



STUDIE 1: AMERICAN PLASTICS COUNCIL

POLYCARBONATE PRODUCTS – LIGHTWEIGHT, SHATTER-RESISTANT, AND SAFE FOR USE

• Read the text once.

- What ideas does the text express?
- How does the American Plastic Council try to convince the reader that there's no health risk in using plastic?
- What effect does the text have on you (seems rather scientific or partial)?
- What's the structure of the text?
- Read the text again very careful.
- Is there written that Bisphenol A does not have adverse health effects in no way?
- Are the assertions in the text based on clear and understandable arguments/evidence?
- What arguments does the text list to demonstrate that Bisphenol A is harmless?
 - Are these arguments credible / convincing / scientific?
- What does the American Plastics Counsil say about studies that have come to other results?
- The following five quotations appear at totally different positions in the text.
- «(...) such low levels of BPA poses no known health risk.»
- «(...) the weight of evidence does not support claims of low-dose effects from BPA.»
- «(...) the "low-dose hypothesis" for BPA is unproven.»
- «None of these adverse health claims have been proven, (...)»
- «(...) there is no scientific basis for human health concerns from exposure to low doses of BPA.»
 - Does «no known health risk» mean that there are no risks at all?
 - How much is a «low-dose»? Does this mean that a higher dose has harmful effects?
 - Why do they consistently talk about a «low-dose»?
- The American Plastics Council writes that there's no evidence supporting the health

claims. Discuss: Does this mean that there are no consequences for the health? Or have they just not been proven yet? If studies presenting other results are considered as non pertinent, how will a proof ever be possible?



STUDIE 2: THE WORK GROUP FOR SAFE MARKETS

BABY'S TOXIC BOTTLE – BISPHENOL A – LEACHING FROM POPULAR BABY BOTTLES

- Read the text.
 - What's the message of the text?
 - What effect does the text have on you?
- What's the structure of the text?
- Are the findings of «The Work Group For Safe Markets» based on credible arguments/evidence?
- Compare the two studies.

American Plastics Council vs. The Work Group For Safe Markets

- Which study has more credibility?
- What do you think about Bisphenol A. Is it dangerous or harmless?
- Whose arguments are more understandable? Whose argumentation is more scientific?
- Discuss the following quotations in class.

| American Plastics Council | The Work Group For Safe Markets |
|---|--|
| «() the weight of evidence does not support claims of low-dose effects from BPA.» | «Mounting evidence indicates that low dose exposure to bisphenol A can lead to adverse health effects.» |
| «() such low levels of BPA poses no known health risk.» | «() even low levels of repeated exposure may lead to adverse health effects.» |
| «() the "low-dose hypothesis" for BPA is unproven.» | «() two recent panels in the U.S. have pointed to potential health effects of exposure to bisphenol A.» |
| «None of these adverse health claims have been proven, ()» | «These results show that low doses of bisphenol A can disrupt hormone action within cells by competitively displacing naturally occurring hormones.» |



(...) there is no scientific basis for human health concerns from exposure to low doses of BPA."
«Studies have shown that bisphenol A can, at low doses, significantly stimulate the release of the hormone prolactin and activate breast cancer cells."
«Polycarbonate pastic is safe for use in costumer products.»
«Coupled with the konwledge of increasing rates of infertility, prostate and breast cancer and other conditions such as diabets and obesity in the human population, the possible effects of hormone disruptiors like bisphenol A cannot be ignored.»

• Debate in class

Half of the class is representing the «American Plastics Council», the other half speaks out in favour of «The Work Group For Safe Markets».

Try to use arguments that are derivable from the studies.







Polycarbonate Products

Lightweight, Shatter-resistant, and Safe for Use

Polycarbonate products have been safely used by consumers for decades. Recently, you may have received inquiries about polycarbonate plastic and a substance called bisphenol A or BPA, which is used to make polycarbonate. The manufacturers of BPA and polycarbonate have prepared this information sheet so that you can be better informed about the safety of polycarbonate products. Because it is lightweight and shatter-resistant, polycarbonate is used to make a wide variety of products ranging from CDs, cell phones and safety glasses to food contact products such as baby bottles, water bottles and food storage containers.

Q: Is polycarbonate plastic safe?

Extensive research conducted over almost 50 years of safe use provides strong reassurance that there is no basis for human health concerns from exposure to low doses of BPA.

Polycarbonate plastic has been authorized for use in food contact applications by government agencies worldwide and safely used for more than 50 years. During that time, polycarbonate and BPA have been extensively studied and tested for health and safety by both manufacturers and government agencies. Such tests have demonstrated that consumer exposure to BPA does not pose a risk to human health.

