

**California Chamber of Commerce  
National Federation of Independent Business  
AdvaMed – Advanced Medical Technology Association  
California League of Food Processors  
International Formula Council  
California Manufacturers and Technology Association  
California Citizens Against Lawsuit Abuse  
Grocery Manufacturers Association  
California Grocers Association  
American Chemistry Council  
Can Manufacturers Institute  
Civil Justice Association of California  
Consumer Specialty Products Association  
Industrial Environmental Association  
Juvenile Products Manufacturers Association  
North American Metal Packaging Alliance, Inc.  
California Healthcare Institute**

April 11, 2011

The Honorable Betsy Butler  
Member of the Assembly  
State Capitol  
Sacramento, CA 95814

RE: **AB 1319 (Butler) – OPPOSE**  
*Set for hearing 4/26/11 – Assembly Environmental Safety & Toxic Materials Cmte.*

Dear Assembly Member Butler:

The above listed organizations must regretfully inform you of our collective opposition to your AB 1319. In our view, this legislation runs contrary to the consensus of the scientific community and international regulatory agencies that have concluded BPA is safe as used. Consider the following:

- **US Food and Drug Administration and Department of Health and Human Services reaffirmed that “BPA is not proven to harm children or adults” (January 2010).**

On January 15, 2010 FDA issued a statement regarding the use of BPA in food contact applications, including baby bottles, cups and infant formula cans. When asked if the FDA thought BPA was unsafe, Dr. Joshua Sharfstein of the FDA responded “**If we thought it was unsafe, we would be taking strong regulatory action.**”

The FDA did not urge parents to stop using food products that include BPA. “FDA is not recommending that families change the use of infant formula or foods, as the benefit of a stable source of good nutrition outweighs the potential risk of BPA exposure.” Regarding baby bottles, Dr. Sharfstein stated “**FDA does support the use of baby bottles with BPA.**”

**CONSUMERS UNION RESPONSE TO FDA’S SO-CALLED AFFIRMATION OF BPA SAFETY:**

This is a very misleading interpretation of the FDA’s significant change in its position on the safety of BPA. The January 2010 FDA update (<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm197739.htm>) reflects FDA’s newfound concerns regarding the safety of BPA:

“Studies employing standardized toxicity tests have thus far supported the safety of current low levels of human exposure to BPA. **However, on the basis of results from recent studies using novel approaches to test for subtle effects, both the National Toxicology Program at the National Institutes of Health and FDA have some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children [bolded for emphasis].** In cooperation with the National Toxicology Program, FDA’s National Center for Toxicological Research is carrying out in-depth studies to answer key questions and clarify uncertainties about the risks of BPA. In the interim:

- FDA is taking reasonable steps to reduce human exposure to BPA in the food supply. These steps include:
  - **supporting the industry’s actions to stop producing BPA-containing baby bottles and infant feeding cups for the U.S. market;**
  - facilitating the development of alternatives to BPA for the linings of infant formula cans; and
  - supporting efforts to replace BPA or minimize BPA levels in other food can linings.
- FDA is supporting a shift to a more robust regulatory framework for oversight of BPA.
- FDA is seeking further public comment and external input on the science surrounding BPA.

FDA is also supporting recommendations from the Department of Health and Human Services for infant feeding and food preparation to reduce exposure to BPA.”

**CONSUMERS UNION RESPONSE TO SHARFSTEIN’S 1/10/2010 STATEMENT, “FDA does support the use of baby bottles with BPA”:** This statement was in fact **retracted by Dr. Sharfstein** in a follow-up interview with the Milwaukee Journal Sentinel posted January 15, 2010 (<http://www.jsonline.com/watchdog/watchdogreports/81724607.html>):

“In a conference call with the media Friday, Joshua Sharfstein, the FDA’s principal deputy commissioner, added confusion to the announcement by saying that the FDA supported the use of BPA in baby bottles. Industry executives were quick to quote him. But Sharfstein later called the newspaper to clarify. “We do not support BPA in baby bottles,” he said. “We support companies that remove BPA from baby bottles. I apologize for the confusion.”

- **Regulatory bodies around the world have assessed the science on BPA and have determined that BPA is safe for use in food contact products.**

**CONSUMERS UNION RESPONSE:** This statement does not accurately reflect the extensive concern, dialogue, marketplace changes, and regulatory actions including bans, taken by a number of international countries, including their regulatory agencies, starting with the United States.

