and breast cancer	6
BPA and other chronic health conditions	8
BPA exposure in children	8
Polycarbonate baby bottles as a source of exposure	9
Canadian Government ban of BPA baby bottles	10
The withdrawal of BPA baby bottles in the US	11
BPA and US federal action	12
US health agencies and BPA	14
Danish Parliament call for BPA bottle ban	13
The UK, EU and BPA	13
Conclusions and recommendations	15

Introduction

Bisphenol A, more commonly abbreviated to BPA, is a ubiquitous chemical with a global production at 4 billion kg in 2006.¹ It is used in the production of polycarbonate plastics that are clear and nearly shatter-proof. The plastic recycling number 7 is sometimes imprinted on polycarbonate plastics, but as the number 7 code is used as the catchall for 'other plastics', even this limited labelling is very unclear.

BPA can be found in many products including water bottles, eyeglass lenses, CDs and DVDs, household electronics, and car components. It is also synthesised as epoxy resins for coatings on the inside of food and beverage cans, including baby milk cans, as well as a component in thermal paper used for receipt printing.

BPA was known to have oestrogenic effects from as early as the 1930s. Since 1997 an extensive body of studies and reviews, aggregating to several hundred peer-reviewed scientific papers, have drawn attention to the health effects of low level exposure to BPA, at levels that are environmentally relevant i.e. that people in the UK and in the rest of the developed world are exposed to every day.

The vast majority of these studies on mice, rats and primates as well as cell cultures, have raised serious public health concerns, particularly about the exposure to very young children, who are less able to eliminate the chemical and whose hormonal system is in a rapid state of development. Many of these studies have linked adult, child and pre-natal exposure to an increased risk of breast cancer as well as many other chronic diseases.

These compelling concerns led the Government of Canada to initiate a ban on the use of BPA in polycarbonate baby bottles which will come into effect before the end of 2009. US manufacturers have pre-empted similar moves by regulators and have withdrawn BPA baby bottles from the US market.

With one in nine women in the UK affected by breast cancer at some point in their lives, Breast Cancer UK has produced this report, as part of its No More BPA campaign, to alert the public,

1 http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf

media and policy makers to the scientific case for the UK Government to bring forward public health measures to end the use of BPA in baby bottles in the UK, and for the labelling of all food contact products that contain the chemical. A move supported by over 60% of the British public.²

BPA and the hormonal system

BPA is one of a number of chemicals that can mimic the effects of oestrogen.³ Oestrogen is a natural hormone that binds itself to specific receptors in cells which in turn activate DNA to produce proteins that carry out particular functions within the body.

Because BPA can have a similar effect to oestrogen, it is described as an endocrine disrupting chemical (EDC) - effectively a chemical that can impact the endocrine (hormone) system. As a 2005 paper in the scientific journal, *Environmental Health Perspectives* makes clear: **'The widespread industrial and household use, economic importance, and near ubiquitous presence of BPA in the environment emphasize its risk as an endocrine disruptor'**.⁴

The oestrogenic effects of BPA were originally discovered in the 1930s [E. C. Dodds and Wilfrid Lawson, *Synthetic Oestrogenic Agents without the Phenanthrene Nucleus*, *Nature*, 137 (1936), 996.]. In the 1940s it was proposed for use as a pharmaceutical drug but was dropped in favour of a similar chemical with a more pronounced oestrogenic effect. Between the 1940s to the 1970s, the alternative chemical, Diethylstilbestrol (DES), was actively marketed as an aid to pregnant women suffering from morning sickness and to reduce the rate of miscarriage.

2 http://www.breastcanceruk.org.uk/reports/YouGov_Results_Breast_Cancer_UK_BPA.xls

3 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2199305/?tool=pmcentrez>, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1220264/>, <http://www.environment-agency.gov.uk/business/topics/pollution/39131.aspx>

4 <http://www.questia.com/googleScholar.qst;jsessionid=LDzJ1R1c8P2vydJyJJh8pD1yPkNm23n169L5sPsnrYGVl8L2yhP!-891952362!-368539431?docId=5009163607>

DES was withdrawn from use in 1971 in the US, although it was still available on prescription in the UK until 1975. Its use was eventually banned due to concerns relating to adverse effects on mothers who had been prescribed the drug. According to results from a 1984 study published in the New England Journal of Medicine: **'the incidence of breast cancer per 100,000 woman-years was 134 in the exposed group and 93 in the unexposed group'**.⁵

Subsequent studies since the early 1990s have also linked the children of mothers who took DES during their pregnancy with rare vaginal cancers and breast cancer in later life.⁶

A 2006 study measuring rates of breast cancer in the children of mothers prescribed DES published in the Cancer Epidemiology, Biomarkers and Prevention journal stated that: **'women with prenatal exposure to DES have an increased risk of breast cancer after age 40 years. The findings support the hypothesis that prenatal hormone levels influence breast cancer risk'**.⁷ This is a key assertion in the debate around BPA and breast cancer.

Oestrogen levels and breast cancer

The link between higher oestrogen levels circulating in the body and increased breast cancer risk is well established. According to Cancer Research UK: **'Oestrogen works on some types of breast cancer by triggering the cells to divide and multiply, so the cancer grows'**.⁸ Tamoxifen is an anti-oestrogen drug that has been used for over two decades to treat oestrogen-receptor positive breast cancer.