Q: Does BPA leach from polycarbonate food containers?

During polycarbonate production,

BPA is incorporated into the polymeric structure of the plastic. While there is some potential for trace amounts of BPA to migrate from polycarbonate, the level is far below safety-based standards set by government bodies such as the European Union's Scientific Committee on Food (EU SCF). In fact, the human body rapidly metabolizes and excretes BPA, and exposure to such low levels of BPA poses

no known health risk. The U.S. Food and Drug Administration (US FDA) and other regulatory agencies worldwide authorize the use of polycarbonate in food contact applications.

Q: Why would I have heard about BPA?

There has been an ongoing debate in the last decade about the hypothesis that some substances may disrupt natural hormonal systems and cause adverse health effects ("endocrine disruption"). For BPA, this debate originated with small, exploratory studies conducted with a limited number of laboratory animals that reported reproductive and developmental effects from low doses of BPA. However, the effects were not found when the experiments were repeated by other researchers. Reproducibility of experimental results by other scientists is absolutely critical in determining whether a study's findings can be accepted as valid, and is an accepted practice in the scientific community.

Large-scale well-conducted research sponsored by both industry and government agencies, and specifically designed to look for low-dose reproductive and developmental effects, also found no evidence of such effects. These comprehensive studies were conducted in accordance with Good Laboratory Practices (GLP, the accepted quality standard for scientific research) and published in peer-reviewed scientific journals.

In 2004, an expert scientific panel was convened by the Harvard Center for Risk Analysis at the request of the plastics industry. This panel of independent experts concluded, after a comprehensive review, that the weight of the evidence does not support claims of low-dose effects from BPA. An updated evaluation reached a similar conclusion after reviewing studies published through February 2006.

These scientific panel conclusions confirm what government and scientific bodies worldwide – including the EU SCF and Scientific Committee on Toxicity,



Ecotoxicity and the Environment (EU CSTEE); the US FDA and Environmental Protection Agency (US EPA); and the Japanese Ministry of Economy, Trade and Industry (METI) – have concluded upon review of the evidence: the "low-dose hypothesis" for BPA is unproven.

The endocrine disruption debate has led to many scare stories, urban myths and Internet-spread rumors about avoiding products made with polycarbonate for fear of adverse health effects, including birth defects, sterility, premature puberty, genetic damage, and cancer. None of these adverse health claims have been proven, and extensive research conducted over almost 50 years of

safe use provides strong reassurance that there is no scientific basis for human health concerns from exposure to low doses of BPA (see below). Polycarbonate plastic is safe for use in consumer products.

Q: Where can I find more information?

Additional information about polycarbonate plastic and BPA is available at www.bisphenol-a.org, including information sheets and a summary of key published research.

For further inquiries, please contact Dr. Steven Hentges of the American Plastics Council at 703.741.5588 or steve_hentges@plastics.org.

Significant Studies Supporting the Safety of Polycarbonate Plastic

2001

Study conducted at the Safety Research Institute for Chemical Compounds and sponsored by the Japanese Ministry of Health and Welfare – Rats exposed to low doses of BPA over three generations showed no adverse health effects.

Report released by the National Toxicology Program (NTP) on its scientific peer review of low-dose effects – The panel noted "the inability of other credible studies in several different laboratories to observe low dose effects of BPA, and the consistency of these negative studies [showing no reproductive or developmental effects from low-dose exposure]."

2002

Review of the NTP report by the US EPA confirmed the panel's conclusions that the "low-dose hypothesis" has not been proven.

Study conducted at Research Triangle Institute and sponsored by a plastics industry consortium – Rats exposed to low doses of BPA over four generations showed no adverse health effects.

Detailed review by EU SCF confirms that BPA is safe in food contact applications.

2003

Comprehensive risk assessment of BPA by the European Commission and reviewed by EU CSTEE – "The CSTEE agrees with the conclusion of the RAR [Risk Assessment Report] that there is no convincing evidence that low doses of bisphenol A have effects on developmental parameters in offspring."

2004

Scientific evaluation by an expert panel convened by the Harvard Center for Risk Analysis – "[T]he panel found no consistent affirmative evidence of low-dose BPA effects for any endpoint."

2005

Comprehensive risk assessment on BPA by the Japanese National Institute of Advanced Industrial Science and Technology, affiliated with METI-"[C]urrent exposure levels of BPA will not pose any unacceptable risk to human health."

Statement from US FDA affirms that current uses of polycarbonate plastic and epoxy resins in food contact are safe — "[B]ased on all the evidence available at this time, FDA sees no reason to change its long-held position that current uses with food are safe."