The most recent, annual, US President’s Cancer Report (2008) states, “: “because of the long latency period of many cancers, the available evidence argues for a precautionary approach to these diverse chemicals, which include (...) bisphenol A.” In recommendations for “What individuals can do,” the Panel recommends that children avoid endocrine disrupting compounds and that all people use BPA-free containers and phthalate free containers to carry

water. [http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP\\_Report\\_08-09\\_508.pdf](http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf)

**Please see CU response for each country specifically outlined by the industry.**

- European Food Safety Authority (September 2010)
- European Commission Risk Assessment (June 2008)

**CONSUMERS UNION RESPONSE: European Commission** has decided to temporarily ban BPA use in baby bottles due to uncertainty over effects of BPA on brain, immune effects and enhanced susceptibility to breast tumors, taking into account the EFSA Sept. 2010 opinion that industry cites as saying BPA is safe.

January 28, 2011. European Commission Directive 2011/8/EU bans BPA in baby bottles: “Until further scientific data are available to clarify the toxicological relevance of some observed effects of BPA, in particular as regards biochemical changes in brain, immune-modulatory effects and enhanced susceptibility to breast tumours, the use of BPA in the manufacture and placing on the market of polycarbonate infant feeding bottles should be temporarily banned.”

See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF>

The EU bans manufacture of BPA containing baby bottles as of March 1, 2011. On June 1, 2011, import and marketing of BPA-containing baby bottles will be banned. See: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/229&format=HTML&aged=0&language=EN&guiLanguage=en>

Even the EFSA Sept. 2010 document, which industry cites as saying the BPA is safe and no need to change the TDI, does admit that there are open questions about “biochemical changes in brain, immune-modulatory effects and enhanced susceptibility to breast tumours.”

- Swiss Federal Office of Public Health (February 2009)
- French Food Safety Authority (February 2010)

**CONSUMERS UNION RESPONSE: France** temporarily banned BPA in baby bottles (July 2010), based on two opinions of French Food Safety Authority (AFSSA), which raised concerns about behavioral effects of low doses on newborn rats exposed in utero and during first few months of life, and report of National Institute of Health and Medical Research (INSERM).

“On 6 July 2010 the French Government informed the Commission, and on 9 July 2010 the Member States, that it has decided to apply the safeguard measures . . . to temporarily ban the manufacture, import, export and placing on the market of feeding bottles containing BPA. The French Government substantiated its safeguard measure with two opinions issued by the French Food Safety Authority (AFSSA) on 29 January and 7 June 2010 and the report published on 3 June 2010 by the National Institute of Health and Medical Research (INSERM).”

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF>

- Dutch Food and Consumer Product Safety Authority (November 2008)
- Danish Environmental Protection Agency (October 2008)

**CONSUMERS UNION RESPONSE: Denmark** has temporarily banned the use of BPA in any plastic materials in contact with food intended for children ages 0-3, based on risk assessment from National Food Institute at the Technical University of Denmark (March 2010).

“On 29 March 2010 the Danish Government informed the Commission and the Member States that it has decided to apply the safeguard measures . . . to temporarily ban the use of BPA for the manufacture of plastic materials in contact with food intended for children aged 0-3. The Danish Government substantiated its safeguard measure with a risk assessment provided on 22 March 2010 by the National Food Institute at the Technical University of Denmark (hereinafter ‘DTU Food’). The risk assessment covers the evaluation of a comprehensive study carried out on animals exposed to BPA in low doses monitoring the development of the nervous system and the behaviour in newborn rats. DTU Food has also evaluated whether the new data changes its previous evaluation of the toxic effects on the development of the nervous system and behaviour possibly caused by BPA.”

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF>

- German Federal Institute for Risk Assessment (January 2010)

**CONSUMERS UNION RESPONSE: German** government agencies have voiced concern about BPA (June 2010). Umwelt Bundes Amt (Federal Environment Agency) says, in press release, “To protect human health and environment Jochen Flasbarth, president of UBA, recommends producers as well as users of this substance to use alternative substances already at this state of knowledge for reasons of precaution.”

“The Agency [German Federal Environment Agency] advises manufacturers, importers and users of bisphenol A to use alternative substances that pose less risk to human health and the environment in all areas of use that significantly contribute to exposure. This way, an important contribution can be made to product responsibility in the case of a substance for which precautionary protection of humans and the environment is advisable.”

