



January 26, 2014

To: The Honorable Josh Green, Chair
Members, Senate Committee on Health

From: Tim Shestek, Senior Director
State Affairs

Re: **SB 2573 – OPPOSE**

The American Chemistry Council (ACC) must respectfully oppose **SB 2573**, legislation that, among other things proposes to restrict certain chemical ingredients – specifically phthalates and Bisphenol-A (BPA) - that may be used in specifically designed child care articles. Furthermore, the bill proposes to prohibit the Hawaii Health Systems Corporation from purchasing and using vinyl intravenous solution bags and tubing.

In short, ACC believes the legislation conflicts with federal law governing the use of phthalates and the proposed restriction on BPA containing products runs contrary to the consensus of the scientific community and international regulatory agencies that have concluded BPA is safe as used. ACC also believes the PVC prohibition would unnecessarily restrict the availability and use of certain health care devices that are already regulated by the US Food and Drug Administration (FDA).

PHTHALATES

In 2008, the federal government enacted the Consumer Product Safety Improvement Act (CPSIA), (H.R. 4040). The CPSIA is a very broad overhaul of the Consumer Product Safety Act, and it responds, in part, to public concerns about imported toys containing lead. Among the CPSIA's provisions are restrictions on six phthalates in toys and children's products. These restrictions became effective February 10, 2009. The new law preempts state laws that impose similar restrictions on phthalates. <http://cpsc.gov/Regulations-Laws--Standards/CPSIA/Phthalates/Phthalates-Information/>

The restrictions of the CPSIA apply to certain specified phthalates in particular products:

- **DEHP, DBP, and BBP:** there are permanent restrictions on the sale of children's toys and child care articles with concentrations of more than 0.1 percent of di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). The permanent restriction was effective February 10, 2009.
- **DINP, DIDP, and DnOP:** there are temporary (interim) restrictions on the sale of children's toys that can be placed in a child's mouth and child care articles that contain more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP). The interim restriction was effective February 10, 2009. "Child care articles" are defined as consumer products that are designed or intended by the manufacturer for a child who is 3 years old or younger, to facilitate sleeping or feeding, or to help a child who is sucking or teething.

As it relates to phthalates, SB 2573 as drafted would be in direct conflict with Federal law.



BISPHENOL-A (BPA)

SB 2573 also proposes to restrict the use of BPA in toys and various child care articles. The Committee may be interested to know that in July 2012, the U.S. Food and Drug Administration (FDA) amended the federal food additive regulations to no longer allow for the use of BPA containing polycarbonate plastic in products such as infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids. This action was taken because manufacturers are no longer using BPA containing materials to make these products.

The abandonment of these products by manufacturers however should not be interpreted to be an indication that BPA containing products are somehow harmful to human health. The scientific evidence supporting the safety of BPA has been comprehensively and recently examined by many government and scientific bodies worldwide.

The weight of evidence consistently supports the safety of BPA containing products:

U.S. Food and Drug Administration (FDA)

In June 2013, the FDA updated their assessment of BPA. Experts concluded that “available information continues to support the safety of BPA for the currently approved uses in food containers and packaging.” FDA’s current assessment is based on review by FDA scientists of hundreds of studies, including the latest findings from new studies conducted by the agency’s National Center for Toxicological Research. ***In its update FDA, responded to the question “Is BPA safe?” with one unambiguous word: “Yes.”***

<http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm355155.htm>

Health Canada

In September 2012, Health Canada released an updated assessment of BPA. Experts concluded that “current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population, including newborns and young children.”

Food Standards Australia New Zealand (FSANZ)

In April 2012, FSANZ, an independent statutory agency responsible for setting food standards in the two countries, reaffirmed the safety of BPA and stated: “The weight of scientific evidence indicates that exposure to BPA in food does not present a significant human health and safety issue at current exposure levels.”

European Food Safety Authority (EFSA)

In January 2014, EFSA announced the results of a full re-evaluation of BPA and concluded “the health concern for BPA is low at the current level of exposure.” That conclusion is applicable to all age groups, including the offspring of mothers exposed during pregnancy, infants, children, and the elderly. In support of its conclusion, EFSA also stated that exposure to BPA is “well below” the safe intake limit, indicating that BPA is safe as it is currently used.

World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO)

In September 2011, an international panel of experts released a report on their review of all the latest scientific evidence on BPA and concluded that “initiation of public health measures would be premature.” The experts 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.

Japanese National Institute of Advanced Industrial Science and Technology (AIST)

In July 2011, AIST concluded that “the risk of BPA with regard to human health was believed to be very small.” This conclusion is consistent with AIST’s previous 2005 BPA risk assessment. Of note, in its 2011 assessment, the data uncertainty factor was reduced to 25 as compared to 100 in the previous assessment, indicating higher confidence in the scientific data supporting the 2011 conclusion.