2006

Update of the 2004 Harvard panel evaluation – "[T]he weight of evidence does not support the hypothesis that low oral doses of BPA adversely affect human reproductive and developmental health."

Safety of polycarbonate baby bottles affirmed by the German Federal Institute for Risk Assessment – "The BfR does not recognize any health risk for babies that are fed from baby bottles made of polycarbonate."

Background on Bisphenol A (BPA)

n 1936, scientists discovered that **bisphe-nol A** (BPA) could be used as a synthetic hormone that mimicked estrogen, which they thought might be useful to help control difficult pregnancies. Bisphenol A took a back seat to a similar chemical called diethyl sylbestral (DES), which was determined to be more effective in this application. It was not until after it had been given to millions of women that DES was identified as a cancer-causing agent and the cause of serious reproductive defects, including rare vaginal cancer, in the daughters of mothers who had taken DES during pregnancy.⁶

In the 1950s chemists found that BPA could be polymerized to produce commercially viable plastics.7 Bisphenol A is now used to make polycarbonate plastics—the clear or tinted, unbendable plastic used to make some of the most popular baby bottle brands and reusable water bottles, including most Nalgene bottles. Polycarbonate plastic bottles often have the number 7 in the recycling triangle on the bottom of the bottle, falling into the "other" category of plastics, and/or the letters "PC" near the recycling triangle. Other products that often contain BPA include CDs, DVDs, eyeglasses, dental sealants, and epoxy resins used in the lining of food and beverage containers. Currently, 95 percent of baby bottles on the market are made with BPA.8 Worldwide production of bisphenol A exceeds six billion pounds per year and demand for the chemical has risen significantly in recent years.

Exposure to bisphenol A is widespread. The US Centers for Disease Control and Prevention (CDC) found that 95 percent of Americans tested have detectable levels of BPA in their bodies, 9 and a 2008 study shows that BPA levels are lowest in adults, mid-range in adolescents and highest in children. 10 The chemical bond between bisphenol A molecules is unstable, and with time and use, the chemical leaches from bottles

into materials it comes into contact with (for example, milk). Heating bottles or pouring hot liquids into bottles, the presence of acidic or basic foods and beverages, and repeated washing have all been shown to increase the rate of BPA leaching from bottles.¹¹ A January 2008 University of Cincinnati study found BPA

Heating bottles or pouring hot liquids into bottles, the presence of acidic or basic foods and beverages, and repeated washing have all been shown to increase the rate of BPA leaching from bottles.

leaching from Nalgene bottles.¹² An August 2007 Environmental Working Group study found BPA leaches from the inner lining of popular infant formula cans. In March 2007, independent laboratory tests found BPA in over half of 97 cans of name-brand fruit, vegetables, soda, and other commonly eaten canned goods. ¹³

A recent consensus statement by of over 30 expert scientists states that adverse health effects occur at levels in animals within the exposure range typical for people in developed countries, ¹⁴ levels well below the current U.S. Environmental Protection Agency "acceptable" human exposure level of 50 μg/kg/day. The EPA standard was set in 1993 on studies completed in the 1980s.

A recent review of scientific literature demonstrates a wide range of health effects resulting from bisphenol A at significantly lower levels than considered "acceptable", as low as 2 parts per billion in some studies.¹⁵

Health Effects of Bisphenol A

ounting evidence indicates that low dose exposure to bisphenol A can lead to adverse health effects. As a hormone disruptor, bisphenol A causes a response in cells similar to the effect of estradiol (estrogen hormone). Bisphenol A binds with estrogen-related receptors 16 but does not replace the activity of estrogen. As a result, bisphenol A may be adding a "false" estrogen effect in the body, off-setting the hormonal balance required for healthy human development. Experiments with animals link exposure at very low doses to a range of serious health problems including:

- · prostate and breast cancer
- early onset of puberty
- obesity
- hyperactivity
- · lowered sperm count
- miscarriage
- diabetes
- altered immune system¹⁷

Scientists and international organizations have identified bisphenol A as a potential reproductive and developmental toxin, as well as a hormone disrupting chemical leading to a variety of adverse health effects. In addition, two recent panels in the U.S. have pointed to potential health effects of exposure to bisphenol A.^{18,19}

Reproductive and Developmental Effects

A recent review of scientific literature affirms that bisphenol A can alter brain chemistry and the reproductive and immune systems in a variety of animals.²⁰ Some research also indicates that the sexual behavior and sexual development of mice can be impaired and variably altered from bisphenol A-induced hormone disruption.²¹ Another study found that female mice exposed to short-term, low doses of bisphenol A experienced sudden and significant increases in



genetic abnormalities in their eggs.²² In preliminary research based on these genetic abnormalities, researchers have also found that women with a history of recurrent miscarriage had higher blood serum levels of bisphenol A than women with successful pregnancies.²³

Bisphenol A has been reported to suppress the activation of thyroid hormone-regulated genes in rats.²⁴ These results show that low doses of bisphenol A can disrupt hormone action within cells by competitively displacing naturally occurring hormones. These hormones regulate the rate of metabolism and the growth of many systems in the body. Thyroid hormones play a significant role in brain development during fetal life.