[http://www.umweltbundesamt.de/uba-info-presse-e/2010/pe10-033\\_bisphenol\\_a\\_a\\_chemical\\_with\\_adverse\\_effects\\_produced\\_in\\_large\\_quantities.htm](http://www.umweltbundesamt.de/uba-info-presse-e/2010/pe10-033_bisphenol_a_a_chemical_with_adverse_effects_produced_in_large_quantities.htm)

- Food Standards Australia and New Zealand (November 2010)

**CONSUMERS UNION RESPONSE: Australia** June 30, 2010 Australia announced a voluntary ban on BPA in baby bottles. “Australian Parliamentary Secretary for Health announced the phase out of chemical, bisphenol-A (BPA) in baby bottles by major retailers<sup>1</sup>. The voluntary phase out is the result of months of constructive discussions between the Australian Government and retailers” See: <http://www.hktdc.com/info/mi/a/pts/en/1X070M8Y/1/Product-Testing-Standards-and-Corporate-Social-Responsibilities/Australia-Announces-Voluntary-Ban-on-BPA.htm> and

<http://www.foodstandards.gov.au/scienceandeducation/newsroom/mediareleases/mediareleases2010/governmentannouncesb4822.cfm>

**New Zealand** June-July 2010. "Baby bottle suppliers phase out BPA" "Suppliers of baby products are voluntarily phasing out the use of Bisphenol A (BPA) in baby bottles due to consumer concern over the safety of the compound. . . . Brands that have phased out BPA in their products include Avent, Mam, Nuby, Tommee Tippee, and Watties Baby Basics' range of feeding accessories."

[http://www.nzherald.co.nz/nz/news/article.cfm?c\\_id=1&objectid=10657424](http://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=10657424)

- Japanese National Institute of Advanced Industrial Science and Technology (November 2005)

**CONSUMERS UNION RESPONSE:** Japanese manufacturers began to take voluntary action to reduce BPA exposure in foods more than a decade ago, in light of growing public concerns. In fact, they have changed the resin formulations used in cans as well as many plastics. Studies have shown drops in the levels of urinary BPA in Japanese adults as a result of these voluntary initiatives.

- Health Canada (October 2008, July 2009, August 2010)

**CONSUMERS UNION RESPONSE: Canada** "The Government of Canada recently completed a risk assessment of BPA under the Chemicals Management Plan. . . . [and] wants to be prudent and further reduce exposures of newborns and infants under 18 months. Science tells us that exposure levels are below those that could cause health effects, however, due to the uncertainty raised in some studies relating to the potential effects of low levels of bisphenol A, the Government of Canada is taking action to enhance the protection of infants and young children. **The proposed ban applies only to baby bottles made of polycarbonate.**" See: <http://www.chemicalsubstanceschimiques.gc.ca/fact-fait/plastic-plastique-eng.php>

Indeed, a Canadian government fact sheet states that the Canadian government is "moving to ban the importation, sale and advertising of polycarbonate baby bottles." See: Question 14 at: [http://www.chemicalsubstanceschimiques.gc.ca/fact-fait/bisphenol-a\\_qa-gr-eng.php#n](http://www.chemicalsubstanceschimiques.gc.ca/fact-fait/bisphenol-a_qa-gr-eng.php#n)

**October 13, 2010: Canada formally declares BPA a toxic substance**, placing it on Toxic Substance List Schedule 1 of the Canadian Environmental Protection Act. Canadian Minister of Health, Honourable Leona Aglukkaq, Minister of Health, declares "Our science indicated that **Bisphenol A may be harmful to both human health and the environment...** we were the first country to take bold action in the interest of Canadians." See: <http://www.ec.gc.ca/default.asp?lang=En&n=714D9AAE-1&news=74916A27-7F09-411E-B3AB-D1E8A596A2AC>

**October 16, 2010:** Canada's Environment Minister, the Honourable Jim Prentice, announced that the Government of Canada is proposing a new regulatory instrument to address releases of Bisphenol A (BPA) through industrial effluent. . . . "The Government of Canada is taking a comprehensive approach to managing risks associated with Bisphenol A and this latest step addresses industrial use of the chemical in Canada," said Minister Prentice. "The proposed rules will require facilities to develop and implement plans to limit releases of BPA to the environment and to submit ongoing progress reports to the Government of Canada." See: <http://www.ec.gc.ca/default.asp?lang=En&n=714D9AAE-1&news=7800DBA8-475F-46D7-8A0A-683A0143569B>

- The World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) concluded that “initiation of public health measures would be premature.” The panel also concluded that BPA does not accumulate in the body, is rapidly eliminated in urine, and that it is difficult to interpret the relevance of studies claiming adverse health effects from BPA.