Studies conducted around Hormone Replacement Therapy have demonstrated higher incidence rates of breast cancer for women given

5 <http://www.ncbi.nlm.nih.gov/pubmed/6493300?dopt=abstr+actplus>

6 <http://www.ncbi.nlm.nih.gov/pubmed/8405194?dopt=abstr+actplus>

7 <http://www.ncbi.nlm.nih.gov/pubmed/16896041?dopt=abstr+actplus>

8 <http://www.cancerhelp.org.uk/type/breast-cancer/about/risks/breast-cancer-protective-factors>

oestrogen. For example, a 2003 study published in the BMJ Journal Evidence-Based Medicine, which looked at women who had been given oestrogen plus progestin, noted in its findings that:

'Women who received HT [Hormone Therapy] had a greater incidence of total and invasive breast cancer than did women who received placebo; in situ breast cancer cases were not increased. The increase in invasive breast cancer with HT was seen across almost all risk categories. Invasive breast tumours were larger in the HT group and were diagnosed at a more advanced stage than in the placebo group. Women who received HT also had a higher proportion of abnormal mammogram results'.⁹

BPA: the body of evidence

Both the National Institute of Environmental Health Sciences and Environmental Protection Agency in the US brought together 38 of the worlds leading scientists on BPA to: **'evaluate over 700 low dose studies'** on bisphenol A.¹⁰ The resulting document, the Chapel Hill Bisphenol A Expert Panel Consensus Statement published in the Reproductive Toxicology scientific journal in 2007 stated that:

'Exposure to BPA during different life stages differentially influences reproductive cancer etiology and progression... Importantly, much evidence suggests that these adverse effects are occurring in [laboratory] animals within the range of exposure to BPA of the typical human living in a developed country... The wide range of adverse effects of low doses of BPA in laboratory animals exposed both during development

9 <http://ebm.bmj.com/cgi/content/full/8/6/172>

10 http://www.defendingscience.org/case_studies/Battles-Over-Bisphenol-A.cfm

and in adulthood is a great cause for concern with regard to the potential for similar adverse effects in humans. Recent trends in human diseases relate to adverse effects observed in experimental animals exposed to low doses of BPA'.¹¹

A meta-analysis published in December 2007 by the US Journal Sentinel newspaper of 258 scientific studies on the effect of BPA on laboratory animals found that 80%: **'caused problems in the lab animals tested, ranging from allergies to reproductive deformities'**. It also stated that the: **'vast majority of these studies were funded by government agencies and universities'**, whilst: **'[j]ust 12% of the studies found that bisphenol A had no ill effects. Most of those studies were paid for or partially written by scientists hired by the chemical industry'**.¹²

BPA and breast cancer

A substantial number of mammalian animal laboratory studies as well as studies on cancer cell cultures over the last decade have strengthened the hypothesis that environmentally relevant levels of BPA are significant factors in increased risk of breast cancer.

The first study of its type that exposed mice to BPA, conducted by five scientists from Tufts University School of Medicine and Universidad Nacional del Litoral, published in the Biology of Reproduction journal in 2001, concluded in summary that:

'[E]xposure to low, presumably environmentally relevant doses of BPA changes the timing of DNA synthesis in the epithelium and stroma of the mammary gland, resulting in an histoarchitecture that is atypical for a virgin mouse. These changes, which are apparent long after

the period of exposure is over, strengthen the hypothesis that in utero exposure to environmental estrogens may predispose the developing fetus to mammary gland carcinogenesis in adulthood'.¹³

The authors also stated that the results were: **'striking, because these changes are associated with [breast cancer] carcinogenesis in both rodents and humans'**.¹⁴

A study published in the September 2005 edition of the Endocrinology journal, again on mice, noted:

'In conclusion, perinatal exposure to environmentally relevant BPA doses results in persistent alterations in mammary gland morphogenesis. Of special concern is the increased terminal end bud density at puberty as well as the increased number of terminal ends reported previously in adult animals, as these two structures are the sites at which cancer arises in humans and rodents'.¹⁵

While two studies on rats published in 2007 confirmed earlier results in mice, a study published in the January edition of Environmental Health Perspectives journal concluded that: **'[o]ur results demonstrate that the prenatal exposure to low doses of BPA perturbs mammary gland histoarchitecture and increases the carcinogenic susceptibility'**.¹⁶

While a study on rats published in the April 2007 edition of Reproductive Toxicology stated that: **'fetal exposure to 2.5, 25, 250 and 1000 microg bisphenol A/kg body weight/day induces the development of ductal hyperplasias and carcinoma in situ at postnatal day 50 and 95 in rats. These highly**

11 <http://www.environmentalhealthnews.org/newscience/2007/2007-0801bpaconsensus.pdf>