POLYVINYL CHLORIDE (PVC, Vinyl) INTRAVENOUS PRODUCTS PROHIBITION

For more than 50 years, PVCs performance and protectiveness have made it a critical material in such health care products and procedures as blood and intravenous bags, kidney dialysis and blood transfusions, cardiac catheters and endotracheal tubes. Vinyl has a number of characteristics that together make it uniquely suited to medical use:

- It is optically clearer than many alternatives.
- It is kink-resistant. Alternatives frequently kink when bent to angles of 90 degrees or more, which can cut off the flow of blood or vital fluids to a patient if left undetected for any length of time.
- It resists “necking down” – that is, constricting when pulled. Vinyl alternatives can neck down when inadvertently stretched, which can result in a changed inner tubing diameter that affects the fluid delivery rate.
- Medical kits made of vinyl are factory assembled using a technique known as solvent cementing, in which tubing is locked to its connectors and ports by a solvent that evaporates after application. Most PVC substitutes cannot be bonded this way. If joints yank loose and leaks occur, patients can be exposed to flow interruptions, and care givers can be exposed to potentially contagious body fluids.
- Vinyl medical products can also be steam-sterilized and frozen.
- Vinyl is compatible with virtually all pharmaceutical products in healthcare facilities and its relatively low cost helps healthcare facilities contain rising costs.

Please consider that FDA officials and others have noted that efforts to replace vinyl in medical products with alternative materials must be carefully judged to ensure the alternatives are as safe, perform as well, are available, and meet other critical product requirements. Medical devices made from PVC plastic are regulated for safety by the FDA and ACC believes this agency is the most appropriate venue to regulate these and other medical type products.

For the above listed reasons, ACC opposes passage of SB 2573. Thank you in advance for considering our views. If you have any questions or comments, please do not hesitate to contact me or ACC’s Hawai’i based representatives Red Morris and/or John Radcliffe at 808-531-4551.



From: mailinglist@capitol.hawaii.gov
To: [HTHTestimony](#)
Cc: anakama@wik.com
Subject: Submitted testimony for SB2573 on Jan 27, 2014 13:30PM
Date: Monday, January 27, 2014 8:53:59 AM
Attachments: [SB 2573 testimony.pdf](#)

SB2573

Submitted on: 1/27/2014

Testimony for HTH on Jan 27, 2014 13:30PM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Allison		Oppose	Yes

Comments: Jennifer Gibbons of the Toy Industry Association, Inc. will be providing oral testimony. Thank you.

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

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January 27, 2014

Honorable Josh Green, Chair
Senate Committee on Health

RE: **SB 2573 – Relating to Health – In Opposition**
Hawaii State Capitol; Conference Room 229; 1:30 p.m.

Chair Green, Vice Chair Baker and members of the committee:

The Toy Industry Association (TIA) appreciates this opportunity to provide testimony on SB 2573. TIA is a not-for-profit trade association composed of more than six hundred (600) members, both large and small in size, located throughout North America.

TIA and its members have long been leaders in toy safety. In this role, we develop safety standards for toys, working with industry, government, consumer organizations, and medical experts. The U.S.'s risk-based standards are widely used as models around the globe. TIA commends the bill sponsors for their keen interest in the safety of children. However, we would like to address concerns with SB 2573 which proposes, among other things to establish broad restrictions on Bisphenol-A or BPA used in many children's product applications.

BPA is Necessary for Product Safety and Essential Product Characteristics

Polycarbonate is lightweight, highly shatter-resistant, clear, extremely strong, and has high heat resistance, which makes it ideal for use in a wide variety of products. BPA is found in trace amounts in polycarbonate and is not an additive. If you ban BPA, you ban polycarbonate. BPA as used in polycarbonate plastic *is specifically chosen for the safety it imparts to products, making them shatter-resistant and hygienic.* Some of the products that utilize BPA for these safety properties include protective gear such as bicycle helmets, protective shields used in sporting goods and safety glasses, as well as eyeglass lenses, and contact lenses.

BPA is approved by the U.S. Food and Drug Administration (FDA) for very sensitive applications, including medical and food contact use, and, as such, is used widely in food storage containers and medical equipment. These food applications are far more sensitive than toys, where exposure to BPA containing compounds is limited and occasional.

BPA is used less extensively in children's toys but is utilized when shatter-resistant properties are called for to eliminate the risk of breakage – which can lead to the creation of hazards such as small parts (potential choking hazard) and/or sharp edges in a child's environment which can

cause laceration injuries. BPA is also UV-resistant and in a toy application provides strength and durability, reducing breakdown, again, reducing potential small part or sharp edge hazards.