**CONSUMERS UNION RESPONSE:** The 2010 WHO/FAO report does cite concerns regarding the safety of BPA across a variety of endpoints while noting that a “safe” exposure level cannot be calculated at this time. The report also cites the limitations in FDA’s safety limit:

“There is an extensive literature on the evaluation of the health effects of BPA using animal models. At doses of 50 mg/kg bw per day and above, BPA has consistently been found to cause a number of adverse health effects in rodents, including fetal deaths, decreased litter size or decreased number of live pups per litter, and reduced fetal or postnatal growth in rats and mice. Typically, a dose of 5 mg/kg bw per day has been identified as a NOAEL in assessments conducted for regulatory or health-based guidance value setting purposes, based on consideration of two multigeneration studies in rats and mice conducted by Tyl et al. (2002, 2008). These studies are generally considered to be statistically and methodologically sound for the end-points investigated and have sufficient dose groups to support dose–response modelling. However, the changes in brain development, animal behaviour and prostate and mammary gland tissue, suggested in recent research reports as potential effects of exposures to BPA closer to ambient levels, were not investigated in these studies.”

Finally, Rochelle Tyl, who published the studies largely used to calculate FDA’s and WHO/FAO’s NOAEL, has admitted that her studies have significant limitations. They did not look into all of the toxic endpoints identified in other studies. According to the Milwaukee Journal Sentinel, “According to scientists at the meeting, Tyl conceded that there were errors and inconsistencies in the 2008 report that the FDA used as the foundation for its findings. . . . Tyl told the Journal Sentinel in an e-mail that **her studies do not claim that BPA is safe. Her studies were not designed to cover all aspects of the chemical's effects. They simply show no effects to the reproductive system of rats and mice that were exposed to the chemical at low doses**, she said.” From: Kissinger, M. and S. Rust. 2009. “Consortium rejects FDA claim of BPA’s safety.” Milwaukee Journal Sentinel, April 11, 2009. At: <http://www.jsonline.com/watchdog/watchdogreports/42858807.html>

- In July 2009 a panel of independent scientific experts convened by the California EPA’s Office of Environmental Health Hazard Assessment unanimously concluded that **BPA should not be listed as a reproductive or developmental toxicant under California’s Proposition 65 law.**

**CONSUMERS UNION RESPONSE:** Most regulatory actions have been taken because of preponderance of concern given the scientific uncertainty that exists. CA Prop 65 lists agents *known* to be harmful---and BPA does lack such certainty. However, this action does not confirm the safety of BPA. There are many other scientific panels and consensus statements that underscore the concern for BPA including the NIH, NTP, FDA Science Advisory Board, the President’s Cancer Review Panel and the Endocrine Society. In addition, we are very concerned about the undue influence of the plastics industry in regulatory decision making process concerning the safety of BPA. One member of the Board was also an employee of Chevron.

- In March 2010, the US Environmental Protection Agency (EPA) released a BPA “Action Plan” that outlines EPA’s review of BPA and their plan for follow-up actions. Notably, EPA did not propose any actions, regulatory or otherwise, regarding human health but will continue to coordinate with FDA and other agencies.

**CONSUMERS UNION RESPONSE:** EPA has initiated a BPA “Action Plan” based on concern about BPA safety (<http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/bpa.html>) . In fact EPA IS considering rulemaking to list BPA on a list of Chemicals of Concern under section 5(4)(b) of the Toxics Substances Control Act (TSCA) and under section 4(a) of TSCA.

- Existing food safety programs are already precautionary - they use safety factors, typically between 100 and 1000, to create a margin of safety between public exposure and levels that cause effects in laboratory animals.

For example, the European Food Safety Authority (EFSA) set a Tolerable Daily Intake (TDI) by applying a safety factor of 100 to the No-Observed-Adverse-Effect-Level from laboratory animal studies. The TDI is the amount of BPA a consumer (including infants) can safely ingest without harm over a whole lifetime.