12 <http://www.jsonline.com/watchdog/watchdogreports/34406849.html>

13 <http://www.bioreprod.org/content/65/4/1215.full>

14 <http://www.bioreprod.org/content/65/4/1215.full>

15 [http://www.ncbi.nlm.nih.gov/pubmed/15919749?ordinal_pos=1&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_SingleItemSuppl.Pubmed_Discovery_RA&linkpos=3&log\\$=relatedarticles&logdbfrom=pubmed](http://www.ncbi.nlm.nih.gov/pubmed/15919749?ordinal_pos=1&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_SingleItemSuppl.Pubmed_Discovery_RA&linkpos=3&log$=relatedarticles&logdbfrom=pubmed)

16 [http://www.ncbi.nlm.nih.gov/pubmed/17366824?ordinal_pos=1&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_SingleItemSuppl.Pubmed_Discovery_RA&linkpos=2&log\\$=relatedarticles&logdbfrom=pubmed](http://www.ncbi.nlm.nih.gov/pubmed/17366824?ordinal_pos=1&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_SingleItemSuppl.Pubmed_Discovery_RA&linkpos=2&log$=relatedarticles&logdbfrom=pubmed)

proliferative lesions have an increased number of estrogen receptor-alpha positive cells. Thus, fetal bisphenol A exposure is sufficient to induce the development of preneoplastic and neoplastic lesions in the mammary gland in the absence of any additional treatment aimed at increasing tumor development'.¹⁷

A review specifically on these and other recent mice and rat studies by four scientists published in the February 2008 edition of the *Basic & Clinical Pharmacology & Toxicology* journal, that referenced 48 peer reviewed studies dating back more than a decade and a half, was more explicit in its findings and implications:

'From a practical perspective, it is now evident that animals and human beings are affected by environmental exposure to hormonally active chemicals at levels previously considered to be irrelevant. These data should raise concerns about the potentially deleterious impact of endocrine disrupting chemicals on human development. Extrapolating evidence from animal studies to human beings should be done cautiously, as differences among strains and species have been reported regarding a variety of parameters. However, the mouse and rat have been shown to be excellent surrogate models for the understanding of the diethylstilboestrol syndrome. All of this evidence should encourage regulatory agencies to apply the precautionary principle and thus ban or substitute those chemicals that are likely to be harmful to the normal development of human beings and animals'.¹⁸

Alongside the animal studies, since 2001 scientists examining the effect of BPA on human breast cancer have demonstrated that the chemical can enhance the proliferation of breast cancer

¹⁷ <http://www.ncbi.nlm.nih.gov/pubmed/17123778>

¹⁸ <http://www3.interscience.wiley.com/cgi-bin/fulltext/119425373/HTMLSTART>

cells that have been cultured in the lab.¹⁹ These findings have been confirmed in numerous other peer reviewed papers, including a study published in the journal of *Pharmacology and Toxicology* in April 2003,²⁰ as well as a 2008 study conducted by scientists at University College London.²¹

A 'Priority Report' study published in the April 2008 edition of the *American Association of Cancer Research*, conducted at the California Pacific Medical Center Research Institute, in collaboration with the Stanford Genome Technology Center, presented findings on BPA exposure to human non-cancerous breast cells.

The researchers extracted small amounts of non-cancerous breast cells from women at high risk of breast cancer or of its recurrence. The cells were exposed to BPA and analysed to see if exposure had altered the gene expression of those cells.²²

Commenting on the findings the Principle Investigator and co-author of the study, Shanaz Dairkee, Ph.D., stated that **"We screened 40,000 genes in normal human cells that had been exposed to BPA and found a striking increase in the sets of genes that promote cell division, increase cell metabolism, and increase resistance to drugs that usually kill cancer cells, and prevent cells from developing to their normal mature forms"** and continued, **"[b]reast cancer patients with this kind of gene expression [brought about through exposure to BPA] tend to have a higher recurrence than other patients, and they have a worse survival rate"**.²³

William Goodson, M.D., Senior Clinical Research Scientist at the Institute and lead Researcher on the study also commented **"Our use of fresh cells for short term cultures in this research is unusual in medical research, which makes the results especially useful because this is the closest we can ethically get to studying the effects of giving BPA directly to living people"**.²⁴

¹⁹ <http://www.jstor.org/pss/4295211>

²⁰ <http://www3.interscience.wiley.com/journal/120094857/abstract>

²¹ <http://carcin.oxfordjournals.org/cgi/reprint/bgn138v1>

²² <http://cancerres.aacrjournals.org/cgi/content/full/68/7/2076>

²³ <http://www.sciencedaily.com/releases/2008/04/080401231554.htm>

²⁴ <http://www.sciencedaily.com/>

A review of Environmental Pollutants and Breast Cancer published in the June 2003 edition Environmental Health Perspectives journal that covered over 120 studies and articles stated that: **'[s]trong toxicologic evidence points to a large number of ubiquitous pollutants that are plausibly linked to breast cancer because they mimic or disrupt hormones known to affect breast cancer risk, initiate mammary tumors in animals, or permanently alter breast development, affecting susceptibility.'** It concluded that: **'[e]ven if the relative risks of environmental factors are modest, discovery of a risk that can be modified would save many thousands of lives'**.²⁵