Studies have shown that bisphenol A can, at low doses, significantly stimulate the release of the hormone prolactin and activate breast cancer cells.²⁵

Low Doses Can Be Dangerous

Recent studies have challenged the current acceptable daily intake level of bisphenol A, as new scientific evidence shows that even low doses of this chemical can disrupt development. The current acceptable level of bisphenol A is set by the U.S. Environmental Protection Agency at 50 µg/kg bodyweight/day, which is a measure in parts per billion (ppb). While Baby's Toxic Bottle measured bisphenol A leaching in levels below the 50 µg/kg/day acceptable daily intake from polycarbonate baby bottles, a number of other scientific studies have shown that bisphenol A levels as low as parts per trillion have been found to alter cell function.²⁶ Parts per trillion expresses a concentration 1,000 times smaller than parts per billion, indicating that extremely low-doses of bisphenol A can be potent. Moreover, exposure to BPA from baby bottles may not be an individual's only source of exposure to BPA, making it difficult to calculate any one person's actual daily dose. Finally, we lack studies to determine the synergistic effect of BPA exposure with other chemicals that an infant, child or adult might be exposed to. This further complicates the accuracy of the EPA's current acceptable daily exposure limit for BPA.

Exposure

Testing of Americans done by the U.S. Centers for Disease Control and Prevention found that 95 per cent of adults studied had bisphenol A in their urine.²⁷ This demonstrates the extent of human exposure since bisphenol A spends approximately 10 hours in the body²⁸ and indicates that we are continuously exposed to bisphenol A²⁹. Animal studies suggest that bisphenol A is quickly absorbed and eliminated, but some residual BPA remains in the intestines, liver and kidneys for a period of several days.³⁰ A recent U. S. biomonitoring project titled *Is It In Us? Chemi*cal Contamination of Our Bodies tested 35 men, women and young people for the presence of a variety of chemicals in their bodies. All of the participants who submitted urine samples had bisphenol A in their urine, and more than half had it in their blood. The levels of bisphenol A

found in the blood and urine of those studied was within the range shown to cause effects in laboratory animal studies, including impacts on cell function.³¹

A November 2007 U.S. National Institute of Environmental Health Sciences expert panel of 38 leading scientists³² found that most people are exposed to bisphenol A at levels higher than those that cause health effects in animal studies. The Washington, D.C.-based Environmental Working Group found high levels of bisphenol A in canned food, including infant formula, ravioli and chicken soup.³³ A 2008 University of Cincinnati study found BPA leaches from the popular polycarbonate Nalgene reusable water bottles.³⁴

Children

Children are especially vulnerable to bisphenol A because endocrine disruptors affect how their bodies grow and develop. Young children still have immature organ systems, high metabolic rates, relatively low bodyweight, and are going through rapid physical development; therefore, even low levels of repeated exposure may lead to adverse health effects.³⁵

An expert panel of the U.S. National Toxicology Program concluded recently that bisphenol A exposure to fetuses and to children could impact their behavioral and neural systems.³⁶ Exposure in the womb is particularly worrisome as fetuses have immature detoxification systems, not equivalent to adults', and they are at a delicate stage of development.³⁷

Bisphenol A is very much present in children's lives. A recent investigation of bisphenol A exposure in preschool children in North Carolina and Ohio (2000–2001) over a 48-hour period found that more than 68 percent of children's liquid food and more than 83 percent of their solid food samples contained bisphenol A.³⁸

Real World Laboratory

Linking the animal and laboratory evidence for bisphenol A with human health effects is diffi-

cult for many reasons, including a lack of concrete data on human exposure, other factors contributing to diseases, and the delay between exposure and some health effects. What cannot be disputed is that a number of tests have detected bisphenol A in human tissue and this

indicates widespread exposure.³⁹ Coupled with the knowledge of increasing rates of infertility, prostate and breast cancer and other conditions such as diabetes and obesity in the human population, the possible effects of hormone disruptors like bisphenol A cannot be ignored.