Elimination of BPA in these important applications could degrade the safety of toys and other consumer products where no safer alternative has been identified.

Scientific Bodies Have Verified the Safe Use of BPA

There is strong science to support the safe use of BPA in toys and consumer product applications. There is extensive research and testimony from experts on the science demonstrating the very low risk associated with BPA as well as the unique safety benefits it provides. Specifically the following authoritative scientific bodies have found BPA to be safe or to not warrant special restrictions or handling:

- In November of 2010, an international panel of experts convened by the World Health Organization to examine the health risks from exposure to the chemical Bisphenol-A (BPA) agreed that it would be “premature” to take any public health measures to regulate or ban BPA.
- In September of 2010, the European Food Safety Authority (EFSA) concluded a review of over 800 studies on BPA and reconfirmed current safe levels of BPA in food products.
- In July of 2009, the California Developmental and Reproductive Toxicant Identification Committee voted unanimously against placing BPA on Proposition 65 - a list of chemicals believed to cause cancer, birth defects or other reproductive harm.
- In 2009, the German Federal Institute for Risk Assessment found that BPA is safe for “normal” use in many product applications and should not be banned.
- In 2010, the U.S. Food and Drug Administration re-reviewed its assessment of the safety of BPA and expressed the need for additional research; but did not propose banning the use of BPA in any product category.
- The U.S. Toxicology Program, in September 2008, issued a report with that did not find BPA to warrant any special restrictions.

A ban on BPA in such broad categories of products; as currently proposed by this legislation does not take into consideration the science supporting its safe use -- or its benefits. **Broad BPA restrictions, like those proposed in SB 2573, are not mandated for toys by any state, federal or national government anywhere in the world.** Inconsistency with existing international, federal and all other state requirements, without regard to scientific risk, threatens the viability of toy manufacturers, distributors and retailers. A broad ban of BPA in toys, as currently proposed in SB 2573, could also force toy manufacturers to use less-tested alternative materials, that may not have the benefits that BPA offers and could result in products that do not hold up to the rigors of children’s play.

Federal Regulation of Phthalates in Children’s Products is Preemptive

SB 2573 also proposes to ban di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) or benzyl butyl phthalate (BBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP) or di-n-octyl phthalate (DnOp) in products intended for use by children under the age of 3. However, the Consumer Product Safety Improvement Act (CPSIA), (H.R. 4040), signed into law on August 18, 2008, already restricts the use of these specific phthalates in toys and children’s

products and has the effect of expressly preempting states and localities from imposing similar restrictions on phthalates in these product categories.

Specifically, the U.S. Consumer Product Safety Commission (CPSC) has issued the following guidance on this topic: “The new lead limits for lead paint and lead content preempt state law as do the new provisions on phthalates and ATVs.”¹ Therefore, these provisions relating to phthalates in SB 2573 are preempted and are unnecessary to include in this legislation.

Conclusion

The Toy Industry Association and its members have always recognized the special relationship we have with children, who are our principal consumers; their safety and well-being is always our top priority. As parents ourselves and an industry devoted to bringing joy (and safety) to childhood, we share your interest in the safety of toys and we urge you to carefully consider the unintended consequences of the provisions proposed in this legislation and how this bill may hurt those doing business in Hawaii, and force consumers to source products through other means, at no measurable increase to product safety. **Therefore, TIA respectfully urges you to oppose broad restrictions on BPA and federally preempted restrictions on phthalates.**

On behalf of the members of the Toy Industry Association and our approximately 600 member companies, we thank you for consideration of our concerns. If you have any questions, please do not hesitate to contact Jennifer Gibbons, Director of State Affairs for TIA, at 646-512-1320 or jgibbons@toyassociation.org.

¹ U.S. Consumer Product Safety Commission guidance on CPSIA Section 231 – Preemption, <http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act/CPSIA-Topics/Section-231-Preemption/>

From: mailinglist@capitol.hawaii.gov
To: [HTHTestimony](#)
Cc: paikoman@yahoo.com
Subject: Submitted testimony for SB2573 on Jan 27, 2014 13:30PM
Date: Monday, January 27, 2014 5:11:20 AM

SB2573

Submitted on: 1/27/2014

Testimony for HTH on Jan 27, 2014 13:30PM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Lisa Hallett	Individual	Support	No

Comments: Aloha, Well, I have to say this is a long time coming. EU (European Union) is so far ahead of us with bans and health - as usual - let's catch up. Our keiki and environment need us to make sound decisions regarding chemicals -banning is a must. Healthy body development (brain and organs, etc.)can start with no exposure to these toxins in toys. This is a wonderful bill who's effects go far including minimizing waste on our islands. Mahalo!!!

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

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