BPA and other chronic health conditions

A study published in the Journal of American Medical Association in the 2008 September edition: **'found that higher urinary concentrations of BPA were associated with an increased prevalence of cardiovascular disease, diabetes, and liver-enzyme abnormalities. [And that] These findings add to the evidence suggesting adverse effects of low-dose BPA in animals'**. The study examined statistically significant links between the responses to a questionnaire about common chronic health conditions and levels of urinary BPA from data collected by the US National Health and Nutrition Examination Survey of 2003-2004. In total data from 1455 adult participants, aged 18 through 74 years were analysed.²⁶

Other laboratory studies have also been published linking BPA with prostate cancer²⁷ and as a potential factor in obesity.²⁸

While a study on non-human primates published in the September 2008 edition of the Proceedings of the National Academy of Sciences of the United States of America journal gave BPA over a 28 day period at the: **'daily dose equal to the current US Environmental Protection Agency's reference safe daily limit'**.²⁹

In a press release from Yale University accompanying the publication of their study, the authors: **'found that BPA inhibits creation of the synaptic connections in the hippocampus and prefrontal cortex, areas of the brain involved with regulation of mood and formation of memory'**.³⁰

Commenting on the report, the study's co-author and associate research scientist at Yale, Tibor Hajszan, stated that **"[o]ur primate model indicates that BPA could negatively affect brain function in humans"** and that **"Based on these new findings, we think the EPA may wish to consider lowering its 'safe daily limit' for human BPA consumption"**.³¹

Hajszan also commented that although daily exposure of an average person to BPA usually does not reach the level that was applied in this study, human exposure to BPA is not limited to a single month, but rather is continuous over a lifetime. **"The negative effect of BPA may also be amplified when estradiol levels are naturally lower than in healthy adults. That is why exposure to BPA may particularly be risky in the case of babies and the elderly"**.³²

The study concludes: **'Although additional studies are needed, especially in primates, these findings further amplify concerns about the widespread use of BPA in the production of materials used in food preparation and storage'**.³³

BPA exposure in children

Babies are more susceptible to BPA than adults, for three major reasons. Babies under 12 months have greater difficulty metabolising BPA because the key liver enzymes required to eliminate BPA from the

releases/2008/04/080401231554.htm

25 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241551/pdf/ehp0111-001007.pdf>

26 <http://jama.ama-assn.org/cgi/content/full/300/11/1303>

27 http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TC0-4M62KBX-1&_user=10&_rdoc=1&_fmt=&_orig=search&_sort=d&_docanchor=&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=bfbfd09ea793e84d428533d429643ec1

28 <http://www3.interscience.wiley.com/journal/119398213/abstract>

29 <http://www.pnas.org/content/105/37/14187>

30 <http://opa.yale.edu/news/article.aspx?id=5978>

31 <http://opa.yale.edu/news/article.aspx?id=5978>

32 <http://opa.yale.edu/news/article.aspx?id=5978>

33 <http://www.pnas.org/content/105/37/14187.full.pdf>

blood and body are substantially lower in infants than those of an adult. In addition, babies exposed to levels of BPA similar to adults receive much higher concentrations due to their smaller body mass. Furthermore, the newborn is more susceptible because its hormonal system is not fully developed.

In a paper published in the April 2009 edition of *Environmental Health Perspectives* journal, two scientists applying chemical mathematical modelling estimated that in a newborn child BPA: **'concentrations at steady state were a maximum of 11 times higher than that in adults'**. The scientists make clear that uncertainties in the rate at which adults clear BPA from their bodies is also represented in their modelling and that: **'these values represent preliminary estimates'**.³⁴

Another author of the study, Prof. Len Ritter, Department of Environmental Biology at Guelph University and Executive Director of the Canadian Network of Toxicology Centres, was, however, quoted as saying in a press release accompanying the study that **"Governments need to move quickly to reduce or eliminate exposure as much as possible, especially in the very young"**.³⁵

These findings were consistent with another study published in April 2009 looking at BPA exposure in premature infants, where samples from 41 babies showed that levels were around 10 times higher than the average adult population and about twice as high as children aged between 6-11. The report noted that: **'[e]arly-life exposures are of great concern with regard to the potential for adverse health consequences throughout the life span'**.³⁶

The findings of a much wider study of urinary concentrations of BPA in 2,517 US participants aged six years and over during 2003-2004, published in January 2008, found that measurable BPA levels were found in 92.6% of the population but that children aged 6-11 and adolescents aged 12-19 had significantly higher concentrations of BPA than adults.³⁷

34 <http://www.ehponline.org/members/2008/0800073/0800073.html>

35 http://www.uoguelph.ca/news/2009/02/bpa_lingers_in.html

36 <http://www.ehponline.org/members/2008/0800265/0800265.html>

37 <http://www.ehponline.org/members/2007/10753/10753>.

A review of the science around BPA published in the July 2009 edition of *Philosophical Transactions*, a Royal Society biology journal, discussed BPA as well as other chemicals found in plastics and stated that: **'Human body burdens of these chemicals are detected with high prevalence, and concentrations in young children, a group particularly sensitive to exogenous insults, are typically higher, indicating the need to decrease exposure to these compounds'**.³⁸

Polycarbonate baby bottles as a source of exposure

A 2007 study by Environment California of five major baby bottle manufacturers,³⁹ and a 2008 study by 15 US and Canadian environmental health charities on six major baby bottle brands⁴⁰ both demonstrated that the polycarbonate bottles leached BPA of between five to eight parts per billion when heated.