- A consumer would have to ingest more than 500 pounds of food and beverages in contact with BPA every day for a lifetime to exceed the TDI set by EFSA
- A 22 pound infant would have to drink more than 423 4 oz bottles per day to exceed the TDI

**CONSUMERS UNION RESPONSE:** Since our first study of BPA in baby bottles in 1999, more than a hundred studies have been published showing a wide range of adverse effects in animals at low doses of BPA --doses that approximate current levels circulating in the human population. We are very concerned about this narrow margin of safety. The NOAEL (no observable adverse effect level) of 5mg/kg/d, used in EFSA’s as well as FDA’s analysis is sorely outdated and based only on a few large dose studies. This erroneous NOAEL has also factored in FDA’s claim that there is a large margin of safety based on current exposure levels. While traditional toxicology with linear dose relationship curves (stemming from the theory "it's the dose that makes the poison") has formed the risk basis for many regulated chemicals, 21st century science demonstrates that not all chemicals follow this linear toxicity, particularly agents that cause hormonal disruption (through cellular receptors and signaling transduction systems), and gene regulation. These agents follow a non-monotonic or inverted-U shaped dose-response curve. ([http://www.consumersunion.org/pub/core\\_product\\_safety/006035.html](http://www.consumersunion.org/pub/core_product_safety/006035.html))

- **WHY DON’T FOOD MANUFACTURERS SIMPLY USE BPA ALTERNATIVES?**

Proponents of banning BPA are incorrect when they suggest alternatives to BPA based canned food liners are readily available for all applications and products. While some canned food products utilize an alternative to epoxy coatings, this use is very limited. Any alternative coating is merely a candidate material until safety and performance is thoroughly evaluated. Recently, the Can Manufacturers Institute and the North American Metal Packaging Alliance said in part to previous legislation, **“There is no readily available, suitable alternative to BPA-based can coatings that meets the essential safety and performance requirements for the broadest spectrum of all foods now packaged in metal containers.”**

**Bear in mind that there are some 125 billion cans produced annually in the US; 28 billion of those are food cans, requiring hundreds of different coating specifications.**

**CONSUMERS UNION RESPONSE:** Given the proprietary nature of epoxy resin formulations, and the “generally recognized as safe” (GRAS) status (<http://www.jsonline.com/watchdog/watchdogreports/81901927.html>, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm061846.htm#Q16>) that most if not all have, the incentives for developing credible alternatives have been limited. Glass is a credible alternative at this time and with additional testing of other plastics and better quality control systems, it does seem possible to provide safer packaging alternative.

- **FOOD SAFETY RISKS MUST BE CONSIDERED FIRST**

Unlike BPA, what has been proven to harm children and families are food borne pathogens that develop from improperly canned foods. For over 50 years epoxy resin has enabled the high temperature sterilization that eliminates the dangers of food poisoning from microbial contaminants. With recent high profile incidences of food contamination resulting in tragic consequences, these risks to food safety must be considered. Furthermore, utilization of unproven alternatives could jeopardize food safety.

**CONSUMERS UNION RESPONSE:** We believe that the plastics industry as well as several of the undersigned of this original document can provide the innovation that we need to develop safer, credible alternatives to BPA. The technology to measure endocrine disrupting potential as well as other toxicity endpoints has been established and should be used by this industry to develop and provide consumers with safe products. No group is advocating for less safe food.

- **DTSC SHOULD IMPLEMENT GREEN CHEMISTRY PROGRAM**

California’s Department of Toxics Substances Control (DTSC) should implement a science-based “Green Chemistry” Program as required by statute. This program was created by the Legislature so that scientific expertise can inform regulatory decision-making regarding chemicals in consumer products.

For the above listed reasons, we are opposed to AB 1319.

Sincerely,



Tim Shestek  
American Chemistry Council

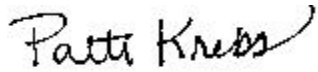


Robert Callahan  
California Chamber of Commerce



Mike Rogge  
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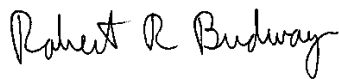




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Mike Dwyer  
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Robert Budway  
Can Manufacturers Institute



Katherine Pettibone  
Civil Justice Association of California



John Hewitt  
Grocery Manufacturers Association



John Kabateck  
National Federation of Independent Business



Robert Rankin  
International Formula Council



Kara Bush  
California Grocers Association



Kristin Power  
Consumer Specialty Products Association



Trudi Hughes  
California League of Food Processors



Consuelo Hernandez  
California Healthcare Institute



Tom Scott  
California Citizens Against Lawsuit Abuse



Kathleen Roberts  
North American Metal Packaging Alliance



Carrie A. Hartgen  
AdvaMed -- Advanced Medical Technology Association

cc: Members, Assembly Environmental Safety & Toxic Materials Cmte