A more recent study published in September 2009, undertaken by Scientists from Harvard University and the National Center for Environmental Health: **'examined the association between use of polycarbonate beverage containers and urinary BPA concentrations in humans'**. The 77 adult participants who successfully completed the study were given BPA-free steel drinks containers in which they consumed cold drinks for the first week and then were provided with polycarbonate bottles that contained BPA. The study found that: **'[u]rinary BPA concentrations increased by 69% after use of polycarbonate bottles'**.⁴¹

The study validated its results by stating that: **'[t]he large increase in mean urinary BPA concentration after regular use of polycarbonate bottles suggests that the systematic BPA variation in the two study phases was by far greater than any random variation due to BPA ingestion from**

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38 <http://rstb.royalsocietypublishing.org/content/364/1526/2079.abstract>

39 http://www.environmentcalifornia.org/uploads/Ve/AQ/VeAQsr6MMu4xA3-2ibnr_g/Toxic-Baby-Bottles.pdf

40 <http://www.chej.org/documents/BabysToxicBottleFinal.pdf>

41 <http://www.ehponline.org/members/2009/0900604/0900604.html>

other sources'. The study also noted in conclusion that: **'we would anticipate higher urinary BPA concentrations after ingestion of hot beverages stored in the same bottles'**.⁴²

Canadian Government ban of BPA baby bottles

Canada is in the final stages of amending by regulation its Hazardous Products Act to prohibit the advertising, sale and importing into Canada of baby bottles containing BPA, and concluded on 10 September 2009, the third public consultation on the Government's plans to introduce the measure.⁴³

As recorded in the *Canada Gazette* (the official newspaper of the Government of Canada and statutory publication for regulatory and legislative announcements) on 27 June 2009, the objective of the ban is to: **'enhance the health and safety of newborns and infants up to the age of 18 months by reducing their risk of developing adverse health effects as a result of exposure to bisphenol A'**.⁴⁴

The Canadian Minister of Health, Leona Aglukkaq, reported in a press release, dated 26 June 2009, on the Canada Health website that **"Our Government is acting to protect its most vulnerable citizens - newborns and infants. Canada is the first country to move ahead with regulations to prohibit polycarbonate baby bottles that contain bisphenol A. We want parents to feel confident that they can safely bottle-feed their newborns and infants"**.⁴⁵

The Government of Canada has specifically cited the necessity to act based on low dose evidence, as the official Regulatory Impact Analysis Statement makes clear:

'Various animal studies where bisphenol A was administered to rodents at low doses

suggested that exposure during gestation and early postnatal life may affect neural development and some aspects of behaviour... newborns and infants up to 18 months of age are still considered to be more susceptible to the potential adverse effects of bisphenol A due to their potentially less effective metabolism and elimination of bisphenol A, increased intake per body weight, increased potential for exposure due to the use of baby bottles, and rapid rate of physical growth and development'.⁴⁶

The Regulatory Impact Analysis Statement also describes the options considered by the Canadian Department of Health in relation to reducing BPA exposure to infants aged 18 months and under, stating that the: **'[s]tatus quo. [i.e.] The continued advertisement, sale and importation of polycarbonate baby bottles that contain bisphenol A is not considered a viable option.'** While: **'[m]andatory labelling to identify the use of bisphenol A in polycarbonate baby bottles cannot achieve the level of protection considered necessary to protect newborns and infants up to the age of 18 months.'** Furthermore, that regulating the levels of BPA in baby bottles to a safe level was also: **'not considered a viable option'** as: **'it is not possible to determine a safe level of bisphenol A exposure for newborns and infants'**.⁴⁷ Therefore leaving the only viable rationale as:

'The prohibition of polycarbonate baby bottles that contain bisphenol A from advertisement, sale and importation in Canada provides the greatest protection to Canadian newborns and infants. This option eliminates one source of bisphenol A exposure to this susceptible group, thus reducing their overall exposure to this substance'.⁴⁸

42 <http://www.ehponline.org/members/2009/0900604/0900604.html>

43 http://www.hc-sc.gc.ca/cps-spc/legislation/consultation/bisphenol_a-eng.php

44 <http://gazette.gc.ca/rp-pr/p1/2009/2009-06-27/html/reg5-eng.html>

45 http://hc-sc.gc.ca/ahc-asc/media/nr-cp/_2009/2009_106-eng.php

46 <http://gazette.gc.ca/rp-pr/p1/2009/2009-06-27/html/reg5-eng.html>

47 <http://gazette.gc.ca/rp-pr/p1/2009/2009-06-27/html/reg5-eng.html>

48 <http://gazette.gc.ca/rp-pr/p1/2009/2009-06-27/html/reg5-eng.html>

The Canadian Government conducted two studies into the benefits and costs of prohibiting BPA in babies bottles, firstly it commissioned the **Technical and Socio-Economic Background Study of Specific Uses of Bisphenol A** (19 January 2009) that was prepared by Cheminfo Services Inc. an independent commercial company, while a further study of the **Analysis of Benefits and Costs of a Proposed Prohibition on the Importation, Sale and Advertising of Polycarbonate Baby Bottles that contain Bisphenol A** (March 2009) was prepared by the Risk Management Bureau of Health Canada.⁴⁹

The Regulatory Impact Analysis Statement, on the basis of these two studies notes that: **'prohibiting the importation, sale and advertising of polycarbonate baby bottles that contain bisphenol A would have negligible (and potentially no) economic impacts on the Canadian industry'**.

It goes on to state that: **'[t]he costs borne by consumers are minimal' as: '[a]lternatives have a broad range of prices, and consumers can buy bottles at lower or higher prices than charged for polycarbonate baby bottles. The estimated range of costs for one household replacing five polycarbonate baby bottles is approximately \$35 to \$65 [approximately £20 to £37], incurred only by households that choose to replace already owned polycarbonate baby bottles'**.⁵⁰

The prohibition regulations on the advertising, sale or importing of baby bottles that contain BPA if contravened incur a possible: **'fine not exceeding one million dollars or to imprisonment for a term not exceeding two years or to both'**⁵¹ are expected to come into force in late 2009.⁵²

The withdrawal of BPA baby bottles in the US

In March of 2009 the six major manufactures of baby bottles in the US, Playtex Products, Gerber,

Evenflo, Avent America, Dr. Brown and Disney First Years, announced that they were ending the sale of bottles containing BPA in the US and Canada. The announcement was made in response to a letter requesting a voluntary ban by the Connecticut Attorney General Richard Blumenthal, and the Attorneys General of Delaware and New Jersey. Quoted in the Washington Post, Blumenthal stated **"The evidence seems too clear and emphatic and unequivocal to say we should simply permit this stuff to go into children on a massive scale... And there's no reason for it, because there are substitutes available"**.⁵³

Despite the voluntary action taken by the manufacturers, on 7 May 2009, the US state of Minnesota enacted legislation (The Minnesota Toxic Free Kids Act, S.F. No. 247) banning BPA from baby bottles and infant training cups, the legislation will come into effect in 2011.⁵⁴

Senator Sandy Rummel, chief author of the BPA legislation in the Minnesota Senate was quoted on Minnesota Public Radio after the official signing of the legislation as saying **"knowing that the products that are on the market today do not have this chemical in it I think brings consistency and comfort to parents who are conscientious."** While the Bill's chief author in the States Lower Chamber, Representative Kate Knuth said, **"The point is we shouldn't have to have a huge public relations and advocacy effort to phase out toxic chemicals. I think that should just happen as a matter of basic public policy"**.⁵⁵

In May 2009, the State of Connecticut followed the example of Minnesota by passing, with an overwhelming vote, an even more stringent Bill by 35-1 in the Senate while a unanimous 135-0 votes in the House⁵⁶ banning from October 2011 the: **'manufacture, sell, offer for sale or distribute in this state any reusable food or beverage container containing bisphenol-A'** as well as: **'any infant**

eng.html

49 Both reports are available on request from Health Canada.

50 <http://gazette.gc.ca/rp-pr/p1/2009/2009-06-27/html/reg5-eng.html>

51 http://laws.justice.gc.ca/eng/H-3/page-3.html#anchorbo-ga:l_III-gb:s_28

52 http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2008/2008_167-eng.php

53 <http://www.washingtonpost.com/wp-dyn/content/article/2009/03/05/AR2009030503285.html>

<http://www.medicalnewstoday.com/articles/141410.php>

<http://www.huntingtonnews.net/columns/090311-staff-columnsbabybottles.html>

54 <http://www.productsafetyletter.com/news/5612-1.html>

55 http://minnesota.publicradio.org/display/web/2009/05/08/minnesota_bpa_ban

56 <http://www.newsinferno.com/archives/6380>

formula or baby food that is stored in a plastic container, jar or can that contains bisphenol-A’.⁵⁷

Also in May 2009 Chicago, the USA’s third largest city with a population of 2.8 million, passed an Ordinance that bans the sale after 2010: **‘of any empty food or drink container containing BPA that is intended for use by children less than 3 years old’.**⁵⁸ A similar ban was also enacted in Suffolk County, Long Island (NY).⁵⁹

According to the respected US Environmental Working Group, by early 2009: **‘[o]ver 20 states [had] introduced bills to reduce children’s exposure to BPA’.**⁶⁰ This figure continues to grow as a news report from August 2009 indicates that: **‘[t]wenty-four states have Bills in the works to restrict the toxin’.**⁶¹

BPA and US federal action

In March of 2009 three Bills were introduced into the US Congress regarding BPA use in food contact products. The Ban Poisonous Additives Act of 2009 was introduced in identical forms into the House of Representatives (H.R. 1523) as well as the Senate (S. 593). The Bill currently enjoys 63 co-sponsors across Congress, and according to the Congressional Research Service Summary: **‘would ban the sale of any food container that is composed, in whole or in part, of bisphenol A or that can release bisphenol A into food’.**⁶² Both these Bills are currently at the Committee stage.

The BPA-Free Kids Act of 2009 (S. 753) was introduced into the Senate on 31 March 2009 and would ban the sale of any: **‘children’s food or beverage container’** that would primarily be used: **‘by children three years old or younger’** and that: **‘is composed in whole or in part of bisphenol A (BPA)**

be treated as a banned hazardous substance under the Federal Hazardous Substances Act’. The Bill is currently with the Senate Commerce, Science, and Transportation Committee and is cosponsored by four senators.⁶³

US health agencies and BPA

The new Administrator of the US Environmental Protection Agency (EPA), Lisa Jackson, announced on 28 September 2009, that BPA would be one of six chemicals that could be reviewed as to its safety as early as December this year, as part of Chemical Action Plans that could lead to, **“action to label, restrict, or ban a chemical”.**⁶⁴

In her speech announcing the move Lisa Jackson warned that, **“advances in toxicology and analytical chemistry are revealing new pathways of exposure. There are subtle and troubling effects of chemicals on hormone systems, human reproduction, intellectual development and cognition. Every few weeks, we read about new potential threats: Bisphenol A (BPA) – a chemical that can affect brain development and has been linked to obesity and cancer – is in baby bottles”.**⁶⁵

The Food and Drug Administration (FDA) in the US is also currently conducting its own review of BPA, led by its Chief Scientist. The FDA had been strongly criticised under the previous administration by scientists and NGOs for heavily relying on studies backed by the chemicals industry in its assessments of BPA. This criticism culminated in the publication of a letter by 36 international BPA scientific experts published in the *Environmental Health Perspectives* journal in March 2009 that stated:

‘The approaches used by academic and government scientists to study the potential health hazards of BPA contrast

57 <http://www.cga.ct.gov/2009/ACT/PA/2009PA-00103-R00HB-06572-PA.htm>

58 <http://archives.chicagotribune.com/2009/may/14/local/chicago-bpa-baby-bottles-14may14>

59 <http://consumerist.com/2009/03/suffolk-county-bans-bisphenol-a-in-baby-bottles.html>

60 <http://www.ewg.org/reports/bpatimeline>

61 <http://www.newsinferno.com/archives/11843>

62 <http://www.govtrack.us/congress/bill.xpd?bill=s111-593&tab=summary>

63 <http://www.govtrack.us/congress/bill.xpd?bill=s111-753&tab=summary>

64 <http://yosemite.epa.gov/opa/admpress.nsf/12a744ff56dbff8585257590004750b6/fc4e2a8c05343b3285257640007081c5!0penDocument>

65 <http://yosemite.epa.gov/opa/admpress.nsf/12a744ff56dbff8585257590004750b6/fc4e2a8c05343b3285257640007081c5!0penDocument>

sharply with those still used by the chemical industry that are relied on by regulatory agencies in the United States and Europe, including the two studies identified by both the US FDA and European Food Safety Authority (EFSA) as central to the decision to declare BPA safe at current human exposure levels. By using outdated and insensitive assays that were supposed to have been replaced by a new battery of screens and tests by 2000 [as mandated by the U.S. Congress in 1996 in the Food Quality Protection Act (1996), but which has, as yet, still not occurred], these studies conducted using GLP (Good Laboratory Practice) fail to find any adverse effects'.⁶⁶

Whilst responding to this and other criticisms from both scientists and policy makers, Dr. Hamburg the new Head of the FDA, giving evidence at a Congressional Committee Hearing on 3 June 2009 stated in her reply to a question about whether the FDA was concerned about BPA that:

“Well, we are concerned... We are taking another look at the BPA issue. The acting chief scientist at the FDA has been asked to take the lead on this because, of course, this is a decision where we have to bring the best available scientific data to bear. We need to look at all of the studies and examine them. But it is an issue of great consequence for Americans. As a mother as well as a physician, it is an issue that I think we need to look at seriously”.⁶⁷

⁶⁶ <http://www.ehponline.org/members/2008/0800173/0800173.html>

⁶⁷ http://energycommerce.house.gov/Press_111/20090603/transcript_20090603_he.pdf

Danish Parliament's call for BPA baby bottle ban

On 29 May 2009, the Danish Parliament passed a resolution calling for the end of the use of BPA in baby bottles. While the resolution is non-binding, the Danish Minister for Food, Thomas Elvensø stated that he was in: **“dialogue with the industry on a voluntary phase out of baby bottles’ containing bisphenol A”** as part of: **“the government’s focus on reducing child total intake of endocrine disruptors”**.

The UK, EU and BPA

In a letter from the Rt. Hon. Dawn Primarolo, Minister of State for Health, to Andrew Pelling MP, dated 3 June 2009, the Minister states that the Food Standards Agency (FSA) is: **‘satisfied that there is no risk to the health of UK consumers’** from BPA food contact products⁶⁸. Furthermore, in an email dated 15 September from the Contaminants Branch of the FSA, the representative makes clear that they: **‘do not think it is necessary for people to avoid food containers made from plastics that use BPA’**.⁶⁹

Both the letter from Dawn Primarolo as well as the email from the FSA point to the European Food Safety Authority (EFSA) assessment published in July 2008 as being a principle source for the UK Government when clarifying its policies in relation to the safety of BPA in food contact products. The Minister goes on to explain that: **‘the EFSA has made an exhaustive search of the literature on BPA and reports that inform its conclusions are referenced in each opinion’**.⁷⁰

⁶⁸ Letter from Dawn Primarolo, Minister of State for Health to Andrew Pelling MP, dated 3 June 2009, available on request.

⁶⁹ Email from Food Standards Agency, dated 15 September 2009, available on request.

⁷⁰ Letter from Dawn Primarolo, Minister of State for Health to Andrew Pelling MP, dated 3 June 2009, available on request.

But independent scientists have questioned whether this is the case. A May 2009 paper published in the Journal of Reproduction notes that:

'Recent reviews of BPA by both the US Food and Drug Administration (FDA) and the European Food Safety Authority (EFSA) have concluded that current human exposure levels are "safe". These conclusions, however, are based largely on data from a few standard multi-generation studies, some of which were conducted under outdated guidelines. Because these studies were supported by industry, the implication has been made that they may be less than objective. Despite this criticism and the fact that these studies are at odds with the results of hundreds of studies conducted in academic settings, the data from standard multi-generation protocols have been perceived by regulatory agencies as definitive. As detailed in a recent commentary, however, these "definitive" studies have major flaws. Specifically, in addition to the deficiencies in standard multi-generation protocols detailed above (e.g., the use of outdated protocols that do not consider contemporary endpoints like analyses of effects on meiotic chromosome behavior in germ cells, epigenetic programming, and neurobehavior), Myers and colleagues detail significant flaws in each of the previous standard multi-generation studies of BPA'.⁷¹

The four authors of the above paper - Patricia A. Hunt, Martha Susiarjo (both from the Washington State University), Carmen Rubio (Universidad de Valencia), and Terry J. Hassold (University of Pennsylvania) - also note that because the protocols on which agencies like EFSA rely lack the necessary sensitivity it: **'has allowed BPA manufacturers to**

⁷¹ <http://www.bioreprod.org/content/early/2008/12/31/bioreprod.109.077008.full.pdf>

suggest that concerns about the safety of BPA are unfounded'.⁷²

The commentary referred to in the Journal of Reproduction was authored by 36 scientific experts on BPA and published in March 2008. It makes clear that EFSA have predominantly relied on: **'two industry-funded GLP [Good Laboratory Practice] studies of BPA'** and that they have rated those studies: **'to be superior to hundreds of [other] studies'** and that the: **'studies on which the agencies based their decisions have serious conceptual and methodologic flaws'.⁷³**

The commentary from the 36 scientists continues:

'Regulatory agencies in the United States and the European Union (EU) have justified the decision to declare the estrogenic chemical bisphenol A (BPA) safe at current levels of human exposure based on a few studies conducted using Good Laboratory Practices (GLP). In contrast, these agencies have rejected for consideration in their risk assessment of BPA hundreds of laboratory animal and mechanistic cell culture studies conducted by academic and government scientists reporting harm at very low doses of BPA. These studies were rejected primarily because they were not conducted using GLP. We suggest that decisions based on this logic are misguided and will result in continued risk to public health from exposure to BPA, as well as other manmade chemicals'.⁷⁴

In the September 2008 edition of the Journal of the American Medical Association two independent scientists offered an explanation as to why the FDA previously and EFSA still currently continue to refuse to accept the hundreds of peer reviewed academic papers on BPA, namely that:

⁷² <http://www.bioreprod.org/content/early/2008/12/31/bioreprod.109.077008.full.pdf>

⁷³ <http://www.ehponline.org/members/2008/0800173/0800173.html>

⁷⁴ <http://www.ehponline.org/members/2008/0800173/0800173.html>

'One factor that may be contributing to the refusal of regulatory agencies to take action on BPA in the face of overwhelming evidence of harm from animal studies reported in peer-reviewed publications by academic and government scientists is an aggressive disinformation campaign using techniques ("manufactured doubt") first developed by the lead, vinyl, and tobacco industries to challenge the reliability of findings published by independent scientists'.⁷⁵

Conclusions and recommendations

While further studies on BPA and its effects will be conducted, the body of scientific evidence to date demonstrates that ending the use of this chemical in baby bottles is a sensible and warranted step for the UK Government to take, as levels of exposure in newborns and very young children are, comparatively, many times higher than in the adult population.

Alternatives to BPA use in baby bottles are already available on the UK market, though, as the Canadian Government has demonstrated, this in itself is not a sufficient safeguard against the risk to such a vulnerable group.

The Food Standards Agency (FSA) and the European Food Safety Authority (EFSA) have relied on outdated and flawed studies backed predominantly by the chemicals industry and disregarded hundreds of independent scientific peer reviewed papers that question the validity that low levels of BPA are safe.

The UK Government should end the use of BPA in baby bottles as a matter of priority by introducing regulations, similar to those already introduced in Canada and expected to be brought about in the US, in order to decrease the exposure to BPA of newborns and very young babies.

There is also a compelling argument for adequate labelling of all food contact items, including those aimed at adults. Scientific studies, particularly those that have demonstrated that BPA exposure to pregnant women can impact on health outcomes in children, warrant serious attention.

The UK Government should introduce measures to ensure that clear labelling is used on all food contact products that contain BPA to allow consumers to make informed choices about their own level of exposure to BPA, and provide advice, in particular to pregnant women and breast cancer patients, on how to reduce their BPA intake levels.



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⁷⁵ <http://jama.ama-assn.org/cgi/content/full/300/11/1353?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=bisphenol&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>

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